

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

RICHARD ROE et al.,

Plaintiffs,

v.

PATRICK M. SHANAHAN et al.,

Defendants.

Case No. 1:18-cv-01565 (LMB/IDD)

**DECLARATION OF PETER PERKOWSKI IN SUPPORT  
OF MOTION FOR PRELIMINARY INJUNCTION**

1. My name is Peter Perkowski. I am the Legal & Policy Director of Plaintiff OutServe-SLDN, Inc.
2. I am over 18 years of age, am competent to testify about the information contained in this declaration if needed, and offer this declaration based on my own actual, personal knowledge.
3. OutServe-SLDN is a non-partisan, non-profit, legal services, watchdog, and policy organization that represents the U.S. LGBTQ+ military community—service members, veterans, civilian Department of Defense, and their spouses and families—worldwide. The organization’s mission is to address and end—through litigation, policy advocacy, and education—all forms of unequal or unfair treatment against members of its community based on sexual orientation, gender identity, or HIV status.
4. OutServe-SLDN is in part a membership organization, or the functional equivalent of a membership organization. It has well over 7,000 members—veterans, active-duty

and reserve-component service members, and civilian Department of Defense workers throughout the world who identify as LGBTQ or are living with HIV—and more than 54,000 supporters. OutServe-SLDN also has more than 54 chapters worldwide, including 35 in the United States, and 20 additional special group forums, one of which is the “Positive Forum” for people living with HIV. These chapters are not just social groups: because service members who are LGBTQ+ and/or living with HIV are minority groups that are still sometimes marginalized, stigmatized, or ostracized in the military, the chapters allow these service members to establish emotional support networks and to exchange information that is important for career advancement and professional growth. The chapters also provide a direct link for service members to access services and programs that OutServe-SLDN offers.

5. OutServe-SLDN provides pro-bono advocacy and legal services for members of the military living with HIV. Advocacy work includes working with Congress to change or approve legislation and regulations affecting service members with HIV, as well as working directly with the Department of Defense, the Secretary of Defense, and the service Secretaries on the same issues. Legal services work includes writing and submitting amicus briefs in cases involving HIV-related issues (e.g., *United States v. Forbes*, Court of Appeals for the Armed Forces Case No. 18-0304/NA); filing and litigating impact litigation to change Department of Defense policies; directly representing servicemembers with HIV in administrative-separation and court-martial proceedings; and providing cultural-competency assistance, education and information, and training to Judge Advocate General defense lawyers in all service branches.

6. As Legal & Policy Director, my duties include supervising OutServe-SLDN’s legal department and overseeing its legal-services function. I am therefore familiar with the inquiries that the organization receives from members requesting legal assistance.

7. Since the filing of the Complaint in this matter, OutServe-SLDN's legal department has received numerous calls and emails from service members with HIV who are going through a process like plaintiffs Staff Sergeant (SSgt) Roe and Senior Airman (SrA) Voe in this matter. Many of these service members are currently facing separation. OutServe-SLDN's legal staff, including myself, have spoken to these service members and collected relevant documents from them. The facts set forth below are based on those documents and conversations.

8. K.R. is a Senior Airman who joined the Air Force in 2014 and is currently stationed at an Air Force base outside the United States. SrA K.R. was diagnosed with HIV in late 2016 and was immediately put into the Integrated Disability Evaluation System (IDES) to determine whether he would be returned to duty or instead would be separated because of his medical condition. As with plaintiffs, the boards evaluating SrA K.R. determined that he was not worldwide deployable and therefore unfit for duty, and he was recommended for separation.

9. SrA K.R. appealed to the Secretary of the Air Force (SAF). On November 7, 2018, the SAF's designee—John Vallario, Deputy Director of the SAF Personnel Council—issued a memorandum decision stating: “On behalf of the Secretary of the Air Force, it is directed that Senior Airman [K.R.] be discharged.” A copy of this memorandum is attached to this declaration as Exhibit C1. (To avoid potential stigma and discrimination based on his HIV status, personal identifying information has been redacted to protect SrA K.R.'s anonymity.)

10. The memorandum to SrA K.R. is almost identical to those received by plaintiffs, and it was issued the same day. As a basis for the decision, it states: “[T]he member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR)[.] ...

Therefore, based on his inability to deploy and considering his current career point, the Board determined he is unfit for continued military service and shall be discharged with severance pay.”

11. SrA K.R. has received orders stating that his Date of Separation (DOS) is March 28, 2019. (Because of the large amount of personal identifying information in the separation orders, I have not attached it to this declaration.) SrA K.R. wants to continue serving in the Air Force, and he has the support of his command, who favor his retention. But without an injunction from this Court he will be separated on March 28.

12. SrA K.R. is also a member of OutServe-SLDN’s “Positive Forum,” a secret Facebook group for service members, veterans, and others in the military community who are living with HIV. By virtue of this, and by availing himself of OutServe-SLDN’s legal services, SrA K.R. is a member of OutServe-SLDN.

13. S.H. is a Senior Airman who joined the Air Force in 2016 and is currently stationed at an Air Force base in the southern United States. SrA S.H. was diagnosed with HIV in early 2018 and was immediately put into the IDES to determine whether he would be returned to duty or instead would be separated because of his medical condition. As with plaintiffs, the boards evaluating SrA S.H. determined that he was not worldwide deployable and therefore unfit for duty, and he was recommended for separation.

14. SrA S.H. appealed to the SAF. On December 4, 2018, the SAF’s designee—John Vallario, Deputy Director of the SAF Personnel Council—issued a memorandum decision stating: “On behalf of the Secretary of the Air Force, it is directed that [Airman First Class] [S.H.] be discharged.” (SrA S.H. was promoted from Airman First Class (A1C) to Senior Airman while his appeal was pending.) A copy of this memorandum is attached to this

declaration as Exhibit C2. (To avoid potential stigma and discrimination based on his HIV status, personal identifying information has been redacted to protect SrA S.H.'s anonymity.)

15. The memorandum to SrA S.H. is almost identical to those received by plaintiffs, and by SrA K.R. As a basis for the decision, it states: “[T]he member’s condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR)[.] ... Therefore, based on his inability to deploy and considering his current career point, the [Board] determined he is unfit for continued military service and shall be discharged with severance pay.”

16. SrA S.H. has received orders stating that his DOS is March 28, 2019. (Because of the large amount of personal identifying information in the separation orders, I have not attached it to this declaration.) SrA S.H. wants to continue serving in the Air Force, and he has the support of his command, who favor his retention. But without an injunction from this Court he will be separated on March 28.

17. SrA S.H. is also a member of OutServe-SLDN’s “Positive Forum.” By virtue of this, and by availing himself of OutServe-SLDN’s legal services, SrA S.H. is a member of OutServe-SLDN.

18. D.N. is a Senior Airman who joined the Air Force in 2016 and is currently stationed at an Air Force base in the Midwest United States. SrA D.N. was diagnosed with HIV in early 2018 and was immediately put into the IDES to determine whether he would be returned to duty or instead would be separated because of his medical condition. As with plaintiffs, the boards evaluating SrA D.N. determined that he was not worldwide deployable and therefore unfit for duty, and he was recommended for separation.

19. SrA D.N. appealed to the SAF. On December 5, 2018, the SAF’s designee—Shane Prater, Director of the SAF Personnel Council—issued a memorandum decision stating: “On behalf of the Secretary of the Air Force, it is directed that SrA [D.N.] be discharged.” A copy of this memorandum is attached to this declaration as Exhibit C3. (To avoid potential stigma and discrimination based on his HIV status, personal identifying information has been redacted to protect SrA D.N.’s anonymity.)

20. The memorandum to SrA D.N. is almost identical to that received by plaintiffs and by SrA K.R. and SrA S.H. As a basis for the decision, it states: “[T]he member’s condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR)[.] ... Therefore, based on his inability to deploy and considering his current career point, the [Board] determined he is unfit for continued military service and shall be discharged with severance pay.”

21. SrA D.N. has not yet received orders informing him of his DOS. He wants to continue serving in the Air Force, and he has the support of his command, who favor his retention. But without an injunction from this Court, SrA D.N. will be discharged.

22. SrA D.N. is also a member of OutServe-SLDN’s “Positive Forum.” By virtue of this, and by availing himself of OutServe-SLDN’s legal services, SrA D.N. is a member of OutServe-SLDN.

23. J.B. is a Staff Sergeant who joined the Air Force in 2014 and is currently stationed at an Air Force base in southern United States. SSgt J.B. was diagnosed with HIV in late 2017 and was put into the IDES to determine whether he would be returned to duty or instead would be separated because of his medical condition. As with plaintiffs, the boards

evaluating SSgt J.B. determined that he was not worldwide deployable and therefore unfit for duty, and he was recommended for separation.

24. SSgt J.B. appealed to the SAF. On November 7, 2018, the SECAF's designee—John Vallario, Deputy Director of the SAF Personnel Council—issued a memorandum decision stating: “On behalf of the Secretary of the Air Force, it is directed that Senior Airman [J.B.] be placed on the Temporary Disability Retired List (TDRL) with a disability rating of 60 percent ... .” (SSgt J.B. was a Senior Airman at the time but was subsequently promoted to Staff Sergeant.) A copy of this memorandum is attached to this declaration as Exhibit C4. (To avoid potential stigma and discrimination based on his HIV status, personal identifying information has been redacted to protect SSgt J.B.'s anonymity.)

25. The SAF memorandum to SSgt J.B. is almost identical to those received by plaintiffs, and by SrA K.R., SrA S.H., and SrA D.N, and it was issued the same day as plaintiffs'. As a basis for the decision, it states: “[T]he member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR)[.] ... Therefore, based on his inability to deploy and considering his current career point, the Board determined he is unfit for continued military service and shall be placed on the Temporary Disability Retired List (TDRL) ... .”

26. SSgt J.B. has received orders stating that the date he will be relieved of duty is February 25, 2019. (Because of the large amount of personal identifying information in the separation orders, I have not attached it to this declaration.)

27. SSgt J.B. is also a member of OutServe-SLDN's “Positive Forum.” By virtue of this, and by availing himself of OutServe-SLDN's legal services, SSgt J.B. is a member of OutServe-SLDN.

28. OutServe-SLDN has also heard from members of the Air National Guard (ANG) who are facing separation because their HIV status makes them not worldwide deployable. Q.S. is a Senior Airman in the ANG of a state in the Midwest. SrA Q.S. enlisted in 2011 and was diagnosed with HIV in June 2018. SrA Q.S.'s current enlistment period expires on February 18, 2019, and he wants to re-enlist.

29. But SrA Q.S. is not being allowed to re-enlist. Instead, on January 10, 2019, his command presented SrA Q.S. with Form AF 418—by which commanders may “select” or “non-select” enlisted personnel for re-enlistment—stating that SrA Q.S. was “not selected for reenlistment.” The reason given for non-selecting SrA Q.S. was that his HIV status renders him non-deployable.

30. Without an injunction from this Court, SrA Q.S. will be separated from the ANG as of his Expiration Term of Service (ETS) date of February 18.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 10th day of January, 2019.

  
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Peter Perkowski

# EXHIBIT C1



DEPARTMENT OF THE AIR FORCE  
WASHINGTON, DC

Office of the Assistant Secretary

MEMORANDUM FOR AFPC/DPFDD

FROM: SAF/MRBP

SUBJECT: Physical Evaluation—Senior Airman [REDACTED]

On behalf of the Secretary of the Air Force, it is directed that Senior Airman [REDACTED] be discharged and receive severance pay with a disability rating of 10 percent under the provisions of Title 10, United States Code, Section 1203. This disability rating was determined based on the Veterans Affairs Schedule for Rating Disabilities (VASRD) in accordance with the National Defense Authorization Act of 2008.

Senior Airman [REDACTED]'s case was considered by the Air Force Personnel Board (AFPB), which made a recommendation regarding its disposition. The following rationale is provided for the final decision in this case. The Board considered the member's contention that he is fit and should be returned to duty. The Board noted the member has been compliant with all treatment, is currently asymptomatic, and has an undetectable human immunodeficiency virus (HIV) viral load. Additionally, he is able to perform all in garrison duties, has passed his most recent fitness assessment without any component exemptions, and his commander strongly supports his retention. However, the Board noted the member's condition precludes him from being able to deploy world-wide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR), where the majority of Air Force members are expected to deploy. Deployability is a key factor in determining fitness for duty and the Board recognized the member belongs to a career field with a comparatively high deployment rate/tempo. Therefore, based on his inability to deploy and considering his current career point, the Board determined he is unfit for continued military service and shall be discharged with severance pay.

The applicant also contends that there are numerous Air Force instructions indicating he should not be discharged due to having this condition. In support of this assertion, he includes a copy of a HQ AF/A IP memo, *Retention of Airmen with HIV*, dated 11 Oct 17, which indicates that asymptomatic HIV alone is not unfitting for continued service. However, this memo also indicates AFPC/DP2NP may return Airmen with asymptomatic HIV to duty, or refer them into the Integrated Disability Evaluation System (IDES). There is no evidence to indicate that AFPC/DP2NP's action to refer the member's case into the IDES was somehow inappropriate or contrary to governing instructions. After a thorough review of his case, both the Informal Physical Evaluation Board (IPEB) and Formal Physical Evaluation Board (FPEB) determined that Senior Airman [REDACTED]'s condition rendered him unfit. For the reasons indicated above, the

This document contains information which must be protected IAW AFI 33-332 and DoD Regulation 5400.11; Privacy Act of 1974 as Amended Applies, and it is For Official Use Only (FOUO).

AFPB agrees that his condition precludes him from performing the full range of his military duties and he is therefore unfit for continued military service.

Addressing the applicant's disability rating award, the Board is required by law to rate a disability using criteria outlined in the VASRD. The AFPB typically applies the disability ratings proposed by the Department of Veterans Affairs (DVA) under the Integrated Disability Evaluation System (IDES), as these ratings should be in compliance with the VASRD. The Board therefore assigned a rating of 10 percent for the member's HIV infection. This rating warranted discharge with severance pay.

This action is taken under the authority delegated by the Secretary of the Air Force.

11/7/2018

**X** John K. Vallario

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JOHN K. VALLARIO

Deputy Director, SAF Personnel Council

Signed by: VALLARIOJOHN.K.1069511070

Attachment:  
Additional Information Sheet

# EXHIBIT C2



DEPARTMENT OF THE AIR FORCE  
WASHINGTON, DC

Office of the Assistant Secretary

MEMORANDUM FOR AFPC/DPFDD

FROM: SAF/MRBP

SUBJECT: Physical Evaluation - Airman First Class [REDACTED]

On behalf of the Secretary of the Air Force, it is directed that AIC [REDACTED] be discharged and receive severance pay with a disability rating of zero percent under the provisions of Title 10, United States Code, Section 1203. This disability rating was determined based on the Veterans Affairs Schedule for Rating Disabilities (VASRD) in accordance with the National Defense Authorization Act of 2008.

AIC [REDACTED]'s case was considered by the Air Force Personnel Board (AFPB), which made a recommendation regarding its disposition. The following rationale is provided for the final decision in this case. The AFPB considered the member's contention that he is fit and should be returned to duty. The AFPB noted the member has been compliant with all treatment, is currently asymptomatic, and has a nearly undetectable human immunodeficiency virus (HIV) viral load. Additionally, he is able to perform all in-garrison duties, passed his most recent fitness assessment without any component exemptions, and his commander supports his retention. However, the AFPB noted the member's condition precludes him from being able to deploy worldwide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR), where the majority of Air Force members are expected to deploy. Deployability is a key factor in determining fitness for duty and the AFPB recognized the member belongs to a career field with a comparatively high deployment rate/tempo. Therefore, based on his inability to deploy and considering his current career point, the AFPB determined he is unfit for continued military service and shall be discharged with severance pay.

When addressing the applicant's disability rating award, the AFPB is required by law to rate a disability using criteria outlined in the VASRD. The AFPB typically applies the disability ratings proposed by the Department of Veterans Affairs (DVA) under the Integrated Disability Evaluation System (IDES), as these ratings should be in compliance with the VASRD. Therefore, the AFPB assigned a rating of zero percent to the member's HIV condition, VASRD Code 6351. This disability rating warranted discharge with severance pay.

This action is taken under the authority delegated by the Secretary of the Air Force.

12/4/2018

X *Shane Prater*

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SHANE T PRATER, Colonel, USAF  
Director, SAF Personnel Council  
Signed by PRATER SHANE T 1081079567

Attachment:  
Additional Information Sheet

# EXHIBIT C3



**DEPARTMENT OF THE AIR FORCE**  
**WASHINGTON, DC**

**Office of the Assistant Secretary**

MEMORANDUM FOR AFPC/DPFDD

FROM: SAF/MRBP

SUBJECT: Physical Evaluation – Senior Airman [REDACTED]

On behalf of the Secretary of the Air Force, it is directed that SrA [REDACTED] be discharged and receive severance pay with a disability rating of 10 percent under the provisions of Title 10, United States Code, Section 1203. This disability rating was determined based on the Veterans Affairs Schedule for Rating Disabilities (VASRD) in accordance with the National Defense Authorization Act of 2008.

SrA [REDACTED]'s case was considered by the Air Force Personnel Board (AFPB), which made a recommendation regarding its disposition. The following rationale is provided for the final decision in this case. The AFPB considered the member's contention that he is fit and should be returned to duty. The AFPB noted the member has been compliant with all treatment, is currently asymptomatic, and has a nearly undetectable human immunodeficiency virus (HIV) viral load. Additionally, he is able to perform all in-garrison duties and his commander supports his retention. He passed his most recent fitness assessment with some component exemptions that were not related to his HIV. However, the AFPB noted the member's condition precludes him from being able to deploy worldwide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR), where the majority of Air Force members are expected to deploy. Deployability is a key factor in determining fitness for duty and the AFPB recognized the member belongs to a career field with a comparatively high deployment rate/tempo. Therefore, based on his inability to deploy and considering his current career point, the AFPB determined he is unfit for continued military service and shall be discharged with severance pay.

When addressing the applicant's disability rating award, the AFPB is required by law to rate a disability using criteria outlined in the VASRD. The AFPB typically applies the disability ratings proposed by the Department of Veterans Affairs (DVA) under the Integrated Disability Evaluation System (IDES), as these ratings should be in compliance with the VASRD. Therefore, the AFPB assigned a rating of 10 percent to the member's HIV condition, VASRD Code 6351. This disability rating warranted discharge with severance pay.

This action is taken under the authority delegated by the Secretary of the Air Force.

12/5/2018

X *Shane Prater*

SHANE T. PRATER, Colonel, USAF  
Director, SAF Personnel Council  
Signed by: PRATER.SHANE.T.1081079567

Attachment:  
Additional Information Sheet

### Additional Information Sheet

Your case was reviewed by the Air Force Personnel Board (AFPB) of the Secretary of the Air Force Personnel Council (SAFPC) under authority delegated by the Secretary of the Air Force. The board reviewed all facts and evidence in the case, to include the testimony presented before the Formal Physical Evaluation Board (FPEB) and the remarks of the FPEB (if applicable), the remarks of the Informal Physical Evaluation Board (IPEB), the service medical record (including electronic entries contained in the Armed Forces Health Longitudinal Technology Application, or AHLTA), the Narrative Summary of the Medical Evaluation Board (MEB), the Department of Veterans Affairs (DVA) medical examination, information provided by you and your counsel, and any additional information that was provided.

If you are on extended active duty and have between 15 and 19+ years of active duty service (but less than 20 years), have an essentially stable condition, and wish to return to duty, you may be eligible to apply for the Limited Assignment Status (LAS) program. Please see Chapter 6 of AFI 36-3212 for more information or discuss your options with your Office of Airmen's Counsel (OAC) representative. Note: you are normally not eligible to apply for LAS if you are being placed on the Temporary Disability Retired List (TDRL).

The board is sensitive to your potential need for continuing medical care. Therefore, the board encourages you to utilize the resources of the DVA to the extent that you may be entitled. The DVA is the agency chartered by Congress to provide assistance to all eligible veterans. A full complement of medical services is available at any tertiary-level DVA health care facility. The DVA's Vocational Rehabilitation and Employment Program's mission is to assist veterans with a service-connected disability to prepare for and find suitable employment. Additional information regarding this program can be obtained at the following website: <http://www.benefits.va.gov/vocrehab/index.asp>. The Military Disability Evaluation System (MDES) is responsible for maintaining a fit and vital fighting force. While the MDES considers all of the service member's medical conditions, compensation can only be offered for those medical conditions that cut short a service member's career, and then only to the degree of severity present at the time of final disposition. However, the DVA, operating under a different set of laws (Title 38, United States Code), is empowered to periodically re-evaluate veterans for the purpose of adjusting their disability ratings should their degree of impairment vary over time.

You are also advised of your right to pursue further appeal through application to the Air Force Board for Correction of Military Records (AFBCMR) should you find reason that brings into question the decision of the board. The AFBCMR is an independent body chartered by Congress to redress any Air Force personnel action without influence of previous boards or their respective decisions. You may obtain information on appeal procedures from the AFBCMR website at: <http://www.afpc.af.mil/Board-for-Correction-of-Military-Records>.

# EXHIBIT C4



DEPARTMENT OF THE AIR FORCE  
WASHINGTON, DC

Office of the Assistant Secretary

MEMORANDUM FOR AFPC/DPFDD

FROM: SAF/MRBP

SUBJECT: Physical Evaluation—Senior Airman [REDACTED]

On behalf of the Secretary of the Air Force, it is directed that Senior Airman [REDACTED] be placed on the Temporary Disability Retired List (TDRL) with a disability rating of 60 percent under the provisions of Title 10, United States Code, Section 1202. This disability rating was determined based on the Veterans Administration Schedule for Rating Disabilities (VASRD) in accordance with the National Defense Authorization Act of 2008.

Senior Airman [REDACTED]'s case was considered by the Air Force Personnel Board (AFPB), which made a recommendation regarding its disposition. The following rationale is provided for the final decision in this case. The Board considered the member's contention that he is fit and should be returned to duty. The Board noted the member has been compliant with all treatment, is currently asymptomatic and has a low human immunodeficiency virus (HIV) viral load. Additionally, he is able to perform all in garrison duties, has passed his most recent fitness assessment without any component exemptions, and his commander strongly supports his retention. However, the Board noted the member's condition precludes him from being able to deploy worldwide without a waiver and renders him ineligible for deployment to the Central Command (CENTCOM) Area of Responsibility (AOR), where the majority of Air Force members are expected to deploy. Deployability is a key factor in determining fitness for duty and the Board recognized the member belongs to a career field with a comparatively high deployment rate/tempo. Therefore, based on his inability to deploy and considering his current career point, the Board determined he is unfit for continued military service and shall be placed on the Temporary Disability Retired List (TDRL) with a disability rating of 60 percent.

The member should be reevaluated in 12 months, to consist of an evaluation by an Infectious Disease Specialist (to include comments on interim course/treatment, compliance, current HIV labs/virus status/ treatment, social/industrial impairment, functionality, employability, and prognosis). The member is reminded to bring all of his interim healthcare records to the TDRL reevaluation, to ensure that he receives the correct disability rating. Per DoDI 1332.18, Enclosure 3, Appendix 4, paragraph 2.h, the member shall provide to the examining physician, for submission to the Physical Evaluation Board, copies of all his medical records (civilian, DVA, and all military medical records) documenting treatment since the last disability evaluation.

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Addressing the applicant's disability rating award, the Board is required by law to rate a disability using criteria outlined in the VASRD. It typically applies the disability ratings proposed by the DVA under the Integrated Disability Evaluation System (IDES), as these ratings should be in compliance with the VASRD. The AFPB therefore assigned a rating of 60 percent.

This action is taken under the authority delegated by the Secretary of the Air Force.

11/7/2018

**X** John K. Vallario

JOHN K. VALLARIO  
Deputy Director, SAF Personnel Council  
Signed by: VALLARIO.JOHN.K.1069511070

Attachment:  
Additional Information Sheet

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# EXHIBIT D

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

NICHOLAS HARRISON and  
OUTSERVE-SLDN, INC.

Plaintiffs,

v.

Case No. 1:18-cv-641 (LMB/IDD)

JAMES N. MATTIS, in his official capacity  
as Secretary of Defense; MARK ESPER, in  
his official capacity as the Secretary of the  
Army; and the UNITED STATES  
DEPARTMENT OF DEFENSE,

Defendants.

**EXPERT DECLARATION OF CARLOS DEL RIO, M.D., IN SUPPORT OF  
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

## **I. INTRODUCTION**

1. My name is Carlos del Rio. I have been retained by counsel for Plaintiffs as an expert in connection with this litigation.

2. I am offering this declaration to provide my expert opinions regarding HIV—its etiology, the mechanism by which it operates to undermine a person's immune system, the routes and relative risks of transmission, the care and treatment of people living with HIV, the effect of treatment with antiretrovirals on the immunological and overall health of people living with HIV, and the effect of treatment on the risks of transmission.

3. The opinions I express are my own and do not reflect the official policy of any organization with which I am affiliated. I am not receiving any compensation for my work.

4. I am knowledgeable about the matters set forth below based upon my own knowledge and experience, as well as my review of various materials cited herein.

## **II. PROFESSIONAL BACKGROUND & QUALIFICATIONS**

5. I am the Hubert Professor and Chair of the Department of Global Health and Professor of Epidemiology at the Rollins School of Public Health and Professor of Medicine in the Division of Infectious Diseases at Emory University School of Medicine. I am also Principal Investigator and co-Director of the Emory Center for AIDS Research (CFAR).

6. I am a native of Mexico where I attended medical school at Universidad La Salle, graduating in 1983. I did my Internal Medicine and Infectious Diseases residencies at Emory University. In 1989, I returned to Mexico where I was Executive Director of the National AIDS Council of Mexico (CONASIDA, the Federal agency of the Mexican Government responsible for AIDS Policy throughout Mexico) from 1992 through 1996. In November 1996, I returned to Emory where I have been involved in patient care, teaching and research. I was Chief of the

Emory Medical Service at Grady Memorial Hospital from 2001 to 2009 and I am now the interim Executive Associate Dean for Emory at Grady.

7. My research focuses on early diagnosis, access to care, engagement in care, compliance with antiretrovirals and prevention of HIV. I am the co-Primary Investigator of the NIH-funded Emory-CDC HIV Clinical Trials Unit, Clinical Site Leader for the Adult AIDS Clinical Trials Group (ACTG) and the site Primary Investigator for the HIV Prevention Trials Network (HPTN) of the NIAID/NIH. My international work includes collaborations in the following countries: Georgia, Ethiopia, Kenya, Thailand, Vietnam and Mexico. I have also worked on emerging infections, such as pandemic influenza, and was a member of the WHO Influenza A(H1N1) Clinical Advisory Group and of the CDC Influenza A(H1N1) Task Force during the 2009 pandemic.

8. I am a Member of the Board of Directors of the International Antiviral Society-USA (IAS-USA) and was the Chair of the HIVMA of the Infectious Diseases Society of America (IDSA). I was also a member of the Advisory Committee on HIV, Hepatitis and STD Prevention and Treatment of the Centers for Disease Control and Prevention and Health Resources and Services Administration as well as of the Department of Health and Human Services (DHHS) Antiretroviral Treatment Guidelines Panel. I serve as Chief Section Editor for HIV/AIDS for NEJM Journal Watch Infectious Diseases, Associate Editor for Clinical Infectious Diseases and I am a member of the editorial board of the Journal of AIDS and Global Public Health.

9. I have co-authored 30 book chapters and over 300 scientific papers. Among other honors, I received the James H. Nakano Citation in 2001 and was recognized by the Centers for Disease Control and Prevention for an outstanding scientific paper published in 2000; awarded

the Emory University Marion V. Creekmore Achievement Award for Internationalization; selected by the “Atlanta Magazine” as one of the 55 most influential foreign-born Atlantans in 2007. In 2013, I was elected to the Institute of Medicine of the National Academies.

10. My curriculum vitae is attached, which describes my education, work experience, and publications. *See* Attach. 1 (del Rio CV).

### **III. BACKGROUND ON THE HUMAN IMMUNODEFICIENCY VIRUS**

#### **A. An Introduction to HIV**

11. Since Acquired Immune Deficiency Syndrome (AIDS) was first identified as a cause of death in the United States in the early 1980s, there has been incredible progress in the treatment of this disease. Once considered invariably fatal within a matter of years, HIV is now considered a chronic, manageable condition. Those diagnosed in a timely manner and provided with appropriate care and treatment with antiretroviral medications experience no noticeable effects on their physical health and enjoy a life expectancy that is nearly the same as those who do not have HIV.

12. HIV, which is an acronym for human immunodeficiency virus, attacks the body’s immune system. Specifically, HIV attacks the body’s CD4 cells, also referred to as T-cells. When HIV takes over a CD4 cell, it forces the cell to produce multiple copies of the virus, which in turn take over other CD4 cells.

13. CD4 cells help the immune systems fight off other types of infections. As HIV reduces the number CD4 cells in the body, it becomes increasingly harder for a person to fend off infections or disease.

14. After the acute stage of infection, a person enters a period of clinical latency that can last years. After time, however, if the person does not receive appropriate treatment, the

amount of virus in their blood (i.e., their “viral load”) will rise and their CD4 count will start to drop. Eventually, an untreated individual’s CD4 count will drop below 200 and/or the person will develop an infection the body would be able to fight off under normal circumstances (i.e., an “opportunistic infection”), at which point that person would have an AIDS diagnosis.

**B. The Treatment of HIV**

15. At almost any point in the progression of HIV, however, consistent treatment with antiretroviral therapy will halt and reverse the downward slope in immune function and restore the person to good health.

16. In 1996, effective antiretroviral therapy (ART) became widely available. In the mid-1990’s, medical researchers discovered that a combination of three antiretroviral medications (from at least two different subclasses) would not only prevent HIV from reproducing, but would also prevent the virus from mutating and becoming resistant to the medications, as had been the problem with mono and dual therapy approaches.

17. With adherence to ART, the person’s viral load drops and their CD4 count rebounds. Within several months, the person’s HIV will become “virally suppressed,” defined as less than 200 copies of the virus per milliliter of blood,<sup>1</sup> and shortly after that, they would have an “undetectable”<sup>2</sup> viral load, which is generally defined as less than 50 copies per milliliter of blood.

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<sup>1</sup> See U.S. Centers for Disease Control and Prevention, *Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV* (Dec. 2017), available at <https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf>; U.S. Centers for Disease Control and Prevention, *HIV Treatment as Prevention*, available at [www.cdc.gov/hiv/risk/art](http://www.cdc.gov/hiv/risk/art) (“[V]iral suppression [is] defined as having less than 200 copies of HIV per milliliter of blood.”).

<sup>2</sup> At one time, the testing technologies were not sensitive enough to reliably detect the virus below approximately 50 copies per milliliter. Newer testing technologies are able to detect HIV

18. Every person living with HIV who adheres to their antiretroviral medications will eventually achieve and maintain an undetectable viral load. There is an effective treatment regimen for virtually every person living with HIV, and difficulties in reaching an undetectable viral load are related to a lack of consistent access to the health care and/or other social determinants of health, such as instable housing or food insecurity, that make medication adherence more difficult.

19. Development of resistance to a particular ART regimen does not occur unless the patient is not adherent to their prescribed medications. One of the important features of the ART regimens used today is that if the virus is suppressed the development of mutations that lead to resistance becomes impossible. With three or more medications combatting the virus in different ways at the same time, the virus is not able to mutate around any of those medications. For patients who develop resistance due to non-adherence, switching to a different regimen to which their virus has not developed resistance and to which they are subsequently adherent will return that patient to viral suppression.

20. As drugs have less and less side effects, adherence to ART has grown easier and easier over the past 20 years. Today, most people living with HIV are on a single tablet regimen (“STR”)—in which all three or four medications are combined into one pill—that is taken once a day. STRs have no dietary restrictions, and side effects are minimal and generally very well tolerated.

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below this level, but the term “undetectable” is still used to describe a viral load at or below this level.

21. A person who is diagnosed with HIV in a timely manner and adheres to their prescribed ART has very nearly the same life expectancy as a person who is not living with HIV.<sup>3</sup>

### C. The Transmission of HIV

22. HIV can only be transmitted via certain body fluids—blood, semen, pre-seminal fluid, rectal fluids, vaginal fluids, and breast milk.<sup>4</sup> For transmission to occur, these fluids from a person who has HIV must either come in contact with a mucous membrane or damaged tissue or be directly injected into the bloodstream (with a needle or syringe). Mucous membranes are found inside the rectum, vagina, penis, and mouth. HIV is not spread through saliva, sweat, tears, urine, or feces.

23. Most commonly, HIV is transmitted by engaging in sexual activities or sharing needles or syringes. Outside of the contexts of sexual activity, sharing of injection drug equipment, blood transfusion, needle sticks, or perinatal exposure (including breastfeeding), transmission of HIV is rare. For all other activities—including biting, spitting, and throwing of body fluids—the CDC characterizes the risk as “negligible” and further states that “HIV transmission through these exposure routes is technically possible but unlikely and not well documented.”<sup>5</sup>

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<sup>3</sup> See U.S. Centers for Disease Control and Prevention, *About HIV/AIDS*, available at <https://www.cdc.gov/hiv/basics/whatishiv.html>.

<sup>4</sup> See U.S. Centers for Disease Control and Prevention, *HIV Transmission*, available at <https://www.cdc.gov/hiv/basics/transmission.html>.

<sup>5</sup> See U.S. Centers for Disease Control and Prevention, *HIV Risk Behaviors: Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*, available at [www.cdc.gov/hiv/risk/estimates/riskbehaviors.html](http://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html).

24. Contrary to popular belief, HIV is not an easily transmitted virus. In the absence of treatment and condom use, the CDC estimates that the per-act risk of transmission for the riskiest sexual activity—receptive anal intercourse—is approximately 1.38% (138 out of 10,000 exposures).<sup>6</sup> The per-act risk of transmission for other sexual activities is between zero and .08%.

25. Furthermore, people living with HIV who are virally suppressed or have an undetectable viral load are incapable of transmitting HIV. Advances in understanding of the preventive effects of ART have led the CDC to declare that “...people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV negative partner. See CDC, “Dear Colleague: Information from CDC’s Division of HIV/AIDS Prevention,” Sept. 27, 2017, *available at* <https://www.cdc.gov/hiv/library/dcl/dcl/092717.html> (last viewed June 26, 2018).<sup>7</sup>

26. As further stated in the CDC letter, “Across three different studies, including thousands of couples and many thousands of acts of sex without a condom or pre-exposure prophylaxis (PrEP), no HIV transmissions to an HIV-negative partner were observed when the HIV-positive person was virally suppressed”<sup>8</sup> (i.e., a viral load of less than 200 copies/ml).

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<sup>6</sup> See U.S. Centers for Disease Control and Prevention, *HIV Risk Behaviors: Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*, available at [www.cdc.gov/hiv/risk/estimates/riskbehaviors.html](http://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html).

<sup>7</sup> See U.S. Centers for Disease Control and Prevention, *Treatment as Prevention*, available at [www.cdc.gov/hiv/risk/art](http://www.cdc.gov/hiv/risk/art) (“People living with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative sexual partners.”).

<sup>8</sup> The referenced scientific studies: The HIV Prevention Treatment Network Study No. 052 as published in the *New England Journal of Medicine* 08/11/11, *available at* <https://www.nejm.org/doi/full/10.1056/NEJMoa1105243?query=recirc> curated Related article; PARTNER Study, published in the *Journal of the American Medical Association (JAMA)* July

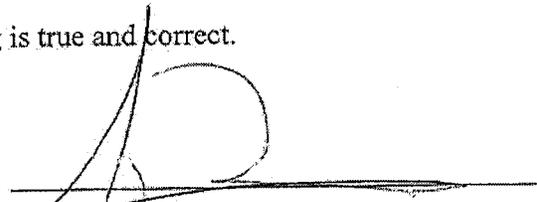
27. Based on these studies regarding the effect of a suppressed or undetectable viral load on sexual transmission risk and the extremely low—and possibly only theoretical—risk of transmission via blood splash and other non-injection activities, I am reasonably certain that it is not possible for a person with a suppressed or undetectable viral load to transmit HIV through such exposures.

#### IV. CONCLUSION

HIV is now a relatively easy to manage, chronic condition that, when properly treated, presents no cognizable risk to the health or safety of others through occupational exposures, including exposures that could potentially occur during military service.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 18 day of July, 2018



Carlos del Rio, M.D.

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12, 2016, available at <https://ncbi.nlm.nih.gov/pubmed/27404185>; and Opposites Attract study reported at the Conference on Retroviruses and Opportunistic Infections (CROI) in 2015, available at <https://www.croiconference.org/sites/default/files/posters-2015/1019LB.pdf> and the International AIDS Conference in 2017.

# Attachment

**EMORY UNIVERSITY  
CURRICULUM VITAE**

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**E-mail Address:** [cdelrio@emory.edu](mailto:cdelrio@emory.edu)

**Birth Date and Place:** August 28, 1959. Mexico City, Mexico

**Citizenship:** United States of America and Mexico

**Websites:**

<http://medicine.emory.edu/infectious-diseases/faculty-directory/del-rio-carlos.html> &  
<https://sph.emory.edu/faculty/profile/#!/cdelrio>

ResearcherID:

<http://www.researcherid.com/ProfileView.action?returnCode=ROUTER.Success&Init=Yes&SrcApp=CR&queryString=KG0UuZjN5WmP6yAsUHlIBIEGQkwtKoQLBlp0gCLTBbs%253D&SID=7Co6dCuimpqh4njckXt>

**Current Titles and Affiliations:**

a. Academic appointments:

April 1, 2009 – present: Hubert Professor & Chair, Hubert Dept. of Global Health,  
Rollins School of Public Health of Emory University

Sept. 1, 2003 – present: Professor of Medicine (Tenured), Emory University School of  
Medicine

b. Clinical Appointments:

March 1997 – July 2011: Active Medical Staff, Grady Health System

Oct 1999 – present: Medical Staff member, The Emory Clinic

July 2011 – present: Active-Courtesy staff member, Grady Health System

June 2013 – present: Infectious Diseases Clinical Chief of Service at Emory University  
Hospital

c. Other administrative appointments:

Jan 16, 2017 – present: Interim Executive Associate Dean for Emory at Grady

Oct 1, 2005 – present: Co-Director, Emory Center for AIDS Research.

Jan. 1, 2007 – present: Clinical Research Site (CRS) Leader at the Ponce de Leon Center  
for the Emory AIDS Clinical Trials Group (ACTG).

**Previous Academic and Professional Appointments:**

1990 – 1996: Associate Professor of Medicine, Universidad La Salle, Mexico City, Mexico.

1989 – 1996: Chief of Infectious Diseases and Chairman of the Infection Control  
Committee, Hospital Angeles del Pedregal, Mexico City, Mexico.

1993 – 1999: National Investigator, National Research Council (Sistema Nacional de Investigadores), Mexico.  
1996 – 1997: Assistant Professor of Medicine (transient appointment), Emory University School of Medicine (EUSM).  
1997 – 2001: Associate Director for Clinical Services at the Ponce de Leon Center of the Grady Health System and Director of the Special Immunology Service at Grady Memorial Hospital  
September 1, 1997 – August 31, 2003: Associate Professor of Medicine (Infectious Diseases), Emory University School of Medicine  
December 18, 1997 – August 31, 2005: Adjunct Associate Professor of International Health, Rollins School of Public Health, Emory University  
September 1, 2005 – March 31, 2009: Adjunct Professor of Global Health, Rollins School of Public Health, Emory University.

**Previous Administrative Appointments:**

1992 – 1994: Executive Director of the National AIDS Council (CONASIDA), Mexico.  
1994 – 1996: General Coordinator of the National AIDS Council (CONASIDA), Mexico.  
1995 – 1997: Member of the Program Coordinating Board, Joint United Nations Program on HIV/AIDS (UNAIDS)  
July 1999 – July 2000: Associate Director of the Internal Medicine Residency Program  
January 1998 – July 2001: Director, Clinical Core of the Emory CFAR  
July 1, 2000 – March 31, 2001: Program Director, Emory Internal Medicine Residency Program  
April 1, 2001 - January 31, 2006: Co-Director, J. Willis Hurst Internal Medicine Program.  
April 1, 2001 - March 31, 2009: Chief of Medical Service, Grady Memorial Hospital  
February 1, 2006 – February 29, 2008: Director for Resident Scholarly Activities, J. Willis Hurst Internal Medicine Residency Program.  
July 1, 2001 – September 30, 2005: Associate Director for Clinical Sciences and International Research, Emory Center for AIDS Research  
July 1, 2004 – June 1, 2006: Executive Director, Hope Clinic of the Emory Vaccine Center.  
February 1, 2006 – March 31, 2009: Vice Chair for Grady Affairs, Dept. of Medicine, EUSM  
March 1, 2008 – May 31, 2010: Program Director, J. Willis Hurst Internal Medicine Residency Program of Emory University.  
Sept. 1998 – June 2015: Director and Principal Investigator, AIDS International Training and Research Program (AITRP) of Emory University.

**Licensures/Boards:**

Georgia Medical License: 027282  
1981: ECFMG (Educational Commission for Foreign Medical Graduates)  
1982: VQE (Visa Qualifying Examination)  
1984: FLEX (Federation Licensing Examination)

**Specialty Boards:**

- 1986, American Board of Internal Medicine (#108785)
- 1988, American Board of Internal Medicine (Infectious Diseases)

**Education:**

- 1977-83: Medical School, Universidad La Salle, Mexico City, Mexico
- 1981-82: Pregraduate internship (senior year of medical school), six months at the University of Oregon, Portland, Oregon and six months at Emory University, Atlanta, Georgia
- 1982-83: Social service, Department of Critical Care Medicine, Instituto Nacional de la Nutrición Salvador Zubirán, Mexico City, Mexico

**Postgraduate Training:**

- 1983-86: Internal Medicine Residency, Emory University School of Medicine, Atlanta, Georgia (five months in JAR year at Johns Hopkins Hospital, Baltimore, MD)
- 1986-88: Infectious Disease Fellowship, Emory University School of Medicine, Atlanta, Georgia
- 1988-89: Chief Resident in Medicine at Crawford Long Hospital of Emory University, Atlanta, Georgia

**Executive Training:**

- Jan 2007: Program for Chiefs of Clinical Services. Department of Health Policy and Management, Harvard School of Public Health.
- Jan 2008: Woodruff Health Sciences Center Quality Academy.

**Committee Memberships:**

- a. National and International:
  - Member of the Scientific Advisory Committee of the Latin-American AIDS Initiative (SIDALAC) (1996 – 2000)
  - Member of the Monitoring of the AIDS Pandemic (MAP) Network (1996 – 2000)
  - Chair, Committee on the Status of Minority Microbiologists, Public and Scientific Affairs Board, American Society for Microbiology (June 1997 - June 2003)
  - CDC, Member of the Task Force to develop the “*HIV Prevention Strategic Plan Through 2005*” (February 2000).
  - Member of the CDC Advisory Committee on HIV and STD Prevention (September 2000 – November 2003)
  - Member of the UNAIDS Performance Monitoring and Evaluation Plan Working Group (1997)
  - NIH Office of AIDS Research, Member of the Planning Group on International AIDS Research Priorities (April, 2001 and February 2002)
  - NIH, Chairman of Special Emphasis Panel for NIH NOT AI-01-018 “*Comprehensive International Program of Research on AIDS*” (August, 2001)
  - NIH, Member of Special Emphasis Panel for NH-00-0048 “*Early detection of HIV: Implications for Prevention Research*” (June 2000)
  - NIH, Member of Special Emphasis Panel for NH-00-004 “*Long-term Maintenance of HIV/STD Behavior Change*” (June 2000)
  - Elizabeth Glaser Pediatric AIDS Foundation, Member of Review Panel for “Call for Action Projects” (January 1996 to present)

- Member, Institute of Medicine’s Committee on the Ryan White Care Act: Data for Resource Allocation, Planning and Evaluation. (January 2002 – October 2003).
- NIH, Member of the Outcomes Committee of the Adult AIDS Clinical Trials Group (July 2001 – December 2006)
- Member, International AIDS Society – USA Core Faculty (April 2002 to present)
- NIH, Chairman of Special Emphasis Panel ZAI1-GPJ-A-S2 “*Comprehensive International Program of Research on AIDS - CIPRA*” (May, 2003)
- CDC, Member Special Emphasis Panel 2003-N-008922 “*A US Clinical Trial Site to Conduct Evaluation of Topical Microbicides in Heterosexual Women and Men*” (August, 2003)
- Member, Education Committee, Infectious Diseases Society of America (2003 – 2005)
- NIH, Member of Special Emphasis Panel ICP-2 “*International Bioethics Reviews*” (March 2004)
- NIH, Member of Special Emphasis Panel ZAI1 GP J-M (M1) “*NIAID Enhancement Awards for Underrepresented Minority Scientists*” (June 28 – 30, 2004)
- CDC, Member on Special Emphasis Panel PA 04156, “*Simplified Procedures for Routine HIV Screening in Acute Care Settings*” (August 17, 2004)
- NIH – Charter Member of the AIDS Clinical Studies and Epidemiology Study Section (formerly AARR-6), November 2004 – July 2009.
- Member of the Board of Directors, International AIDS Society – USA (January 2005 – present)
- NIH, Member of Special Emphasis Panel ZAI1 LD-A-J1 “*Unsolicited Research Project Grant Application*” (January 2006)
- NIH, Member of Special Emphasis Panel ZAI1 SV-A (S1) “*TB/HIV Immune Cell Expression*” (August 2006)
- NIH, Chair of Special Emphasis Panel ZAI1QV-1 “*Review of Clinical Trials and Implementation Grants*” (September 2006)
- NIH, Member of Special Emphasis Panel ZRG1 IC2-B (51) “*Phase II Comprehensive ICOHRTA-AIDS/TB (U2R) Review*” (November 2006)
- Representative of HIVMA on the Education Committee of IDSA (2006 – 2010)
- External Reviewer of the draft report by the Committee on the “*President’s Emergency Plan for AIDS [PEPFAR] Implementation Evaluation*”. (November 2006)
- Member, Institute of Medicine’s Committee on Methodological Challenges in HIV Prevention Trials (January 2007 – February 2008).
- Member, DHHS Panel for Antiretroviral Guidelines for Adults and Adolescents (February 2007 – February 2010 and February 2010 – February 2014)
- NIH, Member of Special Emphasis Panel ZAI1 ESB-A (M1) “*HIV Prevention in Men Review*” (April 2007)
- NIH, Member of Special Emphasis Panel ZRG1 BDA-A (52) “*FICRS Resource and Support Center Review*” (April 2007)
- CDC, Member of Special Emphasis Panel ZPS1 FXR (03) “*Minority HIV/AIDS Research Initiative to Build Capacity in Black and Hispanic Communities and Among Black and Hispanic Researchers to Conduct HIV/AIDS Epidemiologic and Prevention Research – MARF*” (May 2007)

- NIH, Member of Special Emphasis Panel ZAI1 SR-M (1) “*NIAID Clinical Trials Planning Grants*” (June 2007)
- Member of the Board of Directors of the HIVMA - HIV Medicine Association of IDSA - (October 2007 – Oct 2017)
  - Chair of the Board (Oct 2015 – Oct 2016)
- Member of the Board of Advisors of HealthSTAT (July 2007 – present)
- NIH, Member of Special Emphasis Panel ZRG1 ICP2-B (51) “*Global Infectious Diseases Training Program*” (February 2008)
- NIH, Member of Special Emphasis Panel ZRG1 ICP2-B (50) “*International Research in Infectious Diseases*” (February 2008)
- NIH, Member of Special Emphasis Panel ZDA1 NXR-B 13 1, “*International Collaborations for HIV and Drug Abuse*” (April 2, 2008)
- Member of the OpMAN (Optimization of Co-Infection and Co-Morbidity Committee) of the AIDS Clinical Trials Group (May 2008 – May 2010)
- Member of the Advisory Committee on HIV and STD Prevention and Treatment of the Centers for Disease Control and Prevention and Health Resources and Services Administration (July 1, 2008 – June 30, 2012 and July 1, 2012 – December 30, 2016)
- NIH, Member of Special Emphasis Panel ZDA1 NXR-B 08 1, “*Pre-Applications for the Avant-Garde Program*” (April 19, 2009)
- NIH, Member of Special Emphasis Panel ZRG1 AARR-C 22 “*AIDS Fellowship Review*” (July 28-29, 2009)
- Member, Institute of Medicine Committee on HIV Social Security Disability Criteria (Dec 2009 – June 2010)
- Member, WHO Influenza A(H1N1) Clinical Advisory Group (2009)
- Member, CDC Influenza A(H1N1) Task Force (2009)
- NIH, Member of Special Emphasis Panel ZCA1 RTRB-8 M2 R “*A Developing Research Capacity in Africa for the Studies of HIV-Associated Malignancies*” (March 15, 2010)
- NIH, Member of Special Emphasis Panel ZDA1 NXR-B 08 1, “*Pre-Applications for the Avant-Garde Program*” (April 23, 2010)
- Member of the ACTG Executive Committee (June 1, 2010 – May 31, 2013)
- Member of the Board of Directors of the Infectious Diseases Society of America (October 2010 – September 2013)
- Member, Institute of Medicine Committee to Review Data Systems for Monitoring HIV Care (February 2011 – September 2012)
- NIH, Member of Special Emphasis Panel ZRG1 IDM-R (50) R, “*International Research in Infectious Diseases including AIDS (IRIDA)*”. (February 11, 2011)
- NIH, Chair, Special Emphasis Panel ZRG1 F12B-U (20) L, “*Fellowships: Psychopathology, Disabilities, Stress and Aging*.” (February 24, 2011)
- NIH, Member of Special Emphasis Panel ZDA1 NXR-B 15, “*Pre-Applications for the 2011 Avant-Garde Program for HIV/AIDS Research*” (March 28, 2011)
- NIH/NIAID – Charter Member, Acquired Immunodeficiency Syndrome Research Review Committee (AIDS RRC), (July 1, 2011 – June 30, 2015).
- NIH, Member of Special Emphasis Panel ZRG1 AARR-H (55) “*Career Development in International Settings*”. (June 29, 2011)

- NIH/FIC – Member, US-India Joint Working Group on Prevention of Sexually Transmitted Diseases and HIV/AIDS (Oct 31, 2011)
- NIH, Member of Special Emphasis Panel ZDA1 NXR-B, “Pre-Applications for the Avant-Garde Program” (Jan 11, 2012)
- NIH, Chair of Special Emphasis Panel ZRG1 AARR-H, “HIV International Research Training” (Oct 31 – Nov 1, 2012)
- Member of the Board of Director, ACTHIV (April 2013 – present)
- Co-Chair, International Antiviral Society-USA Panel on Development of Recommendations for Biomedical Prevention of HIV Infection (2013)
- NIH, member of Special Emphasis Panel ZAI1 BP-A (S4), “Clinical Trials Implementation UO1 Grants” (Aug 26, 2013)
- NIH, member of Special Emphasis Panel ZRG1 AARR-F (52), “Methodologies and Formative Work for Combination HIV Prevention Approaches” (Dec 16, 2013)
- Member, Office of HIV/AIDS Network Coordination (HANC) Behavioral Sciences Consultative Group (Jan 1, 2015 – Dec 31, 2018)
- NIH/NIAID – Chair, Acquired Immunodeficiency Syndrome Research Review Committee (AIDS RRC), (July 1, 2014 – June 30, 2017)
- Member, UNAIDS Scientific and Technical Advisory Committee (Dec 2014 – present)
- Member, Fulton County Task Force on HIV/AIDS (Dec 2014 – Sept 2017)
- Chair, PEPFAR Scientific Advisory Board (March 1, 2015 – present)
- Vice-Chair, ACTG Underrepresented Populations Committee (Dec 1, 2016 – Nov 30, 2018)

b. Regional and State:

- Member of the Scientific Advisory Committee of the AIDS consortium of Atlanta (1996 – 2004)
- Member of the Board, AID Atlanta (1998 – 2004)
- Member of the Board of Trustees, The Paideia School (1998 – 2004)
- Member of the Parent Council of Emory University (2007 – 2010)
- Member of the Board of Directors, Atlanta Symphony Orchestra (2011 – present)

c. Institutional

- LCME Graduate Medical Education/Continuing Education Committee (1998)
- Dean of School of Nursing Search Committee (1999)
- GME Advisory Committee (July 1999 - present)
- Representative of the School of Medicine on the International Affairs Council (November 2000 to 2009)
- Member of the School of Medicine Faculty Committee on Appointments and Promotions (June 2001 – September 2004)
- Member of the Faculty Council of Emory University (2000- 2004)
- Member, Advisory Board of the Center for the Study of Health, Culture and Society (December 2000 – May 2009)
- Internal Medicine House Staff Evaluation Committee (March 1998 - present)
- Orthopedic Chair Search Committee (2001)
- Medical Executive Committee, Grady Health System (April 2001 – March 2009)

- Chair, Education and Training Subcommittee, Woodruff Health Sciences Center Bioterrorism Taskforce (April 2002 – December 2003)
- Representative of the School of Medicine on the Coordinating Committee for University Internationalization (September 2002 – April 2009)
- Chair, Medical Records Committee, Grady Health System (May 2002 – December 2005)
- Member, EMCF Practice Committee (June 2002 – March 2009)
- Member, Emory GCRC Advisory Committee (June 2002 – June 2007)
- Radiology Chair Search Committee (2003-2004)
- Member, Emory University Strategic Planning Committee (Subcommittees on Global Health and Internationalization).
- Co-Chair, Curriculum Planning Steering Committee of Emory University School of Medicine (September 2004 – December 2005)
- GCRC Director Search Committee (2005)
- Member, Faculty Development Committee for the Department of Medicine (2005 – 2009)
- Chair, Department of Medicine Promotions and Tenure Subcommittee (2005 – 2007)
- Member, Honorary Degrees Committee of Emory University (2006 – 2009)
- Member, Global Health Institute Advisory Committee, Emory University (2006 – present)
- Member, Institute for Developing Nations Academic Board, Emory University (2006 – present)
- Co-Chair Task Force on Faculty and Staff Development, Emory University School of Medicine (December 2006 – August 2007)
- Member, Search Advisory Committee for the Senior Vice President for Health Affairs of the Woodruff Health Sciences Center of Emory University (January – July 2007)
- Member, LCME Faculty Subcommittee (2007)
- Member, Presidential Advisory Committee (PAC) of Emory University (September 2007 – August 2009)
- Member, Surgery Chair Search Advisory Committee (2007-08)
- Member, Director of Critical Care for Emory Healthcare Search Advisory Committee (2008-09)
- Member, Research Advisory Committee of the School of Medicine (March 1, 2009 – August 31, 2010)
- Member, Woodruff Health Sciences Center Research Advisory Council (April 2009 – present)
- Chair of the Research Training and Education subcommittee for the WHSC Research Strategic Plan (August 2009 – May 2010)
- Co-Chair, Culture Transformation Group, Woodruff Health Sciences Center (May 2009 – May 2011).
- Member, Task Force on Protest, Dissent and Community (May 2011 – May 2015)
- Member, Emory University Faculty Advisory Committee for Finance and Administration (Oct 2011 – May 2015)
- Member, Family and Preventive Medicine Chair Search Committee (2012)

- Member, Graduate Medical Education Strategic Planning Committee (2013)
- Member, Director of Yerkes National Primate Research Center Search Committee (2013)
- Member, LCME Taskforce (2015)
- Co-Chair, Emory University's Provost Search Advisory Committee (Oct 2016 – 2017)

**Consultantships:**

- Centers for Disease Control and Prevention, Consultant for the drafting of the "*HIV Prevention Strategic Plan Through 2005*". September 2000.
- Centers for Disease Control and Prevention, External consultant for the "*Control of Neisseria gonorrhoeae infection in the United States*". Oct 10 – 11, 2001.
- Centers for Disease Control and Prevention, Consultant on "*Bioterrorism Education for Clinicians*", August 2002.
- Abbott Laboratories. HOPE Partnership (December 2001 – December 2002)
- Centers for Disease Control and Prevention, Consultant on implementing HIV Testing in Acute Care Settings. March 2004.
- NIH/Harvard Medical School Division of AIDS, Participant in the scientific workshop addressing "*When to Switch HIV Antiviral Therapy in Resource-Limited Settings*". Boston, MA. November 12, 2004.
- Centers for Disease Control and Prevention, Participant in Satellite Broadcast/Web Cast "*Incorporating HIV Prevention into the Medical Care of Persons Living with HIV*". November 13, 2004.
- Centers for Disease Control and Prevention, Consultant in drafting the "*HIV Screening Recommendations for Adults, Adolescents, and Pregnant Women in Health Care Settings*". November 1 – 2, 2005. Published as "*Revised Recommendations for HIV testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*". *MMWR* 2006; 55(RR-14)
- Interagency Task Force on Antimicrobial Resistance, Consultant in drafting "*A Public Health Action Plan to Combat Antimicrobial Resistance*". December 12-13, 2007.
- Centers for Disease Control and Prevention, consultant for the "*External Peer Review of DHAP Surveillance, Research, and HIV Prevention Programs*". April 13 – 15, 2009
- Centers for Disease Control and Prevention, consultant for the "*Consultation on Revised Guidelines for HIV Counseling, Testing, and Referral in non-clinical settings*". June 1 – 2, 2009.
- Centers for Disease Control and Prevention, consultant during a meeting entitled: "*Developing a Rapid Impact Assessment Framework for Pandemic Influenza Response*". August 26, 2010
- Centers for Disease Control and Prevention, consultant for the "*Consultation on Monitoring and Use of Laboratory Data Reported to HIV Surveillance*". Jan 12 – 13, 2011
- Centers for Disease Control and Prevention, consultant for the "*Consultation on MSM Pre-Exposure Prophylaxis (PrEP) Implementation Guidelines*". May 3 – 4, 2011.

- Centers for Disease Control and Prevention, consultant for the “*HIV surveillance Case Definition*”. Feb 7 – 8, 2012.
- Centers for Disease Control and Prevention, consultant for the “*STD Treatment Guidelines 2013*”. April 30 – May 2, 2013.

#### **Editorship and Editorial Boards:**

- Chief Editor, HIV/AIDS *Journal Watch Infectious Diseases (2014 – present)*
- Associate Editor for HIV, *Clinical Infectious Diseases (2016 – present)*
- Senior Clinical Editor, *AIDS Research and Human Retroviruses (2007 – 2017)*
- Editorial board, *AIDS Clinical Care (2000 – 2014)*
- Editorial Board, *Journal of AIDS*
- Editorial Board, *Global Public Health*
- Editorial Board, *Women, Children and HIV*
- Editorial board, *Archives of Medical Research*

#### **Manuscript reviewer**

- AIDS
- AIDS Research and Human Retroviruses
- AIDS and Behavior
- American Journal of Medicine
- American Journal of Public Health
- American Journal of Preventive Medicine
- American Journal of the Medical Sciences
- Annals of Internal Medicine
- Annals of Emergency Medicine
- Archives of Internal Medicine
- Archives of Medical Research
- Clinical Infectious Diseases
- Emerging Infectious Diseases
- Gaceta Médica de México
- JAMA
- Journal of AIDS
- Journal of General Internal Medicine
- Journal of Infectious Diseases
- Lancet
- New England Journal of Medicine
- PLoS One
- Salud Pública de México
- Sexually Transmitted Infections
- Social Sciences and Medicine
- Vaccine

#### **Honors and Awards:**

- 1982 Valedictorian, medical school class of 1982, Universidad La Salle, Mexico
- 1983 Awarded "Los mejores estudiantes de México" (Best students in Mexico)
- 1987 Elected member of A.O.A.
- 1988 Trainee Travel Award, American Federation for Clinical Research
- 1990 Fellow of the American College of Physicians
- 1989, 91, 96 Physician Recognition Award, American Medical Association
- 1992-99 "Investigador Nacional Nivel I" (National Researcher) by the "Sistema Nacional de Investigadores" in Mexico
- 1993 Award "Hermano Miguel" given by the Universidad La Salle in Mexico in recognition of academic achievement
- 1996 Glaxo-Wellcome Foundation Award for Clinical Research. Mexico City, Mexico.
- 1996 Fellow of the Infectious Diseases Society of America
- 2001 James H. Nakano Citation (for an outstanding scientific paper published in 2000)
- 2002 Finalist, Atlanta Business Chronicle "Health-Care Heroes" Award in the

- Physician category
- 2006 Outstanding Achievement Award in the Field of HIV/AIDS awarded by the First Lady of Georgia for "*Personal Contribution in Developing a modern HIV/AIDS Control Program in Georgia*"
- 2007 Marion V. Creekmere Award for Internationalization, Emory University
- 2006, 2007, 2009, 2010, 2011, 2012, 2013 and 2017 "Best Conference Award", as voted by the residents for the most outstanding conference in the Emory Internal Medicine Residency Program.
- 2007 Selected by "*Atlanta Magazine*" as one of the 55 most influential foreign-born Atlantans (October 2007 issue)
- 2009 Elected member of the American Clinical and Climatological Association
- 2011 Elected member of the American Epidemiological Society
- 2011 Silver Pear Research Mentoring Award, Department of Medicine, Emory Univ.
- 2013 Fellows Award for Distinguished Educator in Infectious Diseases, University of Pittsburgh Division of Infectious Diseases
- 2013 Elected to the National Academy of Medicine (formerly the Institute of Medicine)
- 2014 Winner of the Thomas Jefferson Award at Emory University
- 2015 Winner of the Department of Medicine R. Wayne Alexander Research Achievement Award
- 2015 Department of Medicine Research Day, 3<sup>rd</sup> place winner in the "Clinical, Quality and Health Services Research Poster" category.
- 2016 Elected to Delta Omega (Honorary Society in Public Health) by the member students of the Phi Chapter at the Rollins School of Public Health
- 2016 Recipient of the "Ohtli Award" from the Mexican Government for "*distinguished work that benefits the interests of the Mexican community or communities of Mexican origin living in the US*".
- 2017 John P. McGovern Award Lectureship delivered at the 47<sup>th</sup> Annual Meeting of the American Osler Society. Atlanta, GA April 10<sup>th</sup>, 2017.
- 2017 Distinguished Medical Alumni Achievement Award – Emory University School of Medicine
- 2017 Inducted to the Emory MilliPub Club (The MilliPub Club honors and recognizes Emory faculty who have published one or more papers that have garnered more than 1,000 citations).
- 2017 Winner of the Emory University School of Medicine Mentoring Award

**Society Memberships:**

- American College of Physicians
- Member of the American Society for Microbiology
- Asociación Mexicana de Medicina Interna
- Infectious Diseases Society of America
- Asociación Mexicana de Infectología y Microbiología Clínica
- American Federation for Medical Research
- International AIDS Society

**Organization of National or International Conferences:**a. Administrative positions:

- Organizing committee of the 8th International Pathogenic *Neisseria* Conference, October 1992, Cuernavaca, Mexico
- Coordinator of the IV National AIDS Conference, October 1993, Mexico City, Mexico
- Organizing committee of the IV International Conference on Travel Medicine, April 1995, Acapulco, Mexico
- Coordinator of the V National AIDS Conference, November 1995, Mexico City, Mexico
- Scientific Committee, 1<sup>st</sup> IAS Conference on HIV Pathogenesis and Treatment, Buenos Aires, Argentina, July 2001
- Track Co-chair, 2001 National HIV Prevention Conference, Atlanta, GA, August 2001
- Scientific Program Committee Member, 3<sup>rd</sup> Conference on Global Strategies for the Prevention of HIV Transmission from Mothers to Infants. Kampala, Uganda. September 2001.
- International Scientific Committee, XIV International Conference on AIDS, Barcelona, Spain, July 2002
- Scientific Program Committee, 8<sup>th</sup> World STI/AIDS Congress, Punta del Este, Uruguay, December 2-5, 2003.
- Joint Program Committee Track Co-chair, XVI International Conference on AIDS, Mexico City, Mexico, August 2008.
- Track Co-chair, 2009 National HIV Prevention Conference, Atlanta, GA, August 2009
- Planning Committee Member, 36<sup>th</sup> Remington Winter Course in Infectious Diseases. Vail, CO. February 21 - 26, 2010
- Co-Chair, AIDS Vaccine 2010. Atlanta, GA. September 28 – October 1, 2010
- Regional Chair, HIVDART 2010. Los Cabos, Mex. December 7 – 10, 2010
- Planning Committee Member, 37<sup>th</sup> Remington Winter Course in Infectious Diseases. Snowmass, CO. February 6 – 11, 2011
- Member, Clinical Science Track Committee, XIX International Conference on AIDS, Washington, DC. July 22 – 27, 2012
- Member, Scientific Advisory Committee, 2<sup>nd</sup> International Treatment as Prevention (TasP) Workshop. Vancouver, BC. April 22 – 25, 2012
- Member, Scientific Advisory Committee, 3<sup>rd</sup> International Treatment as Prevention (TasP) Workshop. Vancouver, BC. April 22 – 25, 2013
- Co-Chair of Planning Committee, The American Conference for the Treatment of HIV (ACTHIV), Denver, Co. May 8 – 10, 2014
- Scientific Advisory Committee, HIVDART 2014. Key Biscayne, Fla. December 9 – 12, 2014
- Member of the Scientific Program Committee, HIV Drug Therapy in the Americas 2015. Mexico City, Mx. April 16 – 18, 2015.
- Co-Chair of Planning Committee, The American Conference for the Treatment of HIV (ACTHIV), Dallas, Tx. Apr 29 – May 3, 2015
- Member of the Core Committee, HIV & Hepatitis in the Americas 2016. Mexico City, Mx. April 28 – 30, 2016.
- Member of the Core Committee, HIV & Hepatitis in the Americas 2017. Rio de Janeiro, Brazil. April 6 – 8, 2017.

**Research focus:**

My research efforts focus on access to care, linkage to care and barriers to care among HIV-infected hard to reach populations in the United States and abroad. I also do research on treatment and prevention of HIV/AIDS as well as adherence and the impact of therapy on behavior. I also work on TB and other co-infections like HCV and STI's, in particular gonorrhea. Finally, my research has expanded to include the emerging opioid epidemic and looking for ways to improve opioid prescribing and management of pain in clinical settings.

**Grant Support:**a. Active support:

- NIH (2P30 AI 50409). Emory CFAR. (PI: C. del Rio) 08/01/17 – 7/31/22.
- NIH/NIAID (AI069418). Emory-Duke-Orlando-CDC Clinical Trials Unit. (co-PIs: J. Lennox; C. del Rio & M. Mulligan) 12/10/13 – 11/30/20
- NIH/NIDA (1R01DA037768). Improving Physician Opioid Prescribing for Chronic Pain in HIV-infected Persons (co-PIs: J. Samet & C. del Rio), 09/15/2014 – 08/31/2018.
- NIH/NIDA (1R01DA032098-03). Project Retain: Providing Integrated Care for HIV-infected crack cocaine users (co-PIs: L. Metsch & C. del Rio), 07/15/2011 – 04/30/2017 (no cost extension).
- CDC (1H25-PS004311). The Emory Atlanta Gonococcal Isolate Surveillance Project - GISP (PI: C. del Rio), 01/01/14 - 12/31/18.
- NIH/NIDA (5U10DA013720). Florida Node of the Drug Abuse Clinical Trials Network (PI: J. Szapocznik & L. Metsch; Emory site PI: C del Rio) 00/30/2000 – 08/31/2020
- CDC (5T01GH001185). Emory Center for Public Health Training in Complex Humanitarian Emergencies (PI: C. del Rio) 9/1/2015 – 08/31/2018
- NIH (D43 TW007124). Emory-Georgia Tuberculosis Research Training Program (PI: H. Blumberg; Co-PI: C. del Rio), 09/30/04 - 06/30/19.
- NIH (D43 TW009127) Emory-Ethiopia Tuberculosis Research Training Program (PI: H. Blumberg; Co-PI: C. del Rio), 07/1/13 - 01/31/18.

**Lectureship, Seminar Invitations, and Visiting Professorship:** (last ten years)

- \* *“Global and regional priorities in Infectious Diseases”*. Opening plenary talk at the XLII Congress of the National Infectious Diseases Society of Mexico. Puebla, Mx. May 24, 2017
- \* *“Top 10 in HIV”*. Closing Plenary Speaker at the 11<sup>th</sup> Annual ACTHIV meeting. Dallas, TX April 20-22, 2017.
- \* *“Improving patient outcomes by focusing on the HIV Care Continuum”*. Keynote speaker at the Symposium: Emerging Strategies for HIV and Viral Hepatitis Co-Infection Symposium. Atlanta, GA. Dec 1<sup>st</sup>, 2016.
- \* *“What reviewers look for in your RPG application: perspectives from reviewers”*. Invited talk at the NIAID Research Career (“K”) Development: Fostering Science Leaders Workshop. NIH/NIAID Bethesda, MD. November 29, 2016.
- \* *“Health Equity: Improving outcomes in Hard to Reach Populations”*. Invited talk at the 10<sup>th</sup> Annual Meeting of the CFAR Social and Behavioral Sciences Research Network. Miami, FLA. October 20, 2016.

- \* *“The HIV Care Continuum”*. Invited Talk at the Symposium on Clinical and Prevention Care organized by the Fulton County Department of Health and Wellness. Atlanta, Ga. June 20, 2016.
- \* *“High Impact Research Transforming Health Policy”*. HIV Grand Rounds organized by the Univ. of Pennsylvania CFAR. Philadelphia, Penn June 16, 2016.
- \* *“High Impact Research Transforming Health Policy”*. Invited talk at the 3<sup>rd</sup> Annual “Advancing Healthcare Quality Research at Emory University: Symposium. Atlanta, Ga. May 18, 2016.
- \* *“Improving retention and viral suppression among hard-to-reach HIV-infected populations”*. University of Miami CFAR Visiting Professor. Miami, Fla. May 5<sup>th</sup>, 2016.
- \* *“Sexual Transmission and Mosquitoes: A New Phenomenon in Arbovirology?”* Bridging the Sciences: Zika Virus. Atlanta, GA May 1 – 2, 2016.
- \* *“Global Health and US Universities”*, invited speaker at the University of South Carolina Global Health Initiative Workshop. Columbus, SC Oct 22 -23, 2015.
- \* *“Becoming an investigator: From Medicine Resident to Professor of Medicine and CFAR co-Director”*, invited lecture at the NIAID/IDSA Infectious Diseases Careers Meeting 2015. Bethesda, MD June 4 – 6, 2015.
- \* *“Tactical decision making in Health and Humanitarian Supply Chain Management”*. Invited lecture at the Georgia Tech course “Health & Humanitarian Supply Chain Management”. May 14<sup>th</sup>, 2015.
- \* *“Ebola and other Global Issues of Local Concern”*. Invited talk at the 2015 Infectious Diseases Association of California (IDAC) Spring Symposium. Costa Mesa, CA May 2-3, 2015.
- \* *“The Ebola Crisis: Lessons in International Cooperation for Global Health”*. Invited talk at the Association of Academic Health Centers 2015 International Forum. Washington, DC April 20 - 21, 2015.
- \* Keynote speaker *“What will it take to end the AIDS epidemic?”*. Invited talk at the HIV Drug Therapy in the Americas Congress 2015. Mexico City, MEX. April 16 – 18, 2015.
- \* Keynote Address at the 12<sup>th</sup> Annual Graduate Division of Biological and Biomedical Sciences Student Research Symposium. Emory University School of Medicine. Jan 15<sup>th</sup>, 2015.
- \* *“How Far We’ve Come and How Far We Still Need to Go: Engagement in HIV Care for our Most Vulnerable Populations of People Living with HIV in Atlanta and the Southern United States”*. Invited talk at the 16<sup>th</sup> World AIDS Day Symposium organized by the UNC Center for AIDS Research and the Institute for Global Health and Infectious Diseases. Dec 5<sup>th</sup>, 2014.
- \* *“The Past, Present, and Future of Global Health Engagement by Academic Institutions”*. Keynote Lecture at the CFAR HIV Research in International Settings (CHRIS) Meeting hosted by the UCSD CFAR. Oct 1<sup>st</sup>, 2014.
- \* *“Advances in Seek, Test and Treat Strategies/Treatment as Prevention”*. Invited talk at the US-Georgia Program Development Workshop on HIV/AIDS, Tuberculosis and Hepatitis. Tbilisi, Georgia. June 16 – 18, 2014.
- \* *“The Diagnosis and Treatment of HIV infection: Translating research into policy and practice”*. Invited talk at the 7<sup>th</sup> Anniversary of CISIDAT (Consortio de Investigacion sobre VIH/SIDA/TB). Mexico City, Mex. June 5, 2014.

- \* *“Can we end the HIV epidemic”*. Life of the Mind Lecture Series organized by the Provost of Emory University. March 26, 2014.
- \* *“Linkage and Retention: What works and what doesn’t”*. Invited talk at the 4<sup>th</sup> International HIV Workshop on Treatment as Prevention. Vancouver, BC. April 1 – 4, 2014.
- \* *“Challenges in the HIV Continuum of Care and its Relevance to Treatment as Prevention”*. University of Miami CFAR Visiting Professor. February 28, 2014.
- \* *“Current Status of HIV Continuum of Care Research”*, Invited Talk at the 2<sup>nd</sup> National CFAR/APC HIV Continuum of Care Working Group Meeting: Implementation Science to Address the Challenges of the HIV Continuum of Care. Washington, DC. Feb 3 – 4, 2014.
- \* *“The Fight Against AIDS”*, Invited TEDx Talk at Institut LeRosey, Switzerland. Nov 9, 2013 (<http://tedxtalks.ted.com/video/The-Fight-Against-AIDS-Dr-Carlo> & <http://www.youtube.com/watch?v=F2Hz4t66-Ig>)
- \* *“Seek, Test, Treat and Retain Among Vulnerable Populations”*, Invited Speaker to the Spring Meeting of the Massachusetts Infectious Diseases Society. Boston, Mass May 14, 2013.
- \* *“Treatment is Prevention: novel approaches to HIV therapy”*, Key Note Speaker, AIDS United Access to Care Grantee Meeting, Atlanta, GA April 5, 2012.
- \* *“The Future of HIV Prevention”*, Key Note Speaker at the 5<sup>th</sup> Research Meeting on HIV/AIDS diagnosis, care and prevention among vulnerable populations. Mexico City, Mexico. November 14, 2011
- \* *“History of HIV/AIDS in the US”*, Speaker at the 2011 American Conference for the Treatment of HIV (ACTHIV). Denver, CO. April 7, 2011.
- \* *“Building on Success”*. Speaker at the CDC World AIDS Day Event. Atlanta, GA. December 1, 2010
- \* Invited Keynote speaker: *“Evidence Based Global Health”*. Annual Meeting of the Mexican National Epidemiological Surveillance System (Reunion Nacional del Sistema Nacional de Vigilancia Epidemiologica). Cancun, Mex. November 22, 2010
- \* Invited Keynote address: *“Recent Advances in Biomedical HIV Prevention: Translating Research into Practice”*. 5<sup>th</sup> National Scientific Meeting of the CFAR’s Social and Behavioral Sciences Research Network. Atlanta, GA. October 8, 2010
- \* *“14<sup>th</sup> Annual Paul J. Galkin Lectureship”* Brown University, Providence, RI. September 20-21, 2010.
- \* *“University of Massachusetts Center for Global Health Visiting Professor”* University of Massachusetts, Worcester, MA. May 19, 2010
- \* *“Facilitators and Barriers to HIV testing in hospital and other ambulatory care settings”*. Presentation to the Institute of Medicine Workshop to identify facilitators and barriers to HIV testing. Washington DC. April 15, 2010.
- \* *“Tim Gills Visiting Professorship”* University of Colorado at Denver Center for AIDS Research, Denver CO. March 30-31, 2010.
- \* *“Viral Zip Codes: Novel Influenza A (H1N1): what have we learned in the last 6 months?”* Invited speaker at the Fifth Annual National Symposium on Predictive Health “Human Health: Molecules to Mankind”. Atlanta, GA. December 14, 2009
- \* *“Public Health and Health Care: Working Together for HIV Prevention”*. Discussant in CDC Panel for World AIDS Day. Atlanta, GA. December 1, 2009

- \* *“The Healthcare needs of Migrants*. Key Note Speaker at the Hispanic Health Coalition of Georgia Latino Health Summit. Atlanta, GA. February 27, 2009.
- \* *“Challenges in improving the National Response to the HIV/AIDS Epidemic”*. Invited Speaker at the Seminar organized by the Instituto Nacional de Salud Publica and the Secretaria de Salud, Mexico. February 20, 2009
- \* *“Challenges and Controversies in Infectious Diseases in the XXI Century”*. Invited Lecture at the XXI Annual Meeting of the Medical Society of Hospital Angeles, Mexico City, Mex. February 19, 2009
- \* *“Antiretroviral Therapy: 25 years of Progress”*. Medical Grand Rounds, SUNY Downstate Medical Center, Brooklyn NY. December 11, 2008
- \* *“Confronting the Global HIV epidemic: moving forward after Mexico City”*. Invited key note speaker to the Second Annual International; HIV/AIDS Research Day of the UCSD CFAR. San Diego, CA. October 7, 2008
- \* *“In the Eye of the Storm: The Emerging Epidemics of HIV, Hepatitis and Tuberculosis in the Former Soviet Republic of the Caucasus”*. Invited Global Health Institute seminar speaker, University of North Carolina, Chapel Hill, NC. December 8, 2007.
- \* *“Strategies for Initial Antiretroviral Therapy through Complicated Failure: A Case-Based Discussion”*. Lecture presented at the Annual IAS-USA Course Improving the Management of HIV Disease. New York, NY. October 19, 2007
- \* *“New Antiretrovirals”*. Lecture presented at the Annual IAS-USA Course Improving the Management of HIV Disease. Washington, DC. May 23, 2007.
- \* *“Antiretroviral Therapy Failure: A case based discussion”*. Lecture presented at the Annual IAS-USA Course Improving the Management of HIV disease. Atlanta, GA. April 27, 2007.
- \* *“The Perfect Storm: Emerging Epidemics of HIV, HCV and TB in the Republics of the Former Soviet Union”*. Invited Lecture in the course: AIDS: A Multidisciplinary Approach” at the University of Washington. Seattle, WA. April 2, 2007
- \* *“Strategies for Recruitment of Minority Study Participants”*. Invited lecture presented at the symposium “Ethics in Action: Building Trust and Effectiveness in the Clinical Trial Process – Are we doing our best? Organized by the Emory University School of Medicine Clinical Trials Office and the Emory Center for Ethics. Atlanta, GA. March 1, 2006.
- \* *“Antiretroviral Therapy in the Treatment Experienced Patient”*. Lecture Presented at the 13<sup>th</sup> Annual IAS-USA Current challenges in HIV disease. New York, NY. October 17, 2005.
- \* *“Update in HIV infection”*. Lecture presented at the Northside Hospital Internal Medicine Conference. Atlanta, GA. September 8, 2005.
- \* *“Strategies for Providing Care to Hard to Reach Populations”*. Invited Lecture and visiting Professorship at the University of North Carolina, Chapel Hill, NC. June 9 -10, 2005.

**Invitations to National or International Conferences:** (last ten years)

- *“Linkage to Care”* Plenary Speaker at ANAC2016. Atlanta, GA. Nov 10 – 12, 2016
- *“What’s Hot in HIV Clinical Research”*. Invited speaker at IDWeek2016. New Orleans, LA. Oct 26 – 30, 2016
- *“What’s New, What’s Next, What’s Ahead?”* Invited Plenary Speaker at AIDS2016.

Durban, South Africa. July 17 – 22, 2016.

- “*Meeting the Health Care Workforce Challenge*”, Invited speaker at the 2016 Pre-Conference UN 90-90-90 Target Workshop. Durban, South Africa. July 17, 2016.
- “*Diagnosis and management of Zika infected and exposed pregnant women*”, Invited talk at the XXI Congreso Mexicano de Especialistas en Ginecología y Obstetricia, A.C. Mexico City, Mex. June 23, 2016.
- “*Interactive Cases: Infectious Diseases in Travelers*”, Invited speaker at the XLI Congress of the Mexican Infectious Diseases Society. Monterrey, Mex. May 25 – 28, 2016.
- “*Optimizing Adherence to Antiretroviral Therapy: Current and Future Options*”, Invited speaker at IDWeek2015. San Diego, Calif. Oct 7 – 11, 2015.
- “*Update on vaccines for HIV-infected Patients*”, Invited speaker at the 54<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). Washington, DC Sept 5 – 9, 2014.
- “*Infectious Diseases in the context of Global Health*”, Invited Plenary Speaker at the XXXIX Congress of the Mexican Infectious Diseases Society. Acapulco, Mex. May 28 – 31, 2014.
- “*HIV Prevention 2013*”, Invited Plenary Speaker at the 26<sup>th</sup> Annual Conference of the Association of Nurses in AIDS Care (ANAC). Atlanta, GA November 22, 2013
- “*Vaccines in Immunocompromised patients*”, Invited Speaker at the 4<sup>th</sup> International Workshop on HIV & Aging. Baltimore, MD Oct 31, 2013
- “*Addressing the Gaps in the HIV Care Cascade*”. Invited talk at the “Treatment as Prevention and Pre-Exposure Prophylaxis Summit”. London, UK. Sept 22 – 24, 2013.
- “*Early Diagnosis and Treatment of HIV Infection*”, Invited talk at the 15<sup>th</sup> International Symposium on HIV/AIDS of the Mexican Infectious Diseases Society. Queretaro, Mex. Aug 29 – 31, 2013.
- “*Confronting the challenge of infectious diseases among substance abusers*” Invited Conference at the XIII Congress of the Argentinian Society for Infectious Diseases. Mar del Plata, Argentina. June 9 – 11, 2013
- “*Biomedical HIV Prevention*” Invited Conference at the XIII Congress of the Argentinian Society for Infectious Diseases. Mar del Plata, Argentina. June 9 – 11, 2013
- “*Introduction to Global Health*”. Invited Speaker to Lab Medicine 2013. 48<sup>th</sup> Annual Meeting of the Academy of Clinical Laboratory Physicians & Scientists. Atlanta, GA June 6 – 8, 2013
- “*How Should We Spend our Prevention Dollars?* Invited Speaker to the 20<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (CROI). Atlanta, GA March 3 – 6, 2013
- “*Opportunistic Infections in Patients with HIV Infection*” and “*The Pregnant Patient with HIV*”. Invited Speaker at the 39<sup>th</sup> Remington Winter Course in Infectious Diseases. Beaver Creek, CO. February 10 – 15, 2013
- “*The Importance and Implications of Antibiotic Resistance for the Clinician*”. Keynote Speaker at the VII Congreso Grupo Angeles. Mexico City, Mex. Oct 25 – 27, 2012.
- “*Adherence and Retention in Care*”. Invited Speaker to the AWACC (Annual Workshop on Advanced Clinical Care) – AIDS 2012 Conference. Durban, South Africa. October 5, 2012.
- “*Antiretroviral Therapy as Prevention: A Debate on the Role of ART as Prevention in*

*Clinical Practice*". Open Plenary Speaker at the 2012 American Conference for the Treatment of HIV (ACTHIV), Denver, CO. May 10 -12, 2012,

- “*Aging and HIV: Update from CROI*”. Invited Speaker at the 5<sup>th</sup> International Course HIV: Pathogenesis, Prevention and Treatment. Lima, Peru. March 23 – 24, 2012.
- “*Neurological Complications of HIV Infection*” and “*Clinical Spectrum of Acute Retrovirus Syndrome*”. Invited Speaker at the 37<sup>th</sup> Remington Winter Course in Infectious Diseases. Snowmass, CO. February 6 – 11, 2011
- “*Retention in Care*”. Invited Speaker at the 48<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America Vancouver, Canada. October 21-24, 2010
- “*HIV infection – beginning HAART*” and “*HIV infection – Managing opportunistic infections*”. Invited Speaker at the 36<sup>th</sup> Remington Winter Course in Infectious Diseases. Vail, CO. February 21 – 26, 2010
- “*HIV Prevention among hard to reach populations*”. United States-Russia Workshop on HIV Prevention Science organized by the Office of AIDS Research. Moscow, Russia. October 28 – 30, 2009.
- “*The role of Integrase inhibitors in the treatment of HIV infection*”. Invited speaker at the 9<sup>th</sup> International Symposium of the Mexican Association of HIV Providers (AMMVIH). Cancun, Mex. November 22, 2008
- “*Current Issues and Controversies in HIV Infection Management*” Invited panelist to an Interactive Symposium at the 48<sup>th</sup> Annual ICAAC/46<sup>th</sup> Annual IDSA. Washington, DC. October 27, 2008
- “*HIV, STDs and the Global AIDS Pandemic: Lethal Synergy 2008*” Invited panelist to an Interactive Symposium at the 48<sup>th</sup> Annual ICAAC/46<sup>th</sup> Annual IDSA. Washington, DC. October 28, 2008
- “*Treating Tuberculosis in People Living with HIV*”. Invited Plenary Speaker at the Second Eastern Europe and Central Asia AIDS Conference. Moscow, Russian Federation, May 3 – 5, 2008.
- Poster discussant in the session “*New approaches to HIV testing*” at the 15<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (CROI). Boston, MA. February 4, 2008.
- “*New drugs and old challenges in AIDS*”. Invited plenary speaker at the X Mexican National HIV/AIDS Meeting. Leon, Mex. December 1, 2007.
- “*The Metamorphosis of the HIV Epidemic*”. Invited lecture presented at the XXIV National Congress of Biomedical Research in Mexico. Monterrey, NL. Mex. Aug 30, 2007
- “*Management of HIV Infection*”. Invited panelist to an Interactive Symposium at the 44<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America. Toronto, Canada. October 13, 2006
- “*Yellow fever: New Challenges to an Old Scourge*”. Invited lecture presented at the Annual Meeting of the Binford-Dammin Society of Infectious Disease Pathologists. Atlanta, GA. February 12, 2006.
- “*Antiretroviral Therapy and its impact on Public Health*”. Invited speaker at the XI National Public Health Congress. Cuernavaca, Mex. March 2, 2005.
- “*Screening for HIV in Emergency Departments*”. Invited lecture presented at the 2005 National HIV Prevention Conference. Atlanta, GA. June 13, 2005.

**Bibliography:**a. Published and accepted research articles in refereed journals:

1. Gallo S, Marin E, Ramírez A, **del Río C**, Elizondo J, Ramírez J. Colocación Endoscópica de Sondas para Alimentación Enteral. Rev. Gastroenterol Mex. 1984; 49(4): 247-50 [PMID 6442452].
2. Guarner J, **del Río C**, Slade BA. Tuberculosis as a Manifestation of the Acquired Immunodeficiency Syndrome. JAMA 1986; 256(22):3092. [PMID [3783842](#)]
3. **del Río C**, McGowan J. Severe diarrhea in pneumococcal bacteremia: croupous colitis. JAMA 1987; 257(2): 189 [PMID 3795402].
4. Levy D, **del Río C**, Stephens DS. Meningococemia in identical twins: changes in serum susceptibility after rifampin chemoprophylaxis. J Infect Dis 1988; 157:1064-8 [PMID 3129520].
5. **del Río C**, Guarner J, Honig EG, Slade BA. Sputum examination in the diagnosis of *Pneumocystis carinii* pneumonia in the acquired immune deficiency syndrome. Arch Pathol Lab Med 1988; 112:1229-1232 [PMID 3142440].
6. Mirra SS, **del Río C**. The fine structure of AIDS encephalopathy. Arch Pathol Lab Med 1989; 113:858-65. [PMID 2757485]
7. **del Río C**, Stephens DS, Knapp JS, Rice RJ, Schalla WO. Comparison of isolates of *Neisseria gonorrhoeae* causing meningitis and report of gonococcal meningitis in a patient with C8 deficiency. J Clin Microbiol 1989; 27(5): 1045-49 [PMID 2473091/PMC 267480].
8. Guarner J, **del Río C**, Williams P, McGowan JE. Fungal peritonitis caused by *Curvularia lunata* in a patient undergoing peritoneal dialysis. Am J Med Sci 1989; 298 (5): 320-23 [PMID 26837770].
9. **del Río C**, Soffer O, Widell JL, Judd RL, Slade BA. Acute Human Immunodeficiency virus infection temporally associated with rhabdomyolysis, acute renal failure and nephrosis. Rev. Infect Dis 1990; 12(2): 282-85 [PMID 2330481].
10. Guarner J, **del Río C**, Hendrix L, Unger ER. Composite Hodgkin's and non-Hodgkin's lymphoma in a patient with AIDS. In situ demonstration of Epstein-Barr Virus. Cancer 1990; 66(4): 796-800 [PMID 2167145].
11. Beciewicz PA, **del Río C**, Goncalves MA, Lattouf OM, et al. Catastrophic thrombosis of porcine aortic bioprosthesis. Ann Thorac Surg 1990; 50: 817-9 [PMID 2241350].
12. Guarner J, **del Río C**, Carr D, Hendrix LE, Eley JW, Unger ER. Non-Hodgkin's lymphomas in patients with HIV infection: Presence of Epstein - Barr virus by "in-situ" hybridization. Clinical Presentation and Follow-up. Cancer 1991; 68: 2460-65 [PMID 1657357].
13. Majluf-Cruz AS, Hurtado R, Mijangos C, Souto C, **del Río C**, Simón J. Síndrome Hemofagocítico en Asociación a Histoplasmosis en el Síndrome de Inmunodeficiencia Adquirida: descripción de tres casos y revisión de la literatura. (Haemophagocytic syndrome associated to histoplasmosis in AIDS: report of three cases). Sangre 1993; 38(1): 51-55 [PMID 8470036].
14. **del Río C**, Téllez I. Ganancia de peso con el uso del acetato de megestrol (Megace<sup>R</sup>) en pacientes con SIDA y pérdida de peso en México. (Weight gain with the use of Megace<sup>R</sup> in Mexican patients with AIDS). Enf Infecc y Microbiol 1993; 13(5): 249-52.
15. Guarner J, Izazola J, **del Río C**. Los problemas de conteo células T CD4+. (Problems in CD4+ T-cell count). Rev Invest Clin 1994; 46:163-4 [PMID 7914377].

16. Souto-Meriño CA, Simón-Domínguez J, Pulido-Priego MA, Hernández-Pérez A, García-Hernández IC, **del Río C**. Prevalencia de Marcadores para Hepatitis A, B y C en un Hospital de México. (The Prevalence of markers for hepatitis A, B and C in a hospital in Mexico). *Salud Públ Mex* 1994; 36:257-262 [PMID 7940005].
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# EXHIBIT E

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

NICHOLAS HARRISON and  
OUTSERVE-SLDN, INC.

Plaintiffs,

v.

JAMES N. MATTIS, in his official capacity  
as Secretary of Defense; MARK ESPER, in  
his official capacity as the Secretary of the  
Army; and the UNITED STATES  
DEPARTMENT OF DEFENSE,

Defendants.

Case No. 1:18-cv-00641 (LMB/IDD)

**DECLARATION OF TREVOR HOPPE, MPH, PhD**

1. My name is Trevor Hoppe, PhD. I have been retained by counsel for Plaintiffs in the above-captioned case. I have been asked to provide an expert opinion regarding the history of stigma and discrimination against people living with HIV in the United States and use of the public health system and criminal laws to control the behavior of such persons.

2. Except where otherwise stated, I have actual knowledge of the matters stated and would so testify if called as a witness.

3. I am an assistant professor of sociology at the University at Albany, SUNY. My research examines the rise and application of criminal laws related to HIV and other infectious diseases in the United States. I received my doctoral degree from the University of Michigan in 2014 in Sociology and Women's Studies. I also earned a Master's in Public Health in Health Behavior and Health Education from the University of Michigan in 2011. After my doctoral training, I was awarded a postdoctoral fellowship at the University of California at Irvine in the Department of

Criminology, Law and Society. I subsequently joined the sociology faculty at the University at Albany, SUNY, where I research and teach about crime and deviance.

4. I am an active participant in the global HIV research community, having participated in two International AIDS Conferences. In 2011, the Centers for Disease Control and Prevention awarded me the “Young Innovator Award” at their national HIV prevention conference. I have published extensively on the subject, including four peer-reviewed scientific journal articles and a recently published book, *Punishing Disease: HIV and the Criminalization of Sickness*. I consider myself to be an expert in HIV and infectious disease control, permitting me to give the following expert opinion.

5. A true and accurate copy of my curriculum vitae is attached hereto as Exhibit A, and provides a complete overview of my education, training, work experience, and a full list of my publications.

6. I have not testified as an expert at trial or by deposition in the past four years.

7. When the first outbreak of AIDS (acquired immune deficiency syndrome) was reported in the early 1980s, scientists initially did not understand its cause. Young and otherwise healthy patients became very sick across the country, presenting to healthcare providers with a wide array of rare and often deadly infections, commonly Kaposi’s sarcoma and *pneumocystis pneumonia*. Many died—hundreds at first, and then thousands across the United States. Because many of these patients were gay men, initial reports of the disease described it as “gay cancer” or “gay-related immune deficiency” (or G.R.I.D., for short). At the beginning of the epidemic, in addition to hemophiliacs, those most frequently diagnosed with AIDS were members of marginalized and highly stigmatized communities, leading some to collectively and derisively refer to people with AIDS as the “4-H club” (homosexuals, heroin users, Haitians, and

hemophiliacs). In the summer of 1984, the cause of the disease was finally identified, a retrovirus that became known as human immunodeficiency virus (HIV), which could establish itself in any person sufficiently exposed. However, by that time many Americans already believed the cause of the disease to be a deviant lifestyle, a stigmatizing belief that conservative commentators and politicians promoted by labeling AIDS as a punishment from God or “God’s cure” for homosexuality.

8. During the early years of AIDS, people living with HIV faced frequent discrimination and heightened stigma. Doctors turned away HIV-positive patients. Funeral homes refused to bury people who had died of AIDS-related complications. Even children living with the disease were cast out, as 13-year-old Ryan White experienced in Kokomo, Indiana in 1984. A hemophiliac, Mr. White contracted the disease from tainted blood products. Parents at Mr. White’s school successfully petitioned the school board to expel him from the school based on his diagnosis. To this day, people living with HIV continue to face similar forms of discrimination and, in some cases, even violence.

9. Even when untreated, the per-contact risk of sexually transmitting HIV is relatively low.<sup>1</sup> Nonetheless, many Americans not only feared contracting HIV via exposures it had been established presented no risk, such as kissing or sharing a drinking glass, but also as a result of highly improbable scenarios spread through urban legend tales (such as tainted pins planted in movie theater seat cushions).<sup>2</sup> For example, beginning in the 1980s—and even in recent years—

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<sup>1</sup> “HIV Risk Behaviors,” Centers for Disease and Prevention, accessed July 18, 2018.  
<https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html>

<sup>2</sup> Timothy C. Correll, “‘You Know about Needle Boy, Right?’: Variation in Rumors and Legends about Attacks with HIV-Infected Needles,” *Western Folklore* 67 (2008):59-100.

polling firms have consistently found that a substantial portion of Americans mistakenly believe that kissing can transmit HIV.<sup>3</sup>

10. American's fear and ignorance of HIV transmission, coupled with the intense stigma against communities disproportionately impacted by HIV, led to strident calls for invasive measures to control the epidemic. Conservative commentator William F. Buckley famously called for all newly-diagnosed patients to be tattooed as HIV-positive, but there were countless other leaders who called for public health departments to institute quarantine procedures and to criminalize people living with HIV who they viewed as a threat to the health of others.<sup>4</sup>

11. Once HIV was identified, state lawmakers around the country began to consider bills to institute disease control programs targeting this new epidemic. While most of this legislation featured conventional disease control procedures, lawmakers in 45 states also introduced legislation that imposed felony level criminal sanctions in an effort to control the behavior of people living with HIV. Rather than misdemeanor or civil penalties, most HIV-specific criminal legislation enacted in the United States featured felony penalties that carried stiff prison sentences, ranging from 2-3 years to life in prison.

12. No disease in American history has ever been met with a similarly punitive response from lawmakers. The only comparable case is hepatitis C virus (HCV), a viral infection transmitted through blood-to-blood contact (typically needle-sharing) that has been the subject of criminal legislation enacted in a handful of states. Even in states with HCV-specific laws, however, few cases have ever been prosecuted—perhaps because most people who could plausibly file charges are unlikely to do so as it would require reporting criminal drug-using

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<sup>3</sup> Gregory H. Herek, John P. Capitano, and Keith F. Widaman, "HIV-Related Stigma and Knowledge in the United States: Prevalence and Trends, 1991–1999," *American Journal of Public Health*, 92 (2002):371-377.

<sup>4</sup> Gregory H. Herek and Eric K. Glunt, "An Epidemic of Stigma: Public Reactions to AIDS," *American Psychologist* 43 (1988):886-891.

behavior to the police. Other diseases that can cause serious health complications and even death have not faced similar criminal penalties. For example, human papillomavirus (HPV) is a highly contagious, sexually transmitted infection that can cause lesions on the skin. Studies now show that it can also cause cervical cancer—sometimes fatal—many years after initial infection.<sup>5</sup> There have never been campaigns to criminalize HPV exposure. In part, the nonpunitive response to HPV can be credited to two characteristics of the disease that stand in stark contrast to HIV. First, the high prevalence of HPV in adult Americans (upwards of two-thirds of Americans are estimated to be infected) makes criminal sanctions targeting HPV a costly and impractical policy response. Second, the disease is not overwhelmingly concentrated in highly stigmatized communities already viewed as potentially criminal.

13. According to a 2014 report co-authored by staff from the Centers for Disease Control and Prevention and the Department of Justice, 33 states enacted criminal legislation that specifically targets people living with HIV.<sup>6</sup> Although the federal and state governments do not compile official statistics regarding these prosecutions, research has revealed thousands of criminal cases involving people living with HIV who have been prosecuted under HIV-based criminal laws.<sup>7</sup>

14. Most statutes are construed broadly without regard to transmission or even the risk of transmission from the specific activity in question. In most states with such laws, the crime is defined as failing to disclose one's HIV-positive status before engaging in a range of

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<sup>5</sup> Guglielmo Ronco, et al. "Efficacy of HPV-Based Screening for Prevention of Invasive Cervical Cancer: Follow-up of Four European Randomised Controlled Trials," *The Lancet* 383 (2014):524-532.

<sup>6</sup> J. Stan Lehman, et al. "Prevalence and Public Health Implications of State Laws That Criminalize Potential HIV Exposure in the United States," *AIDS and Behavior* 18 (2014): 997–1006.

<sup>7</sup> Amira Hasenbush, *HIV Criminalization in Georgia: Penal Implications for People Living with HIV* (Los Angeles, CA: The Williams Institute at UCLA, 2018); Trevor Hoppe, *Punishing Disease: HIV and the Criminalization of Sickness* (Oakland, CA: University of California Press, 2018); Dini Harsono, Carol L. Galletly, Elaine O'Keefe, and Zita Lazzarini, "Criminalization of HIV Exposure: A Review of Empirical Studies in the United States," *AIDS and Behavior* 21 (2017):27-50; Amira Hasenbush, Ayako Miyashita, and Bianca D. M. Wilson, *HIV Criminalization in California: Penal Implications for People Living with HIV* (Los Angeles, CA: The Williams Institute at UCLA, 2015).

behaviors—typically sexual contacts, however some states also prohibit needle sharing and even spitting, biting, or other nonsexual exposures. Use of a condom or other preventive measures is generally irrelevant. In Michigan, for example, the law prohibits people living with HIV from engaging in “sexual penetration” without first disclosing their HIV status. The law defines sexual penetration as “sexual intercourse, cunnilingus, fellatio, anal intercourse, or any other intrusion, however slight, of any part of a person's body or of any object into the genital or anal openings of another person's body.”<sup>8</sup> Such imprecise statutory language has facilitated the criminalization of a wide range of practices, including those that are unlikely to transmit the disease and also those that could not conceivably transmit HIV. For example, in a case I review in my book, *Punishing Disease*, a Tennessee man who was admitted to the hospital after attempting suicide was charged in 2010 under that state’s HIV exposure law after he bit a hospital attendant.<sup>9</sup> Biting has never definitively been established as a route of HIV transmission; nonetheless, the defendant was sentenced to three years in prison.

15. Lengthy prison sentences are common in these cases. In a study I conducted analyzing 431 prosecutions in six U.S. states between 1992 and 2010, I found that more than three-quarters of defendants convicted under HIV-specific criminal laws were sentenced to jail or prison; of those incarcerated, the average prison term was 92 months (nearly eight years).<sup>10</sup> In 2012, an Iowa man, Nick Rhoades, was accused of engaging in a one-time sexual encounter in which he used a condom; he had an undetectable viral load, which the CDC has recently confirmed

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<sup>8</sup> MCL Annotated § 333.5131.

<sup>9</sup> See pp. 150-151 in Trevor Hoppe. *Punishing Disease: HIV and the Criminalization of Sickness* (Oakland: University of California Press, 2018).

<sup>10</sup> See Chapter 6, “Victim Impact,” in *Ibid.*

reduces the risk of transmission effectively to zero; there was (of course) no transmission; after pleading guilty, Mr. Rhoades was sentenced to 25 years in prison.<sup>11</sup>

16. HIV-specific criminal legislation codified the stigma against the epidemic that was (and is) pervasive in the United States. At the time these laws were implemented, HIV was a largely terminal and untreatable infection. Much has changed since that time. In the vast majority of cases, people diagnosed as HIV positive today are prescribed a pill-a-day treatment regimen that carries few side effects. By reducing the amount of virus in a person's bodily fluids, studies now show that modern treatment protocols can render people living with HIV noninfectious. Another recent life expectancy study estimates that a 20-year-old gay man diagnosed as HIV-positive today and prescribed treatment is expected to live several years longer than men in the general population.<sup>12</sup> Despite these dramatic improvements in HIV science, however, the laws of the 1980s largely remain unchanged. To date, only three states—Iowa, Colorado and California—have changed their laws in response to demands from HIV advocates.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: 7/18/2018

Respectfully,

  
\_\_\_\_\_  
Trevor Hoppe, MPH, PhD

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<sup>11</sup> Brian Cox, "Turning the Tide: The Future of HIV Criminalization after *Rhoades v. State* and Legislative Reform in Iowa," *Northwestern Journal of Law and Social Policy* 11 (2016):28-53.

<sup>12</sup> Hasina Samji, et al. "Closing the Gap: Increases in Life Expectancy among Treated HIV-Positive Individuals in the United States and Canada," *PLoS ONE* 8 (2013): e81355.

# Exhibit A

## Trevor Alexander Hoppe

thoppe@albany.edu | http://www.trevorhoppe.com

### EMPLOYMENT

Assistant Professor, University of North Carolina at Greensboro  
Department of Sociology (Beginning Fall 2018) Greensboro, NC

Assistant Professor, University at Albany, SUNY  
Department of Sociology (2015-Present) Albany, NY

Postdoctoral Fellow, University of California at Irvine  
Department of Criminology, Law and Society (2014-2015) Irvine, CA

### EDUCATION

Ph.D. University of Michigan (2014) Ann Arbor, MI  
Sociology and Women's Studies  
Dissertation: *From Sickness to Badness: Michigan HIV Law as a Site of Social Control*  
Committee: Renee Anspach & David Halperin (Co-Chairs), Sarah Burgard, Sandra Levitsky

- WINNER: American Sociological Association (ASA), Martin P. Levine Dissertation Fellowship
- WINNER: ASA, Medical Sociology Section, Roberta G. Simmons Outstanding Dissertation Award

M.P.H. University of Michigan (2011) Ann Arbor, MI  
Health Behavior and Health Education, School of Public Health

M.A. San Francisco State University (2007) San Francisco, CA  
Human Sexuality Studies

B.A. University of North Carolina at Chapel Hill (2005) Chapel Hill, NC

### PUBLICATIONS

#### **Books:**

2018. *Punishing disease: HIV and the criminalization of sickness*. University of California Press.

- WINNER: 2018 Lambda Literary Award for LGBTQ Studies

2017. Hoppe, Trevor and David Halperin (Eds.). *The war on sex*. Duke University Press

- FINALIST: 2018 Lambda Literary Award for LGBTQ Studies

#### **Journal articles:**

"Punishing sex: Sex offenders and the missing punitive turn in sexuality studies." *Law & Social Inquiry*, 2016, 41(3): 573-94.

"Cruel intentions? HIV prevalence and criminalization during an age of mass incarceration, U.S. 1999-2012." Second author, with Bryan Sykes and Kristen Maziarka. *Medicine*, 2016, 95(16):1-9.

"Social science perspectives on pre-exposure prophylaxis for HIV (PrEP)." Second author, with Judith Auerbach. *Journal of the International AIDS Society*, 2015, 18(S3):19983.

"Disparate risks of conviction under Michigan's felony HIV disclosure law: An observational analysis of convictions and HIV diagnoses, 1992-2010." *Punishment & Society*, 2015. 17:73-93.

- Featured in *Ebony*, *The Nation*, *TheBody.com*

"From sickness to badness: The criminalization of HIV in Michigan." *Social Science & Medicine*, 2014, 101: 139-147.

“Controlling sex in the name of ‘public health’: Social control and Michigan HIV law.” *Social Problems*, 2013, 60: 27-49.

- ASA, Sexualities Section, Best Graduate Student Paper, 2014
- ASA, Sociology of Law Section, Best Graduate Student Paper, 2013
- University of Michigan, Department of Sociology, Mark Chesler Paper Award, 2013

“Circuits of power, circuits of pleasure: Sexual scripting in gay men’s bottom narratives.” *Sexualities*, 2011, 14: 193-217.

- Sociologist AIDS Network Martin Levine Student Essay Award, 2009

#### **Book chapters:**

**Hoppe, Trevor.** “Queer and punishment: Sexual social control and the legacy of ‘nuts, sluts and preverts’” (Book chapter). Forthcoming in Schilt, Kristen, Tey Meadow, and D’Lane Compton (eds.), *Other, Please Specify: \_\_\_\_\_: Queer Methods in Sociology*. Berkeley, CA: University of California Press.

#### **Manuscripts in progress or under review:**

Rebeca Herrero Saenz\*, and **Trevor Hoppe**, “Disease on trial: Microbiological responsibility in HIV exposure and disclosure jury trials, 1992-2014.” *Revise and resubmit*.

**Hoppe, Trevor**, “Othering disease: Spanish flu, Gay-related immunodeficiency, and the stigmatization of infectious disease.” *Revise and resubmit*.

**Hoppe, Trevor**, Bryan Sykes, and Kyle Maksuta\* “Sexual threat: Using group threat theory to explain the rise and spread of American sex offender registries.”

**Hoppe, Trevor**, and Renee Anspach. “Towards a critical sociology of public health.”

*Authors denoted with an asterisk \* are graduate students*

#### **Reviews:**

Hoppe, Trevor. Forthcoming. “Review of *Sex Offenders, Stigma, and Social Control*, by Diana Rickard,” *Contemporary Sociology*.

Hoppe, Trevor. 2017. “Review of *The Straight Line: How the Fringe Science of Ex-Gay Therapy Reoriented Sexuality*, by Tom Waidzunus,” *American Journal of Sociology*, 123(1):312-314.

Hoppe, Trevor. 2011. “Review of *Unlimited Intimacy: Reflections on the Subculture of Barebacking*, by Tim Dean.” *Journal of Sex Research*, 48: 506-8.

Hoppe, Trevor. 2009. “Review of *Sexual Inequalities & Social Justice*, N. Teunis & G. Herdt (Eds.), and *The Health of Sexual Minorities*, I. Meyer & M. Northridge (Eds).” *Culture, Health and Sexuality*, 11: 107-10.

#### **Other publications and media appearances:**

Interview. 2018, March 26. “How state laws criminalize people with HIV.” *The Crime Report*. <https://thecrimereport.org/2018/03/26/how-state-laws-criminalize-hiv-sufferers/>

Interview and Book Review. 2018, March 2. “Creating criminals: The misguided crackdown on HIV/AIDS.” *Undark*. <https://undark.org/article/book-review-hoppe-punishing-disease/>

- Interview. 2018, February 6. "Hepatitis C exposure is a crime in some states; is this the new HIV criminalization?" *The Body*. <http://www.thebody.com/content/80840/hepatitis-c-exposure-is-a-crime-in-some-states-is-.html>
- Interview. 2017, December 12. "What's the future of HIV criminalization activism? An interview with Trevor Hoppe." *The Body*. <http://www.thebody.com/content/80680/whats-the-future-of-hiv-criminalization-activism-a.html>
- Interview. 2017, December 8. "Are we punishing diseases or punishing people? An interview with Trevor Hoppe." *The Body*. <http://www.thebody.com/content/80668/are-we-punishing-diseases-or-punishing-people-an-i.html>
- Hoppe, Trevor. 2017, November 20. "Should we punish the sick?" *Washington Blade*. <http://www.washingtonblade.com/2017/11/20/should-we-punish-the-sick/>
- Interview. 2017, August 14. "Fear and ignorance criminalized HIV. Can science and wisdom undo that?" *Undark*. <https://undark.org/article/hiv-criminalization-laws-aids/>
- Hoppe, Trevor. "Are sex offender registries reinforcing inequality?" *The Conversation*. 2017, August 8. <https://theconversation.com/are-sex-offender-registries-reinforcing-inequality-79818>
- Reposted in *Newsweek*, *San Francisco Chronicle*
- Hoppe, Trevor, and David Halperin. 2017, June 26. "Two years after SCOTUS gay marriage ruling, the road to sexual freedom remains long." *The Hill*. <http://thehill.com/blogs/pundits-blog/civil-rights/337079-two-years-after-scotus-gay-marriage-ruling-long-road-to>
- Hoppe, Trevor. 2017, May 19. "Lawmakers: Don't give in to the 'stealth' moral panic." *Advocate*. <https://www.advocate.com/commentary/2017/5/19/lawmakers-dont-give-stealth-moral-panic>
- Interview. 2016, May 25. "The war on sex offenders is the new war on drugs, which means its about race." *Inverse*. <https://www.inverse.com/article/16109-the-war-on-sex-offenders-is-the-new-war-on-drugs-which-means-it-s-about-race>
- Interview. 2016, April 5. *Stateside*. National Public Radio. <http://michiganradio.org/post/stateside-tuesday-april-5-2016>
- Hoppe, Trevor. 2016, April 3. "The County in Michigan Where HIV is a Crime." *Huffington Post*. [http://www.huffingtonpost.com/trevor-hoppe/the-county-in-michigan-wh\\_b\\_9602758.html](http://www.huffingtonpost.com/trevor-hoppe/the-county-in-michigan-wh_b_9602758.html)
- Hoppe, Trevor. 2015, November 17. "Let's Not Treat Charlie Sheen Like a Criminal." *Huffington Post*. [http://www.huffingtonpost.com/trevor-hoppe/lets-not-treat-charlie-sh\\_b\\_8583710.html](http://www.huffingtonpost.com/trevor-hoppe/lets-not-treat-charlie-sh_b_8583710.html)
- Interview. 2015, May 29. "The reckless prosecution of 'Tiger Mandingo.'" *The Nation*. <https://www.thenation.com/article/reckless-prosecution-tiger-mandingo/>
- Interview. 2013. *More Harm than Good: How Overly Broad HIV Criminalisation is Hurting Public Health*. Documentary Film. Directed by Edwin Bernard, HIV Justice Network. <http://www.hivjustice.net/moreharm/>
- Interview. 2013, March 23. *Strange Fruit*. 89.3 WFPL. <http://wfpl.org/strange-fruit-rob-portman-marriage-equality-trevor-hoppe-criminalization-hiv-0/>

#### AWARDS, GRANTS, SCHOLARSHIPS, AND FELLOWSHIPS

- 2018 Lambda Literary Award for LGBTQ Studies, Lambda Literary Foundation
- 2018 Lavender Award for Excellence in LGBTQ+ Scholarship, University at Albany, SUNY

- 2018 Faculty Research Award Program (FRAP), University at Albany, SUNY (\$9850)
- 2016 Individual Development Award, Campus Professional Development Committee, SUNY-Albany
- 2015 College of Arts and Sciences Conference Travel Fund Program, SUNY-Albany
- 2014 American Sociological Association, Sexualities Section, Best Graduate Student Paper
- 2014 American Sociological Association, Medical Sociology Section, Roberta G. Simmons Outstanding Dissertation Award
- 2013 American Sociological Association, Sociology of Law Section, Best Graduate Student Paper
- 2013 University of Michigan Department of Sociology, Mark Chesler Paper Award
- 2013 Seed Grant, Center for Public Policy in Diverse Societies, Gerald R. Ford School of Public Policy, University of Michigan
- 2013 American Sociological Association Student Forum, Travel Grant
- 2013 Lee Student Support Fund Travel Award, Society for the Study of Social Problems
- 2013 Scholarship, 2nd International Conference for the Social Sciences and Humanities in HIV, Paris, France.
- 2012 ASA, Martin P. Levine Memorial Dissertation Fellowship
- 2012 University of Michigan Rackham Predoctoral Fellowship
- 2012 Scholarship, American Sociological Association Section on Sexualities Mini-Conference
- 2012 Scholarship, International AIDS Conference, Washington, DC.
- 2011 Centers for Disease Control and Prevention, Young Innovator Award
- 2011 Sociologist AIDS Network, Scholarly Activity Award
- 2011 Community of Scholars Fellowship, Institute for Research on Women and Gender, University of Michigan
- 2011 Rackham Graduate Student Candidacy Research Grant, University of Michigan
- 2011 Dissertation Research Grant, Department of Sociology, University of Michigan
- 2011 Student Research Grant, Center for Education of Women, University of Michigan
- 2010 Social Science Research Council, Dissertation Proposal Development Fellowship
- 2009 Sociologist AIDS Network Martin Levine Student Essay Award
- 2009 Dean's Scholarship, School of Public Health, University of Michigan (Declined)
- 2008 Rackham Graduate Student Pre-Candidacy Research Grant, University of Michigan
- 2007 Herbert E. Boynton Scholarship, University of Michigan
- 2006 SFSU University Scholarship, San Francisco State University
- 2006 Jim Brogan Teaching Scholarship, San Francisco State University

#### **INVITED LECTURES AND PRESENTATIONS**

"Punishing disease: HIV and the criminalization of sickness"

- Department of Women's Studies, University of Michigan, March 2019, Ann Arbor, MI
- Saint Louis University, April 2018, St Louis, MO
- Washington University in St. Louis, April 2018, St Louis, MO

- Middlebury College, April 2018, Middlebury, VT
- Concordia University, March 2018, Montreal, QC, Canada
- Muskegon Community College, March 2018, Muskegon, MI
- Harvard Law School, January 2018, Cambridge, MA
- University of Arizona, January 2018, Tucson, AZ
- HIV is Not a Crime II National Training Academy, May 2016, Huntsville, AL
- HIV Criminalization Working Group, Yale University, April 2016, New Haven, CT
- Department of Sociology, Grand Valley State University, April 2016, Grand Rapids, MI
- Department of Sociomedical Sciences, UCSF, March 2016, San Francisco, CA
- Department of Sociology, UCLA, November 2015, Los Angeles, CA

“Queer and punishment: Sexual social control and the legacy of ‘nuts, sluts and preverts,” Queer Methods in Sociology Conference, Harvard University, April 2016, Cambridge, MA.

“Punishing sex: Sex offenders and the missing punitive turn in sexuality studies,” The Sexualities Project at Northwestern (SPAN) Annual Workshop, April 2015, Chicago, IL

“Surveying the criminalization of HIV in the United States: Preliminary findings.” The Williams Institute, University of California at Los Angeles, October 2013, Los Angeles, CA.

“Making sense of disparate outcomes in Michigan trial court HIV nondisclosure convictions: The modifying impact of the partner’s gender.” York University, April 2013, Toronto, ON.

“The criminalization of HIV.” Invited Lecture, WS 212, “Global HIV/AIDS Epidemic.” April 2013, Ann Arbor, MI.

“HIV criminalization in Michigan: Criminal justice and public health in contest.” Wayne State University, March 2013, Detroit, MI

“The criminalization of HIV/AIDS.” Wayne State University, November 2012, Detroit, MI

“‘Equal time’: Gays, media, and the myth of equality.” Invited panelist, Indiana University, April 2012, Bloomington, IN

“The criminalization of HIV.” Invited lecture, “Global HIV/AIDS Epidemic.” March 2012, Ann Arbor, MI.

“HIV disclosure laws in the United States: Theory, practice, and politics.” Summer Institute on Sexuality, San Francisco State University, June 2011, San Francisco, CA.

“Using sociological theory to understand pleasure and power: Bottom identity among gay men as a case study.” Summer Institute on Sexuality, San Francisco State University, June 2011, San Francisco, CA.

“Historical mobilizations of ‘public health’ against public sex venues.” Summer Institute on Sexuality, San Francisco State University, June 2010, San Francisco, CA.

“Remembering Eric Rofes.” Against Health Conference, University of Michigan, October 2006.

## CONFERENCE PRESENTATIONS

“Victim impact: Analyzing disparities by race, gender, and sexuality under state HIV exposure and disclosure laws,”

- American Sociological Association Annual Meeting, August 2017, Montreal, CA.
- International AIDS Conference [Poster presentation], July 2017, Paris, France.

“One million and counting? How policy levers will impact the future of sex offender registries in the United States,” Law & Society Association Annual Meeting, June 2017, Mexico City, MX.

“Punishing HIV: Does race impact sentencing under criminal HIV exposure and disclosure laws in the United States?” [Poster presentation] International AIDS Conference, July 2016, Durban, ZA.

“Punishing disease: HIV and the criminalization of sickness”

- International Sociological Forum, July 2016, Vienna, Austria
- Law and Society Association, June 2016, New Orleans, LA
- American Sociological Association Annual Meeting, August 2015, Chicago, IL

“Punishing sex: Sex offenders and the missing punitive turn in sexuality studies.”

- After Marriage Conference at CUNY, October 2016, New York, NY
- American Sociological Association, August 2016, Seattle, WA
- American Society of Criminology, November 2015, Washington, DC
- Law & Society Association Annual Meeting, May 2015, Seattle, WA
- Pacific Sociological Association Annual Meeting, April 2015, Long Beach, CA

“HIV stops with me: The repolarization of post-AIDS HIV prevention.”

- Association for the Social Sciences and Humanities in HIV, July 2015 Cape Town, ZA
- American Sociological Association Annual Meeting, August 2014, San Francisco, CA.

“Controlling the criminally sick: A systematic analysis of HIV disclosure trial court cases in Michigan.”

- American Sociological Association Annual Meeting, August 2013, New York, NY
- Society for the Study of Social Problems Annual Meeting, August 2013, New York, NY
- 2<sup>nd</sup> International HIV Social Science and Humanities Conference, July 2013, Paris, France
- 17th Annual Sørensen Memorial Conference, Columbia University, April 2013, New York, NY
- Western Society of Criminology, February 2013, Berkeley, CA
- National Women’s Studies Association Annual Meeting, November 2012, Oakland, CA
- American Sociological Association Section on Sexualities Mini-Conference, August 2012, Denver, CO
- International AIDS Conference, August 2012, Washington, DC

“From sickness to badness: Towards a theory of medical social control beyond medicalization.”

- American Sociology Association Annual Meeting, August 2012, Denver, CO
- Gendered Borders and Queer Frontiers Conference, Madison, WI, March 2012

“Controlling sex in the name of ‘public health’: Social control and Michigan’s HIV disclosure law.”

- Making (In)Appropriate Bodies Conference, Vienna, Austria, December 2011
- American Sociological Association Annual Meeting, Las Vegas, NV, August 2011
- National HIV Prevention Conference, Atlanta, GA, August 2011
- Law & Society Association Annual Meeting, San Francisco, CA, June 2011
- Midwest Sociological Society Annual Meeting, St. Louis, MO, March 2011
- Doing Queer Studies Now: A Graduate Conference, Ann Arbor, MI, October 2010
- Midwest Law & Society Retreat, Madison, WI, October 2010.

“Circuits of Power, Circuits of Pleasure: Sexual Scripting in Gay Men’s Bottom Narratives”

- American Sociological Association Annual Meeting, San Francisco, CA, August 2009
- National Gay Men’s Health Summit, Seattle, WA, October 2008

“Resisting Public Health: Working within the Gay Men’s Health Movement to Produce Change.”

LumpenCity: Marginalizing Discourses | Discourses of Marginalization, Toronto, ON, Canada, March 2009.

“Being Gay Post-HAART: Young Gay Men Negotiating Desire, Risk, and Heteronormativity.”

- AIDS in Culture IV, Mexico City, Mexico, December 2007
- LGBTI Health Summit, Philadelphia, PA, March 2007.

## PUBLIC LECTURES AND READINGS

“Punishing disease: HIV and the criminalization of sickness”

- Flyleaf Books, Chapel Hill, NC, March 2018
- LGBT Center of Raleigh, Raleigh, NC, March 2018
- Center on Halsted, Chicago, IL, February 2018
- West Hollywood Library, Los Angeles, CA, January 2018
- Bluestockings, New York, NY, December 2017
- William Way LGBT Center, Philadelphia, PA, November 2017
- Red Emma’s Bookstore, Baltimore, MD, November 2017

“Reframing HIV: From ‘prevention’ to ‘management.’” National Gay Men’s Health Summit, August 2010, Fort Lauderdale, FL.

“Power and rethinking risk.” Gay Men’s Health Summit, October 2009, Seattle, WA

“Bus stops, billboards and you: campaigning for queer health.” San Francisco Lesbian, Gay, Bisexual, and Transgender Community Center, July 2008, San Francisco, CA.

## TEACHING EXPERIENCE

**Assistant Professor**, Department of Sociology, UNC-Greensboro 2018 - Present

- “Global Deviance,” Fall 2018
- “Law and Society,” Fall 2018

**Assistant Professor**, Department of Sociology, University at Albany, SUNY 2015 - 2018

- “Sociology of Deviant Behavior,” Fall 2015, Fall 2016, Spring 2017, Fall 2017, Spring 2018
- “Sociology of Sexualities,” Spring 2018
- “The Global HIV/AIDS Epidemic,” Fall 2016
- “The Sociology of Law” (Graduate Seminar), Spring 2017

**Primary Instructor**, University of Michigan 2009, 2014

- “Sociological Analysis of Deviance” (SOC 488), Spring 2014
- “Sociology of Sexuality” (SOC 345), Spring 2009

**Graduate Student Instructor**, University of Michigan 2008 – 2014

- “Introduction to Sociology” (SOC 100), Fall 2008, Fall 2010, Winter 2011
- “Sociology of Marriage & The Family” (SOC 344), Winter 2009
- “The Global HIV/AIDS Epidemic” (WOMENSTD / ANTHRO 212), Winter 2012, Fall 2013
- “History of Sexuality” (HIST 369), Winter 2010
- “Men’s Health” (WOMENSTD 300), Fall 2009

**Teaching Assistant**, San Francisco State University 2006 – 2007

- “Variations in Human Sexuality” (SOC 400), Spring 2006, Fall 2006, Spring 2006

**REVIEWER FOR THE FOLLOWING PUBLICATIONS**

*Social Problems, Sociological Forum, Sexualities, Law & Social Inquiry, PLOS One, Theoretical Criminology, Contemporary Sociology, Culture, Health & Sexuality, Men and Masculinities, AIDS & Behavior, Journal of Homosexuality, Archives of Sexual Behavior, Sexuality Research & Social Policy, Women's Studies Quarterly, Studies in Law, Politics & Society, Oxford Bibliographies*

**PROFESSIONAL SERVICE**

- 2018 – 2021 Council Member-Elect, American Sociological Association Section on Sociology of Law
- 2018 – 2021 Editorial Board, *Social Problems*
- 2016 – 2019 Council Member-Elect, American Sociological Association Section on Sexualities
- 2017 – 2018 Member, Undergraduate Committee, University at Albany Department of Sociology
- 2017 Member, Distinguished Book Award Committee, ASA Section on Sex and Gender
- 2016 – 2017 Member, Executive Committee, University at Albany Department of Sociology
- 2016 – 2017 Chair, Advancement Committee, University at Albany Department of Sociology
- 2015 – 2016 Member, Advancement Committee, University at Albany Department of Sociology
- 2014 – 2015 Member, Selection Committee, Roberta G. Simmons Outstanding Dissertation Award, American Sociology Association Section on Medical Sociology
- 2014 – 2015 Member, Selection Committee, Best Graduate Student Paper Award, American Sociology Association Section on Sexualities
- 2013 – 2014 Member, Nominations Committee, American Sociology Association Section on Sex and Gender
- 2013 – Member, Criminalization of HIV Transmission and Exposure Working Group Law, Policy and Ethics (LPE) Core, Center for Interdisciplinary Research on AIDS (CIRA), Yale University
- 2013 Co-chair with Eric Mykhalovskiy of “Social Science, Criminal Law and HIV Transmission Risks: Novel Research” and “Viral Politics: HIV Criminalization & Social Inquiry” Panels, 2<sup>nd</sup> International HIV Social Sciences and Humanities Conference
- 2012 – Invited Abstract Reviewer, International AIDS Conference
- 2012 “Sex and Justice” Thematic Panel Organizer, American Sociological Association Section on Sexualities Mini-Conference
- 2012 Roundtable Discussant, American Sociological Association Section on Sexualities Mini-Conference
- 2011 – Martin Levine Paper Prize Committee, Sociologist AIDS Network
- 2011 – 2012 Graduate Student Representative-Elect, Section on Sexualities, American Sociological Association
- 2011 – 2012 Organizer, “Sex and Justice” Conference, University of Michigan
- 2011 – 2012 Graduate Admissions Committee, Department of Sociology, University of Michigan
- 2010 – 2011 Personnel Committee, Department of Sociology, University of Michigan
- 2010 Martin Levine Paper Prize Committee, Sociologist AIDS Network

*Curriculum vitae: Trevor Hoppe*

9

- 2009 – 2010 Search Committee, HIV/AIDS Cluster Hire, Department of Women’s Studies, University of Michigan
- 2009 – 2010 HIV/AIDS Survey Course Development Committee, Department of Women’s Studies, University of Michigan
- 2009 – 2010 Organizer, “Doing Queer Studies Now” Graduate Conference, University of Michigan

**PROFESSIONAL AFFILIATIONS**

Member, American Sociological Association (ASA)

- Sections: Medical Sociology; Crime, Law and Deviance; Sex and Gender; Sexualities; Sociology of Law

Member, American Sociology of Criminology (ASC)

Member, Law and Society Association (LSA)

Member, Society for the Study of Social Problems (SSSP)

Member, International AIDS Society (IAS)

# EXHIBIT F

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

NICHOLAS HARRISON and  
OUTSERVE-SLDN, INC.

Plaintiffs,

v.

JAMES N. MATTIS, in his official capacity  
as Secretary of Defense; MARK ESPER, in  
his official capacity as the Secretary of the  
Army; and the UNITED STATES  
DEPARTMENT OF DEFENSE,

Defendants.

Case No. 1:18-cv-641 (LMB/IDD)

**EXPERT DECLARATION OF CRAIG W. HENDRIX, M.D., IN SUPPORT OF  
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

## **I. INTRODUCTION**

1. My name is Craig W. Hendrix. I have been retained by counsel for Plaintiffs as an expert in connection with this litigation.

2. I am offering this declaration to provide my expert opinions regarding the U.S. Department of Defense and U.S. Army policies with respect to people living with HIV, including the purported medical justifications for preventing individuals living with HIV from joining the United States military, from being commissioned as officers, and—if already in the military—from deploying outside the United States.

3. As detailed below, it is my opinion that there are no medical justifications for excluding individuals from serving in any capacity in the military or from being deployed outside of the United States based solely on their HIV-positive status.

4. The opinions I express are my own and do not reflect the official policy of any organization with which I am affiliated. I am not receiving any compensation for my work.

5. I am knowledgeable about the matters set forth below based upon my own knowledge and experience, as well as my review of various materials that are cited herein. I have reviewed and concur with the opinions expressed by Dr. Carlos del Rio in the declaration he has submitted in support of this motion.

## **II. PROFESSIONAL BACKGROUND & QUALIFICATIONS**

6. Currently, I am a Professor of Medicine and Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine. I have 28 years of experience in the design and conduct of translational clinical pharmacology studies, mostly of antiretroviral drugs for HIV treatment and prevention. In 2015, I was appointed as the Wellcome Professor

and Director, Division of Clinical Pharmacology and Director of the Drug Development Unit in the Division.

7. Before joining the Johns Hopkins medical school faculty, I served on active duty for 10 years in the U.S. Air Force (USAF). During that time, after completing my medical training, I was the Director of the HIV Medical Evaluation Unit (MEU) and HIV Program at the Wilford Hall USAF Medical Center in San Antonio, Texas, from July 1989 to June 1994. As Director of the HIV MEU, my responsibilities included screening service members for HIV, monitoring the condition of HIV-positive service members, studying behavioral risk factors associated with HIV, and educating service members about the prevention and treatment of HIV.

8. I received my undergraduate degree in Applied Biology at the Massachusetts Institute of Technology in 1978, and I received my medical degree from Georgetown University, *magna cum laude*, in 1984. I completed internship and residency in internal medicine on the Osler Medical Service, and fellowships in Infectious Diseases and Clinical Pharmacology at The Johns Hopkins Hospital.

9. For nearly 30 years, I have evaluated, treated, and/or conducted research with thousands of individuals living with HIV. I have authored or co-authored over 190 papers in peer-reviewed journals on topics related to HIV treatment, prevention, and education. My current research focuses on development of antiretroviral drugs to prevent HIV infection. This involves oral, topical, and injectable HIV microbicide development. I conduct small, intensive sampling studies of pharmacokinetics (PK)<sup>1</sup> and pharmacodynamics (PD) of drugs for HIV

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<sup>1</sup> Pharmacokinetics describes the drug concentration-time courses in body fluids resulting from administration of a certain drug dose, while pharmacodynamics describes the observed effect resulting from a certain drug concentration.

prevention with a focus on developing methods to better understand HIV and drug distribution in the male genital tract, female genital tract, and lower gastrointestinal tract. I also support numerous HIV pre-exposure prophylaxis development studies from phase I to phase III, largely as the leader of the Pharmacology Core Laboratory of both the Microbicide Trial Network and HIV Prevention Trials Network.

10. My curriculum vitae is attached, which describes my education, work experience, and publications. *See* Attach. 1 (Hendrix CV).

**III. MEDICAL JUSTIFICATIONS FOR EXCLUDING PEOPLE LIVING WITH HIV FROM MILITARY SERVICE, INCLUDING DEPLOYMENT OUTSIDE THE UNITED STATES, ARE UNFOUNDED**

11. Being HIV positive is entirely compatible with military service. The Department of Defense has recognized this for many years by permitting people who seroconvert (i.e., acquire HIV and develop HIV antibodies) after entering service to continue to serve. Moreover, I understand the Navy has allowed service members with HIV to deploy for selected overseas missions since 2012, while the Air Force has granted some waivers for overseas assignments for its members living with HIV who are otherwise medically fit for deployment. As I discuss below, the articulated reasons the DoD and Army have advanced for the disparate treatment of people living with HIV simply do not justify excluding them from or restricting their military service.

**A. Military Policies Regarding People Living with HIV**

**1. Accession Ban**

12. I understand that, under Department of Defense (DoD) Instruction 6485.01 (Human Immunodeficiency Virus (HIV) in Military Service Members),<sup>2</sup> it is the U.S. military's policy to deny eligibility for military service to persons with HIV for "appointment, enlistment, pre-appointment, or initial entry training for military service" pursuant to DoD Instruction ("DoDI") 6130.03. In other words, people living with HIV are barred from entering the military or from being appointed an officer if they seroconvert after joining the military, as Mr. Harrison did.

13. Despite this general policy prohibiting people living with HIV from joining the military or being appointed as an officer, DoDI 6485.01 states that an active duty service member with HIV who it has been determined is otherwise "fit for duty will be allowed to serve in a manner that ensures appropriate medical care."<sup>3</sup> Only service members with HIV who are determined to be unfit for duty are to be separated.<sup>4</sup>

14. Department of Defense Instruction 6130.03 (Medical Standards for Appointment, Enlistment, and Induction into the Military Services) sets forth guidance regarding the physical and medical standards required for military service.<sup>5</sup> These standards state that individuals who are considered for appointment, enlistment, or induction into the Medical Services must be:

- (1) Free of contagious diseases that may endanger the health of other personnel.

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<sup>2</sup> U.S. Department of Defense Instruction 6485.01, at ¶3.a. (June 7, 2013), available at <http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/648501p.pdf>.

<sup>3</sup> *Id.* at Enclosure 3: Procedures, ¶3.c.

<sup>4</sup> *Id.* at Enclosure 3: Procedures, ¶3.e.

<sup>5</sup> U.S. Department of Defense Instruction 6130.03 (May 6, 2018), available at <http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/613003p.pdf>.

(2) Free of medical conditions or physical defects that may reasonably be expected to require excessive time lost from duty for necessary treatment or hospitalization, or may result in separation from the Military Service for medical unfitness.

(3) Medically capable of satisfactorily completing required training and initial period of contracted service.

(4) Medically adaptable to the military environment without geographical area limitations.

(5) Medically capable of performing duties without aggravating existing physical defects or medical conditions.<sup>6</sup>

15. HIV is among the specified “disqualifying conditions” under DoDI 6130.03.<sup>7</sup>

16. I also understand that Army Regulation 600-110 (Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus)<sup>8</sup> implements DoDI 6485.01 and describes various policies and responsibilities related to HIV with respect to Army personnel. Specifically, the Army indicates its policies are meant to reflect: [1] the risks incident to military service for the person with HIV; [2] the risk of transmission to other personnel; [3] the overall impact of people living with HIV in Army units and on readiness posture; and [4] the safety of military blood supplies.<sup>9</sup> Similar to DoDI 6485.01, AR 600-110 states that personnel with HIV are not eligible for appointment on enlistment into the active Army, the Army National Guard, or the U.S. Active Reserve.<sup>10</sup> Again, however, the Army regulation states that active duty soldiers with HIV who do not demonstrate progressive clinical illness or immunological

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<sup>6</sup> *Id.* at ¶1.2.c.

<sup>7</sup> *Id.* at 5.23.b. (“Presence of human immunodeficiency virus or laboratory evidence of infection or false-positive screening test(s) with ambiguous results by supplemental confirmation test(s).”).

<sup>8</sup> U.S. Army Regulation 600-110 (Apr. 22, 2014), available at [https://armypubs.army.mil/epubs/DR\\_pubs/DR\\_a/pdf/web/r600\\_110.pdf](https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r600_110.pdf).

<sup>9</sup> *Id.* at Section III, ¶1-15.

<sup>10</sup> *Id.* at Section III, ¶1-16.a.

deficiency during periodic evaluations will not be involuntarily separated solely because they have HIV.<sup>11</sup>

## 2. Conditions for Deployment and Deployment Restrictions

17. I further understand that Department of Defense Instruction 6490.07 (Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees) provides guidance on medical conditions that limit deployment. DoDI 6490.07 indicates that it is DOD policy that service members with existing medical conditions may deploy only when the following conditions are met:

(1) The condition is not of such a nature or duration that an unexpected worsening or physical trauma is likely to have a grave medical outcome or negative impact on mission execution.

(2) The condition is stable and reasonably anticipated by the pre-deployment medical evaluator not to worsen during the deployment in light of physical, physiological, psychological, and nutritional effects of the duties and location.

(3) Any required, ongoing health care or medications anticipated to be needed for the duration of the deployment are available in theater within the Military Health System. Medication must have no special handling, storage, or other requirements (e.g., refrigeration, cold chain, or electrical power requirements). Medication must be well tolerated within hard environmental conditions (e.g. heat or cold stress, sunlight) and should not cause significant side effects in the setting of moderate dehydration.

(4) There is no need for routine evacuation out of theater for continuing diagnostics or other evaluations. (All such evaluations should be accomplished before deployment.)<sup>12</sup>

18. DoDI 6490.07 specifically identifies HIV as a medical condition that precludes a service member's deployment outside of the United States.<sup>13</sup> DoDI 6490.07 provides that a

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<sup>11</sup> *Id.* at Section III, ¶1-16.e.

<sup>12</sup> *Id.* at ¶4.b.

<sup>13</sup> Department of Defense Instruction 6490.07, Encl. 3 (Medical Conditions Usually Precluding Contingency Deployment) at ¶e(2) (Feb. 5, 2010), available at <http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/649007p.pdf>.

service member living with HIV shall not be deployed on a “contingency deployment” (*i.e.*, a deployment of over 30 days located outside the continental United States in a location with medical support from only temporary military medical treatment facilities) unless a medical waiver is granted.<sup>14</sup>

**B. Policies Underlying the Physical and Medical Standards for Military Service and Deployment Do Not Justify the Exclusion of People Living with HIV**

**1. There is No Danger to the Health of Other Personnel**

19. People living with HIV in the military pose no cognizable danger to the health of other personnel in the military. HIV cannot be transmitted by working alongside or having casual contact with someone who is living with HIV, including sharing bathroom facilities; sharing equipment, utensils, and tableware; or exercising or engaging in physical activities. This fact is borne out by the military’s policy that allows people living with HIV to continue to serve in the military, as long as they are medically fit for duty. AR 600-110 explicitly acknowledges that “[t]here is no basis for civilian employees to refuse to work with fellow employees, Soldiers, or agency clients who have . . . HIV or AIDS. The concerns of such employees will be addressed with education and counseling.”<sup>15</sup>

20. Similarly, there is no basis for any service member to refuse to serve with people living with HIV. As stated above, the Navy has already taken steps to allow service members

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<sup>14</sup> *Id.* at ¶4.c (“Individuals with the conditions in Enclosure 3, based on medical assessments in accordance with Enclosure 2 and Reference (1), shall not deploy unless a waiver can be granted according to the procedures in section 3 of Enclosure 2.”); *id.*, Encl. 2 (Procedures) at ¶2.a (“In general, DoD personnel with any of the medical conditions in Enclosure 3, and based on a medical assessment, shall not deploy unless a waiver is granted. Consideration should be made for the nature of the disability and if it would put the individual at increased risk of injury or illness, or if the condition is likely to significantly worsen in the deployed environment.”).

<sup>15</sup> U.S. Army Regulation 600-110, Section III, at ¶1-16.p.

living with HIV to serve overseas on a case-by-case basis.<sup>16</sup> That decision was based on the explicit recognition that: “There is no demonstrated risk of transmission of infection in normal daily activities.”<sup>17</sup>

21. Furthermore, there is no risk—beyond a hypothetical one—of battlefield transmission of HIV. Transmission via the types of exposure that may take place on the battlefield—such as “blood splashes” or those experienced while one soldier is providing care to a wounded soldier with HIV—are not well documented routes of transmission. The risk of an exposure that could result in transmission under such circumstances is at most a theoretical risk. In addition, recent research has established that a person with HIV who is adherent to their medications, and therefore has a suppressed or undetectable viral load, is incapable of transmitting HIV through the most intimate forms of contact. It is reasonable to conclude the risk of transmission through battlefield activities that present at most a theoretical risk of transmission is also effectively zero if the person with HIV has a suppressed or undetectable viral load.

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<sup>16</sup> U.S. Navy, Secretary of the Navy Instruction 5300.30E (Management of Human Immunodeficiency Virus, Hepatitis B Virus and Hepatitis C Virus Infection in the Navy and Marine Corps), ¶ 3.c.(2) (Aug. 13, 2012) (“Selected AC members on a case-by-case basis in consultation with the treating HIV Evaluation and Treatment Unit (HETU), Navy Bloodborne Infection Management Center (NBIMC), and PERS-82 (for sailors) or United States Marine Corp (USMC) Manpower & Reserve Affairs (M&RA) (for Marines) may be assigned to selected ships and Outside the contiguous United States (OCUNUS) commands, as agreed on by all three consultants and the receiving command; the receiving command has the final say on acceptance.”).

<sup>17</sup> Department of Defense, *Report to Congressional Defense Committees on Department of Defense Personnel Policies Regarding Members of the Armed Forces with HIV or Hepatitis B*, at 7 (Sept. 2014), available at <https://health.mil/Reference-Center/Reports/2014/09/22/DoD-Personnel-Policies-Regarding-Members-of-the-Armed-Forces-with-HIV-or-Hepatitis-B>.

22. Finally, in the exceedingly rare event that a battlefield exposure were to occur that presented anything more than a theoretical risk of transmission, post-exposure prophylaxis could be provided to the person exposed, thereby further decreasing whatever minimal hypothetical risk of transmission existed. There is simply no support for the idea that a soldier living with HIV would present a danger to the health and safety of other military personnel, including comrades on the battlefield.

**2. Adhering to an ART Regimen Does Not Require “Excessive Time”**

23. Adherence to an effective ART regimen does not require much time—it is as simple as taking medication every day. The HIV medications commonly prescribed today have no special handling, storage or other requirements. These medications generally tolerate hard conditions, such as hot or cold stress and sunlight, well. Taking medication once or twice a day, as people living with HIV do, requires very minimal time, especially if that person is on a single tablet regimen (STR), which is literally one pill taken once a day. The time and effort required is similar to that expended by service members deployed overseas who are prescribed daily medication for prophylaxis of malaria.<sup>18</sup> I understand that Mr. Harrison, for example, took a daily dose of doxycycline when he was deployed in Afghanistan.

24. The medical monitoring of a person living with HIV is also limited. According to U.S. HIV treatment guidelines, viral load typically should be measured every 3-4 months, although that period may be extended to once every 6 months for individuals whose viral load

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<sup>18</sup> Army Public Health Center, *Malaria Field Guide: The Prevention, Diagnosis and Treatment of Malaria in U.S. Africa Command* (May 2016), available at [https://phc.amedd.army.mil/PHC%20Resource%20Library/TG336\\_MalariaFieldGuide\\_May2016.pdf](https://phc.amedd.army.mil/PHC%20Resource%20Library/TG336_MalariaFieldGuide_May2016.pdf).

has been suppressed for more than 2 years and whose clinical and immunologic status is stable.<sup>19</sup> Viral load testing is routine and requires only drawing and testing a blood sample. Where such testing is not immediately available in theater, a blood sample may easily be shipped to a lab that engages in the type of testing required. Moreover, point-of-care viral load testing that returns results within 90 minutes is becoming increasingly prevalent and cost efficient.

25. General practitioner physicians are capable of engaging in the type of medical monitoring and care required for people living with HIV. In the U.S., primary care physicians are expected and often called upon to provide care to a person living with HIV. In fact, physicians' assistants and nurse practitioners also often provide HIV-related care in the United States. The physicians of the Armed Forces are more than capable of providing necessary care to a person living with HIV, alongside other types of health care provided to all members of the military, regardless of where they are stationed. If additional provider training is required in some instances, such training would be easy for the Armed Services to provide to its healthcare professionals. In the rare event that the expertise of an infectious disease doctor was required to care for a deployed service member, the on-site medical staff could consult with the many qualified infectious disease doctors employed by the Armed Services or a telemedicine session could be arranged between the infectious disease specialist and the service member with HIV.

### **3. People with HIV Can Complete Training and Serve Full Terms**

26. People living with HIV who adhere to their prescribed ART regimen are physically able to complete training and serve full contract terms in the Armed Forces. As far

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<sup>19</sup> See U.S. Department of Health and Human Services, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV*, , available at <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/458/plasma-hiv-1-rna--viral-load--and-cd4-count-monitoring>.

back as 2004, when DoD mandated universal two-year interval HIV testing, the DoD's Armed Forces Epidemiology Board explained that "There is no evidence that HIV infection, per se, affects physical fitness."<sup>20</sup> The same remains true today. As explained in a 2015 article in the *Medical Surveillance Monthly Report*: "In the past 30 years, HIV-1 infection has gone from an untreatable disease marked by inexorable clinical progression through extreme debility to death to a treatable disease that is compatible with active service throughout a full career in the U.S. military."<sup>21</sup> As an example, I understand that Mr. Harrison, who was diagnosed with HIV in 2012, received a PULHES<sup>22</sup> score in 2014 of 1 for each of the six factors that are considered, reflecting a "high level of medical fitness" under Army Regulation 40-501 (Standards of Medical Fitness).<sup>23</sup> There should be no effect on the physical fitness and capabilities of any person with HIV who is adhering to their prescribed ART regimen

27. Similarly, any person with HIV who is adhering to their prescribed ART regimen will be able to serve without aggravating their condition. People living with HIV who are virally suppressed should not experience any HIV-related symptoms or complications of any kind related to their HIV. Provided they are able to continue taking their medications, inhospitable

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<sup>20</sup> Office of the Assistant Secretary of Defense, Health Affairs Policy Memorandum – Human Immunodeficiency Virus Interval Testing (Mar. 29, 2004), available at <https://www.health.mil/Reference-Center/Policies/2004/03/29/Policy-Memorandum---Human-Immunodeficiency-Virus-Interval-Testing>.

<sup>21</sup> J. Brundage, D. Hunt & L. Clark, *Durations of Military Service after Diagnoses of HIV-1 Infections Among Active Component Members of the U.S. Armed Forces 1990-2013*, Armed Forces Health Surveillance Center, *Medical Surveillance Monthly Report*, Vol. 22, No. 8 (Aug. 2015), available at <https://health.mil/Reference-Center/Reports/2015/01/01/Medical-Surveillance-Monthly-Report-Volume-22-Number-8>.

<sup>22</sup> PULHES is an acronym for Physical stamina, Upper extremities, Lower extremities, Hearing/ears, Eyes, and Psychiatric.

<sup>23</sup> U.S. Army Regulation 40-501 (Standards of Medical Fitness), Chapter 7, ¶7-3.d(1) ("An individual having a numerical designation of '1' under all factors is considered to possess a high level of medical fitness.").

environmental conditions and/or challenging work conditions should have no effect on the person living with HIV's health or their ability to serve.

**4. People with HIV Are Adaptable to the Military Environment Without Geographical Area Limitations**

28. People living with HIV are adaptable to the military environment and can deploy worldwide without geographical limitations. As described above, the military environment—regardless of the geographic specifics of that environment—should have no effect on a person with HIV's health or ability to serve. And because it is relatively easy to provide the health care necessary to a person living with HIV (also described in detail above)—and has been for more than a decade—there should be no geographic limitations on an HIV-positive person's service. Again, I understand the Navy has already adopted policies to allow service members living with HIV to serve overseas. Due to this policy, as of September 2017, approximately 55 sailors have been assigned to various overseas and/or operational assignments without any adverse events.<sup>24</sup> There are no geographic locations that would pose an issue for a person living with HIV, as long as that individual adheres to their ART regimen.

**5. There is No Impact on Medical Readiness**

29. Individuals living with HIV can serve without any adverse impact on medical readiness.<sup>25</sup> In the medical context, Department of Defense Instruction 6025.19 (Individual

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<sup>24</sup> J. Okulicz, C. Beckett, J. Blaylock, S. Hakre, B. Agan, N. Michael, S. Peel, P. Scott, and S. Cersovsky, *Review of the U.S. Military's Human Immunodeficiency Virus Program: A Legacy of Progress and a Future of Promise*, Armed Forces Health Surveillance Center, *Medical Surveillance Monthly Report*, Vol. 24, No. 9 (Sept. 2017), available at <https://health.mil/Reference-Center/Reports/2017/01/01/Medical-Surveillance-Monthly-Report-Volume-24-Number-9>.

<sup>25</sup> U.S. Department of Defense Instruction 6025.19 (Individual Medical Readiness), at ¶ 3 (June 9, 2014), available at <http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602519p.pdf> (explaining that

Medical Readiness) establishes medical readiness standards for deployment for individuals as follows: (1) a current periodic health assessment (every 12 months); (2) the absence of deployment-limiting medical conditions; (3) dental readiness to specified standards; (4) immunization standards germane to the theater of operation; (5) current medical readiness laboratory tests; and (6) possession of appropriate individual medical equipment.<sup>26</sup> As discussed above, there is no basis for including HIV as a deployment-limiting medical condition, and individuals living with HIV can otherwise satisfy the other elements of medical readiness.

#### **6. There is No Danger to the Safety of Military Blood Supplies**

30. Allowing people living with HIV to serve poses no danger to the safety of military blood supplies. Since 1962, the Armed Services Blood Program has provided blood products for all service members, working to collect, process, store, distribute, and transfuse blood worldwide.<sup>27</sup> People who have been diagnosed with HIV are informed that they can no longer donate blood—and there is no evidence that they attempt to do so. Any risk to the blood supply would arise from those who are unaware they are living with HIV. The military, however, has protocols in place to prevent donations from those who are unaware they are HIV positive, has screened service members for decades and closely monitors which service members are living with HIV as part of its plan to protect the battlefield blood supply.<sup>28</sup> These efforts have

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it is DoD policy “to promote a healthy and fit fighting force that is medically prepared to provide the Military Departments with the maximum ability to accomplish their deployment missions throughout the spectrum of military operation.).

<sup>26</sup> U.S. Department of Defense Instruction 6025.19 (Individual Medical Readiness), Encl. 3 (June 9, 2014), available at

<http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602519p.pdf>.

<sup>27</sup> Armed Services Blood Program, About Us, available at

<http://www.militaryblood.dod.mil/About/default.aspx>

<sup>28</sup> J. Okulicz, C. Beckett, J. Blaylock, S. Hakre, B. Agan, N. Michael, S. Peel, P. Scott, and S. Cersovsky, *Review of the U.S. Military’s Human Immunodeficiency Virus Program: A Legacy of*

been successful. For example, one study of HIV among U.S. Army soldiers found that, of service members who seroconverted while deployed in Afghanistan or Iraq over the period 2001-2007, “[n]one were emergency blood transfusion donors or recipients.”<sup>29</sup> Indeed, in the general public, the National Institute of Health has stated: “Your risk of getting HIV from a blood transfusion is lower than your risk of getting killed by lightning. Only 1 in 2 million donations might carry HIV and transmit HIV if given to a patient.”<sup>30</sup> Allowing people living with HIV to serve will not change the screening measures already in place to protect the blood supply, which are primarily aimed at preventing transmission from those who are undiagnosed.

31. In the context of battlefield emergency transfusions, i.e., the “walking blood bank,” the safety of the blood supply may be ensured by continuing to screen service members for HIV and informing individuals who test HIV positive that they cannot act as emergency blood transfusion donors. This will have negligible impact on the overall blood supply. Not only are battlefield transfusions relatively rare,<sup>31</sup> the percentage of service members living with HIV is and would continue to be relatively low (i.e., people living with HIV comprise

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*Progress and a Future of Promise*, Armed Forces Health Surveillance Center, *Medical Surveillance Monthly Report*, Vol. 24, No. 9 (Sept. 2017), available at <https://health.mil/Reference-Center/Reports/2017/01/01/Medical-Surveillance-Monthly-Report-Volume-24-Number-9>

<sup>29</sup> P. Scott et al., *Short Communication: Investigation of Incident HIV Infections Among U.S. Army Soldiers Deployed to Afghanistan and Iraq, 2001-2007*,

<sup>30</sup> U.S. Department of Health & Human Services, National Heart, Lung, and Blood Institute, *Blood Transfusion*, available at <https://www.nhlbi.nih.gov/health-topics/blood-transfusion>.

<sup>31</sup> See T. Ballard, P. Rohrbeck, M. Kania, & L. Johnson, *Transfusion-Transmissible Infections Among U.S. Military Recipients of Emergently Transfused Blood Products, June 2006-December 2012*, *Medical Surveillance Monthly Report*, Vol. 21, No. 11 (Nov. 2014) (stating that “According to the Armed Services Blood Program (AFBP), the U.S. military transfused 237,100 units of blood products between June 2006 and December 2012. Thus, the 4,857 non-FDA-compliant units represented approximately 2% of the total blood products” and indicating that “[n]o cases of HIV” resulted from these transfusions).

approximately one-third of one percent of the population of the United States, and just .027% of active duty service members).<sup>32</sup> Furthermore, there are various other factors that often disqualify individuals as emergency blood donors, such as blood type<sup>33</sup>—making people living with HIV no different from these other groups who are allowed to serve and deploy. Finally, the use of blood substitutes is on the rise, which should result in even less need for emergency battlefield transfusions from other service members.

#### IV. CONCLUSION

In my opinion, there is no medical justification for preventing or restricting the military service and overseas deployment of people living with HIV.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 18th day of July, 2018



Craig W. Hendrix, M.D.

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<sup>32</sup> United States Census Bureau. *American Factfinder: Monthly Population Estimates for the United States: April 1, 2010 to December 1, 2016*, [https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP\\_2017\\_PEMONTHN&prodType=table](https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2017_PEMONTHN&prodType=table) (last visited July 18, 2018); Armed Forces Health Surveillance Center (AFHSC), *Update: Routine Screening for Antibodies to Human Immunodeficiency Virus, Civilian Applicants for U.S. Military Service and U.S. Armed Forces, Active and Reserve Components, January 2010–June 2015*, Medical Surveillance Monthly Report, Aug. 2015, 2-8.

<sup>33</sup> *Emergency War Surgery*, 4th ed. (2014), Chapter 33 (Blood Transfusions), available at <http://www.cs.amedd.army.mil/FileDownloadpublic.aspx?docid=189c4a13-522f-4d91-9236-a109d7b5ee4d>.

# Attachment

## CURRICULUM VITAE

The Johns Hopkins University School of Medicine

10 JUL 18

Craig W. Hendrix

(Date of this version)

### DEMOGRAPHIC AND PERSONAL INFORMATION

#### Current Appointments

##### *University*

Wellcome Professor and Director, Division of Clinical Pharmacology  
Appointment effective 1/1/2015

Professor of Medicine, Division of Clinical Pharmacology (Primary)  
Appointment effective 1/1/2009

Professor of Medicine, Division of Infectious Diseases (Secondary)  
Appointment effective 1/1/2009

Professor of Pharmacology and Molecular Sciences (Secondary)  
Appointment effective 1/1/2009

Professor of Epidemiology (Secondary)  
Appointment effective 1/1/2009

Director, Drug Development Unit, Division of Clinical Pharmacology  
Appointment effective 7/1/1998

Director, Division of Clinical Pharmacology  
Appointment effective 1/1/2015

##### *Hospital*

Medical Staff, The Johns Hopkins Hospital  
Appointment effective 8/1/1994.

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**EDUCATION AND TRAINING**

<i>Year</i>	<i>Degree/Cert.</i>	<i>Institution</i>	<i>Discipline</i>
1978	S.B.	Massachusetts Institute of Technology	Applied Biology
1984	M.D.	Georgetown University	Medicine
7/84-6/85	Intern	The Johns Hopkins Hospital	Internal Medicine
7/85-6/87	Resident	The Johns Hopkins Hospital	Internal Medicine
9/86-7/89	Post-Doctoral Fellow	Johns Hopkins University	Infectious Diseases
7/87-7/89	Post-Doctoral Fellow	Johns Hopkins University	Clinical Pharmacology Mentor: Paul S. Lietman

**PROFESSIONAL EXPERIENCE**

<i>Dates</i>	<i>Position</i>	<i>Institutions</i>
1989-1994	Clinical Assistant Professor	Department of Medicine University of Texas Health Sciences Center San Antonio, TX
1989-1994	Staff Physician	Department of Infectious Diseases Division of Medicine Wilford Hall USAF Medical Center Lackland AFB, TX
1989-1994	Director	Human Immunodeficiency Virus Unit Department of Infectious Diseases Wilford Hall USAF Medical Center Lackland AFB, TX
1993-1994	Director	Human Immunodeficiency Virus Research & Education Program Department of Infectious Diseases Wilford Hall USAF Medical Center Lackland AFB, TX
1990-1993	Assistant Professor	Department of Medicine Uniformed Services University of Health Sciences Bethesda, MD

**PROFESSIONAL EXPERIENCE**

<i>Dates</i>	<i>Position</i>	<i>Institutions</i>
1992-1994	Associate Scientist (Adjunct)	Southwest Foundation for Biomedical Research and Education San Antonio, TX
1993-1996	Associate Professor	Department of Medicine Uniformed Services University of Health Sciences Bethesda, MD
1994-2000	Senior Scientist	Department of Prevention Research, Division of Retrovirology Walter Reed Army Institute of Research Rockville, MD
1994-1996	Associate Professor (Part-Time)	Division of Clinical Pharmacology, Department of Medicine Johns Hopkins University School of Medicine (JHUSOM) Baltimore, MD
1997-1999	Ind. Mobilization Augmentee	U.S. Air Force Reserve Preventive Medicine Division Office of the Surgeon General Bolling AFB, DC
1997- 2008	Associate Professor	Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD
1997-1998	Clinical Director	Drug Development Unit Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD
1998-2001	Director (Acting)	Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD
1998-2008	Associate Professor	Division of Infectious Diseases Department of Medicine, JHUSOM Baltimore, MD

**PROFESSIONAL EXPERIENCE**

<i>Dates</i>	<i>Position</i>	<i>Institutions</i>
1998-present	Director	Drug Development Unit Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD
1999-2008	Associate Professor	Department of Pharmacology and Molecular Sciences, JHUSOM Baltimore, MD
1999-2008	Associate Professor	Department of Epidemiology Johns Hopkins University Bloomberg School of Public Health Baltimore, MD
1998-2008	Associate Professor	Division of Infectious Diseases Department of Medicine, JHUSOM Baltimore, MD
2007-2013	Co-Director	Drug Development Core Institute for Clinical and Translational Research Johns Hopkins University Baltimore, MD
2007-2014	Director (Interim)	Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD
2007-2014	Director (Interim)	Clinical Pharmacology Analytical Laboratory Division of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD
2009-present	Professor	Division of Clinical Pharmacology Department of Medicine Johns Hopkins University School of Medicine Baltimore, MD
2009-present	Professor	Department of Pharmacology and Molecular Sciences Johns Hopkins University School of Medicine Baltimore, MD

**PROFESSIONAL EXPERIENCE**

<i>Dates</i>	<i>Position</i>	<i>Institutions</i>
2009-present	Professor	Department of Epidemiology Johns Hopkins University Bloomberg School of Public Health Baltimore, MD
2012-2014	Co-Director	Behavioral Science Core Center for AIDS Research Johns Hopkins University Baltimore, MD
2014-present	Deputy Director Director	Institute for Clinical and Translational Research Translational Sciences Core Johns Hopkins University School of Medicine Baltimore, MD
2014-present	Director Member	Laboratory Core Executive Committee Center for AIDS Research Johns Hopkins University Baltimore, MD
2014-present	Affiliated Faculty Member	Center for Nanomedicine Wilmer Eye Institute, JHUSOM Baltimore, MD
2015-present	Director	Division of Clinical Pharmacology Wellcome Professor of Clinical Pharmacology Department of Medicine, JHUSOM Baltimore, MD
2016-present	Director (Contact)	Clinical Pharmacology Training Program Division of Clinical Pharmacology, JHUSOM Baltimore, MD

**PUBLICATIONS****Original Research**

1. Smith CR, Petty BG, **Hendrix CW**, Kernan WN, Garver PL, Fox K, Beamer A, Carbone K, Threlkeld M, Lietman PS. Ceftriaxone Compared with Cefotaxime for Serious Bacterial Infections. *J Infect Dis* 1989;160(3):442-7.
2. Kornhauser DM, Petty BG, **Hendrix CW**, Woods AS, Nerhood LJ, Bartlett JG, Lietman PS. Probenecid and Zidovudine Metabolism. *Lancet* 1989;2(8661):473-5.
3. Lorentsen KJ, **Hendrix CW**, Collins JM, Kornhauser D, Petty BG, Klecker RW, Flexner C, Eckel RH, Lietman PS. Dextran Sulfate is Poorly Absorbed after Oral Administration. *Ann Intern Med* 1989;111(7):561-6.
4. Lucey DR, **Hendrix CW**, Andrzejewski C, McGlasson D, Ward WW, Melcher GP, Zajac RA, Boswell RN. Hepatitis C Antibody in a Non-Hemophiliac Cohort Infected with the Human Immunodeficiency Virus. *Viral Immunol* 1990;3(4):295-301.
5. Lucey DR, McGuire SA, Clerici M, Hall K, Benton J, Clifford AB, Ward WW, Shearer G, Boswell RN, **Hendrix CW**. Comparison of Spinal Fluid Beta 2-Microglobulin Levels with CD4+ T lancet Count, In Vitro T Helper Cell Function, and Spinal Fluid IgG Parameters in 163 Neurologically Normal Adults Infected with the Human Immunodeficiency Virus Type 1. *J Infect Dis* 1991;163(5):971-5.
6. **Hendrix CW**, Volberding PA, Chaisson RE. HIV Antigen Variability in ARC/AIDS. *J Acquir Immun Defic Syndr* 1991;4(9):847-850.
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### Review Articles

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2. **Hendrix CW**, Sulkowski MS. Hepatotoxicity of antiretroviral therapy and drug-drug interactions with antiviral therapies for hepatitis C infection. In: Strategies for the Management of HIV/HCV Co-infection. Seacaucus: Projects in Knowledge, 2002.

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1. Committee on the role of institutional review boards in health services research data privacy protection. Institutional Review Boards and Health Services Research Data Privacy. A Workshop Summary. Institute of Medicine, Washington, D.C. May 2000.
2. Committee on the Role of institutional review boards in health services research data privacy protection. Protecting Data Privacy in Health Services Research. A Workshop Summary. Division of Health Care Services. Institute of Medicine, National Academy Press. Washington, D.C. 2000.
3. Veronese F, Anton P, Fletcher CV, DeGruttola V, McGowan I, Becker S, Zwierski S, Burns D; **Workshop Organizing Committee**. Implications of HIV PrEP trials results. AIDS Res Hum Retroviruses. 2011 Jan;27(1):81-90.

### Editorials (Invited)

1. **Hendrix CW**. When is a PrEP candidate ready for phase 3? Lancet HIV DOI: [http://dx.doi.org/10.1016/S2352-3018\(16\)30162-X](http://dx.doi.org/10.1016/S2352-3018(16)30162-X)

### Letters, Correspondence

1. **Blatt SP, Hendrix CW**. Delayed-Type Hypersensitivity and AIDS. Ann Intern Med 1994;120(4):343-44. (Letter)
2. **Hendrix CW**. Consideration of the prevalence of CMV retinitis alters the assessment of a serum cytomegalovirus DNA test. J Infect Dis 1995;171(6):1688. (Letter)
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**FUNDING****Extramural Funding (current, pending, previous)*****Current***

Dates: 01/09/2017-01/01/2019  
 Title: A Phase I Multi-Compartment Pharmacokinetic Study of Cabotegravir Long-Acting in Healthy Adult Volunteers  
 Grant Number: GSK Protocol 201767  
 Sponsor: ViiV/GSK  
 Total Direct Costs: \$729,798  
 Principal Investigator: **C. Hendrix**  
 Role: **PI.** Provide protocol development/execution and PK/PD data analysis and interpretation for clinical development of long-acting implantable HIV prevention strategy.  
 Effort: 10%

Dates: 07/07/2015-06/30/2020  
 Title: Sustained Long Acting Prevention Against HIV Program Operation  
 Grant Number: UM1 AI120184-01 (Program Project Grant)  
 Sponsor: NIH  
 Total Direct Costs: \$72,770  
 Principal Investigator: Thomas Hope (Northwestern University)  
 Role: **Project Co-Leader, Site PI.** Provide protocol development/execution and PK/PD data analysis and interpretation for clinical development of long-acting implantable HIV prevention strategy.  
 Effort: 20%

Dates: 07/01/2014 - 06/30/2019  
 Title: Development of Rectal Enema As Microbicide (DREAM)  
 Grant Number: U19 AI113127-01 (Program Project Grant)  
 Sponsor: NIH  
 Total Direct Costs: \$ 16,323,328  
 Total Costs: \$ 20,677,877  
 Principal Investigator: **C. Hendrix**  
 Effort: 20%

Dates: 07/01/2014 - 06/30/2019  
 Title: Systemic development of microbicide Intravaginal rings for HIV prevention  
 Grant Number: U19AI113048-01  
 Sponsor: NIH  
 Total Direct Costs: \$ 16,662,549  
 Principal Investigator: Marc Baum (Oak Crest Institute of Science)  
 Effort: 5%  
 Role: **Project PI.** Design, conduct, and data analysis of clinical studies to develop a combination vaginal microbicide ring.

**FUNDING****Extramural Funding (current, pending, previous)***Current*

Dates: 04/01/2014-03/31/2019  
Title: HIV-1 reservoir dynamics in the female genital tract  
Grant Number: R01 AI08538091-02  
Sponsor: NIH  
Total Direct Costs: \$43,580  
Principal Investigator: Athe Tsibris (University of Washington)  
Role: Pharmacologist. Relationship between antiretroviral (ARV) drug concentrations in the blood and female genital tract is a key component of understanding HIV persistence and decay in anatomic reservoirs.  
Effort: 2%

Dates: 01/01/2014-11/30/2020  
Title: Pharmacology Network Lab, HIV Prevention Trials Network (HPTN)  
Grant Number: UM1AI068613-08  
Sponsor: NIH  
Total Direct Costs: \$ 2,577,018 (Pharmacology Network Lab)  
Principal Investigator: **C. Hendrix**  
Role: Principal Investigator Pharmacology Group. Design and analysis of pharmacology studies and coordination of analytical laboratory to support HPTN clinical studies of HIV pre-exp[osure prophylaxis].  
Effort: 10%

Dates: 01/01/2014-11/30/2020  
Title: Pharmacology Network Laboratory, Microbicide Trials Network (MTN)  
Grant Number: UM1AI106707 (Laboratory Center [LC]), UM1AI068633 (Leadership & Operations Center [LOC])  
Sponsor: NIH  
Total Direct Costs: \$1,832,004 (Pharmacology Network Lab)  
Principal Investigator: **C. Hendrix**  
Role: Director, Rectal Microbicide Program (LOC), Pharmacology Core Leader Laboratory Center; Principal Investigator for design, execution, and analysis of MTN clinical trials.  
Effort: 15%

Dates: 07/01/2013 - 06/30/2018 (NCE)  
Title: The effect of Depo-Provera on HIV susceptibility, immune activation, and PrEP PK  
Grant Number: 1R01HD077887-01  
Sponsor: NIH  
Total Direct Costs: 1,749,106  
Principal Investigator: **C. Hendrix** (Multi-PI with Jenell Coleman). Clinical studies to describe interaction between tenofovir and depo-medroxyprogesteron and impact on pharamcology, immunology, endocrinology, and virology.  
Effort: 20%

**FUNDING****Extramural Funding (current, pending, previous)*****Current***

Dates: 07/01/2011-06/30/2018 (NCE)  
 Title: Mucus Penetrating Particles For Rectal Microbicides  
 Grant Number: R33 AI094519-03  
 Sponsor: NIH  
 Total Direct Costs: \$ 282,000  
 Principal Investigator: Justin Hanes  
 Role: Pharmacologist. This project will develop mucus penetrating particles for colorectal drug delivery of rectal microbicides for protection against HIV and other STDs. Role is to provide clinical pharmacology for product development to maintain feasibility for future human use of the products.  
 Effort: 5%

Dates: 09/17/2007-05/31/2018  
 Title: Institutional Clinical and Translational Science Award (CTSA)  
 Grant Number: NCATS 1UL1TR001079-01  
 Sponsor: NIH  
 Total Direct Costs: \$ 7,485,218  
 Principal Investigator: D. Ford  
 Role: **Deputy Director ICTR, Translational Science Core Director**  
 Effort: 10%

Dates: 08/01/2012-07/31/2019 (NCE)  
 Title: Development and Evaluation of Dual Compartment Microbicides  
 Grant Number: 1U19AI101961  
 Sponsor: NIH/NIAID  
 Total Direct Costs: \$3,224,012  
 Principal Investigator: Buckheit (ImQuest Pharmaceuticals, Inc.)  
 Role: **Project PI.** Design, conduct, and analysis of clinical studies to develop a combination rectal microbicide IQP-0528/tenofovir.  
 Effort: 21%

Dates: 09/01/2012-08/31/2018 (NCE)  
 Title: Efficacy & Safety of Multitargeted Combination Microbicides to Prevent HIV & HSV  
 Grant Number: 5U19AI076980  
 Sponsor: NIH/NIAID  
 Total Direct Costs: \$ 2,874,915  
 Principal Investigator: Herold (Albert Einstein College of Medicine)  
 Role: **Core PI.** Design, sample analysis, PK/PD analysis, vaginal microbicide  
 Effort: 5%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 04/01/2014 - 03/31/2018  
Title: Pharmacostatistical Modeling and Simulation of Randomized Clinical PrEP Trials  
Grant Number: ID OPP1099837  
Sponsor: Bill and Melinda Gates Foundation  
Total Direct Costs: \$925,281  
Principal Investigator: **C. Hendrix.** Pooled data from 5 RCTs to estimate concentration-response within and among PrEP RCTS. Development and integration of PK, PD, and disease response models to perform clinical trial simulation.  
Effort: 5%

Dates: 07/01/10-05/31/15 (NCE)  
Title: Exploratory pharmacokinetics of UC781 and Tenofovir vaginal microbicide gel v film  
Grant Number: 1U19AI082639  
Sponsor: NIH  
Total Direct Costs: \$1,599,703  
Principal Investigator: Hillier (Magee Women's – University of Pittsburgh)  
Role: **Project PI.** Develop combination antiretroviral vaginal microbicide formulation, in both a gel and film formulation.  
Effort: 18%

Dates: 9/23/09-8/31/14 (NCE)  
Title: Combination HIV Antiretroviral Rectal Microbicide Program (CHARM)  
Grant Number: 1U19AI082637  
Sponsor: NIH/NIAID  
Total Direct Costs: \$2,240,713 year 1  
Principal Investigator: McGowan (Magee Women's Research Institute, Univ Pittsburgh)  
Role: **Site PI.** Design, conduct, and analysis of clinical studies and laboratory operations to develop a combination rectal microbicide.  
Effort: 18%

Dates: 06/04/08-06/03/15  
Title: Provision and management of a Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases.  
Grant Number: HHSN272200800026C  
Sponsor: NIH-NIAID-DMID  
Total Direct costs: \$886,965  
Principal Investigator: Zenilman  
Role: **Site PI.** Management of Johns Hopkins East Baltimore Phase I site; study design, execution, data analysis  
Effort : 10%

Craig W. Hendrix., MD

Curriculum Vitae

**FUNDING****Extramural Funding (current, pending, previous)**

Dates: 07/01/06 - 12/31/13  
 Title: Pharmacology Network Lab, HIV Prevention Trials Network (HPTN)  
 Grant Number: UM1 AI 068613  
 Sponsor: NIH  
 Total Direct Costs: \$ 1,599,150 (Pharmacology Network Lab)  
 Principal Investigator: **C. Hendrix**  
 Role: Principal Investigator Pharmacology Core Lab. Design and analysis of pharmacology studies and co-supervision of analytical laboratory to support HPTN clinical studies to investigate the use of anti-retroviral drugs for the prevention of transmission of HIV.  
 Effort: 5%

Dates: 07/01/06 - 12/31/13  
 Title: Pharmacology Network Laboratory, Microbicide Trials Network (MTN)  
 Grant Number: U01 AI 068633 subaward 26-3301-4221  
 Sponsor: NIH  
 Total Direct Costs: \$1,777,370 (Pharmacology Network Lab)  
 Principal Investigator: **C. Hendrix**  
 Role: Principal Investigator for design, execution, and analysis of MTN clinical trials; Supervision of Pharmacology Network Laboratory providing analytical support to the MTN; Scientific leadership at the Executive Committee and Biomedical Science Committee  
 Effort: 20%

Dates: 02/01/10-01/31/14  
 Title: Impact of maternal HAART on HIV-infected breastfeeding infants: Malawi  
 Grant Number: 1R01AI087139-01A1  
 Sponsor: NIH/NIAID/DAIDS  
 Total Direct Costs: \$373,102  
 Principal Investigator: Eshleman  
 Role: Co-Investigator – Pharmacologist responsible for PK data analysis  
 Effort: 1%

Dates: 12/01/09-11/30/13  
 Title: Origin and evolution of HIV-1 drug resistance in the RT-SHIVmne Macaque Model  
 Grant Number: 1R01AI080290-01A2  
 Sponsor: NIH  
 Total Direct Costs: \$42,684(total direct, JHU project)  
 Principal Investigator: Ambrose (Univ of Pittsburgh)  
 Role: Site PI. Pharmacology design, assay development, and PK data analysis  
 Effort: 3%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 09/01/09-08/31/13  
 Title: Safety, Efficacy, Mechanisms of Ginseng in HIV-related Fatigue  
 Grant Number: R01 AT005526-01  
 Sponsor: NCCAM  
 Total Direct Costs: \$1,330,311  
 Principal Investigator: Andrade  
 Role: Director of clinical research unit, PK data analysis.  
 Effort: 4%

Dates: 09/01/09-12/31/12  
 Title: Pre-exposure HIV prophylaxis adherence in rural Uganda  
 Grant Number: Partners PrEP Study (Bangsberg at MGH)-JHU subaward  
 Sponsor: Bill and Melinda Gates Foundation  
 Total Direct costs: \$400,000  
 Principal Investigator: Bangsberg  
 Role: Design/analysis of the pharmacokinetic aspects of the study and laboratory assays to examine the relationship between drug level, adherence, and product sharing.  
 Effort: 5%

Dates: 09/01/09-12/31/12  
 Title: Pre-exposure HIV prophylaxis adherence in rural Uganda  
 Grant Number: Partners PrEP Study (Bangsberg at MGH)-JHU subaward  
 Sponsor: Bill and Melinda Gates Foundation  
 Total Direct costs: \$400,000  
 Principal Investigator: Bangsberg  
 Role: Design/analysis of the pharmacokinetic aspects of the study and laboratory assays to examine the relationship between drug level, adherence, and product sharing.  
 Effort: 5%

Dates: 11/01/09-04/30/12  
 Title: A pilot study of Pre-Exposure Prophylaxis (PrEP) to evaluate safety, acceptability, and adherence in at-risk populations in Kenya, Africa  
 Grant Number: JHURSA0901  
 Sponsor: International AIDS Vaccine Initiative  
 Total Direct Costs: \$72,326  
 Principal Investigator: **Hendrix**  
 Role: Pharmacological sub-study design and analysis. Supervision of lab assay of samples for drug concentration.  
 Effort: 2%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 09/01/09-08/28/11  
 Title: Pharmacokinetic interactions of Ribavirin and Abacavir in healthy volunteers  
 Grant Number: Contract  
 Sponsor: GlaxoSmithKline  
 Total Direct costs: \$367,185  
 Principal Investigator: Andrade  
 Role: **Pharmacologist.** Support in design and analysis of investigator initiated Ribavirin-Abacavir drug-drug interaction study.  
 Effort: 1%

Dates: 05/01/09-04/30/10  
 Title: Distribution of orally-administered Tenofovir into colon and vaginal tissue for the prevention of sexual HIV transmission.  
 Grant Number: Contract  
 Sponsor: Gilead  
 Total Direct costs: \$78,358  
 Principal Investigator: **C. Hendrix**  
 Role: Design, execution, analysis of study of tenofovir to evaluate the PK of the drug and phosphorylated moieties in blood, tissue (colon and vaginal) and cells using LC/MS/MS and accelerator mass spectrometry.  
 Effort: 1%

Dates: 01/01/07 – 12/31/08  
 Title: Epithelial Injury and HIV Penetration after Simulated Ejaculation  
 Grant Number: 106755-41-RGMT  
 Sponsor: amfAR (American Foundation for AIDS Research)  
 Total Direct Costs: \$ 100,000  
 Principal Investigator: **C. Hendrix**  
 Role: Principal Investigator (design, execution, and analysis) of study is to evaluate the effect of anal sexual practices on the rectum and distal colon which might affect the study and development of effective HIV microbicides for rectal use.  
 Effort: 4%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 09/01/06-09/01/07  
 Title: Prophylactic Antimalarial Activity of DB289 in Volunteers Challenged with *Plasmodium falciparum*  
 Grant Number: C06-015  
 Sponsor: Immtech Pharmaceuticals  
 Total Direct Costs: \$ 466,548  
 Principal Investigator: T. Shapiro  
 Role: Contribute to design and pharmacokinetics data analysis. Investigator-initiated prophylactic antimalarial activity of DB289 in volunteers challenged with plasmodium falciparum.  
 Effort: 10%

Dates: 8/01/06 - 7/31/09  
 Title: Microbicide Development Program.  
 Grant Number: NIH U19 AI060614  
 Sponsor: NIH  
 Total Direct Costs: \$ 1,429,670  
 Principal Investigator: P. Anton (UCLA)  
 Role: Project PI. Project 5 to evaluate pharmacokinetics, toxicity, and acceptability of enema and gel as drug delivery device for UC781, a non-nucleoside reverse transcriptase inhibitor, as topical HIV microbicides.  
 Effort: 30%

Dates: 04/01/06 – 03/31/07  
 Title: CV-N Microbicide Program: A Phase I Study to Determine the Safety, Tolerance, and Acceptability of the Vaginal Distribution of Cyanovirin.  
 Grant Number: U19 AI051650 Program Project Grant (R. Bax, Biosyn, PI)  
 Sponsor: NIH  
 Total Direct Costs: \$ 237,747  
 Principal Investigator: **C. Hendrix** (Project)  
 Role: Project PI responsible for design, execution, analysis of phase I Cyanovirin vaginal microbicide safety and pharmacokinetics.  
 Effort: 10%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 1/1/06-12/31/07  
Title: The Distribution of CD4 Cells and HIV-sized Particles Following Simulated Vaginal Intercourse.  
Grant Number: GPOA 0005004100  
Sponsor: US Agency for International Development (through International Partnership for Microbicides)  
Total Direct Costs: \$ 157,896  
Principal Investigator: **C. Hendrix**  
Role: Principal investigator for design and conduct of a clinical study to image T-cell and HIV-sized particle migration in the female genital tract lumen and tissue following exogenous administration of radiolabeled autologous lymphocytes using simulated coitus.  
Effort: 5%

Dates: 01/18/06-01/17/07  
Title: Correlation of Free and Total Indinavir Concentrations in Seminal Plasma with the Concentrations in Blood Plasma in HIV-Infected Patients  
Grant Number: Medical School Project  
Sponsor: Merck Pharmaceuticals  
Total Direct Costs: \$ 20,816  
Principal Investigator: **C. Hendrix**  
Role: Phase I study of HIV infected and healthy volunteers to explore the exposure of protein free indinavir in blood and semen. Principal investigator supervising post-doctoral fellow on the project.  
Effort: 1%

Dates: 11/04/05-11/03/06  
Title: A Study of the Pharmacokinetic Interaction between AMD11070 and Substrates of CYP 3A4 and 2D6 Enzymes in Healthy Volunteers  
Grant Number: C-308 CTA  
Sponsor: AnorMED  
Total Direct Costs: \$ 211,050  
Principal Investigator: **C. Hendrix**  
Role: An investigator-initiated phase I study of the pharmacokinetic interaction of AMD11070 and two CYP 450 probe drugs, midazolam (CYP 3A4) and dextromethorphan (CYP 2D6). Principal investigator responsible for protocol design, execution, data analysis.  
Effort: 10%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 07/1/05-06/30/08  
Title: Safety and Efficacy of Tenofovir as Pre-Exposure Prophylaxis of HIV infection in Heterosexually Active Young Adults in Botswana and Injection Drug Using Adults in Thailand.  
Grant Number: GAB-05-C-0459  
Sponsor: Centers for Disease Control  
Total Direct Costs: \$ 178,565  
Principal Investigator: **C. Hendrix**  
Role: Design and analysis of pharmacokinetic-pharmacodynamic sub-study of daily Tenofovir Disoproxil Fumarate for the prevention of HIV infection in heterosexually active young adults in Botswana; supervision of laboratory sample analysis for tenofovir drug levels in study.  
Effort: 5%

Dates: 04/01/05-03/31/08  
Title: Distribution of HIV in the Distal Gastrointestinal Tract  
Grant Number: P30 AI042855  
Sponsor: NIH (Hopkins Center for AIDS Research [CFAR])  
Project Direct: \$ 59,792  
Principal Investigator: **C. Hendrix** (Project)  
Role: Principal Investigator of Developmental Pilot Grant from CFAR to describe the distribution of HIV and CD4 cells in the distal gastrointestinal tract following simulated coitus in order to establish the distribution of infectious material following receptive anal intercourse.  
Effort: 1%

Dates: 12/04/04-12/03/06  
Title: A Phase I, drug interaction study to assess steady-state plasma methadone enantiomer pharmacokinetics following co-administration of methadone qd with Fosamprenavir 700 mg bid + RTV 100 mg bid in opiate-dependent, HIV-adult subjects.  
Grant Number: COL 012577 CTA  
Sponsor: GlaxoSmithKline  
Total Direct Costs: \$ 383,729  
Principal Investigator: **C. Hendrix**  
Role: PI, design, execution, data analysis of investigator-initiated phase II study of the PK/PD methadone and fosamprenavir.  
Effort: 1%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 7/23/04-4/23/07  
 Title: Pharmacokinetics of Efavirenz during treatment of HIV-1 infected subjects with hepatic impairment.  
 Grant Number: M01 RR000052; AI266-917  
 Sponsor: NIH; Bristol Myers Squibb  
 Total Direct Costs: \$ 128,843  
 Principal Investigator: **C. Hendrix**  
 Role: Site principal investigator, a multi-center phase I study of the pharmacokinetics of Efavirenz in HIV infected persons.  
 Effort: 1%

Dates: 11/01/02 – 04/30/07  
 Title: Candida Ecology in the Intensive Care Unit.  
 Grant Number: M01 RR00052  
 Sponsor: NIH  
 Total Direct Costs: GCRC Clinical Study Support  
 Principal Investigator: **C. Hendrix**  
 Role: Study Candida in ICU following several years of antifungal prophylaxis.  
 Effort: 1%

Dates: 11/01/02 – 10/30/03  
 Title: Sampling Frequency Limitations of Drugs in Whole Semen Ejaculates.  
 Grant Number: M01 RR00052  
 Sponsor: NIH  
 Total Direct Costs: GCRC Clinical Study Support  
 Principal Investigator: **C. Hendrix**  
 Role: Design/execution of study to determine the sampling interval for semen that does not interfere with local drug permeability.  
 Effort: 1%

Dates: 1/1/02 – 06/30/06  
 Title: A Phase I First in Human Dose Escalation Study of the Pharmacokinetics and Safety of AMD070 in Healthy Volunteers  
 Grant Number: U01AI 27668-18S1 Adult AIDS Clinical Trials Unit (Flexner, PI)  
 Sponsor: NIH  
 Total Direct Costs: \$ 4,527,600 (full U19, not project)  
 Principal Investigator: **C. Hendrix** (Project)  
 Role: Protocol Chair for Multi-center phase I first-in-human, pharmacokinetic study, responsible for protocol design and coordinating study execution.  
 Effort: 10%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 10/01/01 – 12/31/07  
Title: A U.S. Clinical Trial Site to Conduct Evaluations of Topical Microbicides in Men Who Have Sex with Men (MSM).  
Grant Number: 200-2001-08015  
Sponsor: Centers for Disease Control  
Total Direct Costs: \$ 1,748,272  
Principal Investigator: **C. Hendrix**  
Role: Design and execution of clinical studies to develop methods for the assessment of distribution and clearance of candidate microbicides.  
Effort: 10%

Dates: 10/01/01- 9/30/03  
Title: Prevention of Adenoviral Infection in Basic Military Trainees  
Grant Number: DAMD17-02-1-0213  
Sponsor: US Army Medical Research and Materiel Command  
Total Direct Costs: \$243,452  
Principal Investigator: **C. Hendrix**  
Role: Design, execution, and analysis of In vitro and clinical evaluation of nucleoside analogues to prevent adenoviral infection in military trainees.  
Effort: 10%

Dates: 07/01/01 – 06/30/02  
Title: The Ecological Impact of Antifungal Prophylaxis in the ICU.  
Grant Number: M01 RR00052  
Sponsor: NIH  
Total Direct Costs: GCRC Clinical Trial Support  
Principal Investigator: **C. Hendrix**  
Role: PI, epidemiology of SICU Candida following fluconazole prophylaxis.  
Effort: 1%

Dates: 02/01/01-01/01/02.  
Title: Antiretroviral pharmacodynamics in the male genital tract. (Developmental Pilot Project) Hopkins Center for AIDS Research  
Grant Number: P30 AI042855 (Bartlett, PI)  
Sponsor: NIH (Hopkins Center for AIDS Research [CFAR])  
Total Direct Costs: \$ 55,000.  
Principal Investigator: **C. Hendrix** (Project)  
Role: Design, execution, and analysis of clinical studies to localize drugs within the male genital tract.  
Effort: 10%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 09/01/00-06/30/05  
 Title: Pharmacology of Antiretroviral Drugs in the Genital Tract to prevent HIV Transmission.  
 Total Direct Costs: \$ 533,040.  
 Grant Number: K24 AI 01825  
 Sponsor: NIH  
 Principal Investigator: **C. Hendrix**  
 Role: Midcareer Investigator Award for Patient-Oriented Research is to support academic career development and mentoring of fellows  
 Effort: 50%

Dates: 09/29/00 – 02/28/04  
 Title: HIV-HCV Coinfection: Antiviral therapy and fibrosis.  
 Grant Number: R01 DA13806-01  
 Sponsor: NIH  
 Total Direct Costs: \$ 1,696,615  
 Principal Investigator: D. Thomas  
 Role: Pharmacokinetic/pharmacodynamic study of HIV/HCV treatment.  
 Effort: 10%

Dates: 10/01/99 – 09/30/02  
 Title: Tuberculosis Treatment Consortium Grant.  
 Sponsor: CDC  
 Principal Investigator: R. Chaisson  
 Role: Site investigator; development of clinical protocols for pharmacokinetic studies of anti-TB drugs.  
 Effort: 10%

Dates: 06/1/99 – 08/31/04  
 Title: Graduate Training Program in Clinical Investigation.  
 Grant Number: T32 HL04141  
 Sponsor: NIH  
 Principal Investigator: F. Adkinson  
 Role: Course director, lecturer “Principles of Drug Development”; Research Committee.  
 Effort: 3%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 03/01/99 - 02/28/06  
 Title: Pharmacology Core Laboratory, HIV Prevention Treatment Network (HPTN)  
 Grant Number: U01AI46745-05  
 Sponsor: NIH  
 Total Direct Costs: \$ 627,980  
 Principal Investigator: **C. Hendrix** (B. Jackson, HPTN Laboratory, PI)  
 Role: Pharmacologist for HPTN drug studies. Develop of novel methods to assess pharmacology of drugs in the male genital tract.  
 Effort: 10%

Dates: 02/01/99-01/31/02  
 Title: Effect of AMD-3100 on HIV positive Patients.  
 Grant Number: M01 RR000052; AMD3100-2001  
 Sponsor: NIH; AnorMED  
 Total Direct Costs: \$ 207,659  
 Principal Investigator: **C. Hendrix**  
 Role: PI, design and analysis for 6-site phase II PK-PD study of novel antiretroviral chemokine receptor blocker.  
 Effort: 10%

Dates: 02/01/99 - 01/31/00  
 Title: The Effect of Accutane on the Pharmacokinetics and Pharmacodynamics of Oral Contraceptive Tablets in Healthy Pre-menopausal Women with Severe Recalcitrant Nodular Acne.  
 Grant Number: M01 RR000052; NR15888/M01508  
 Sponsor: NIH; Roche  
 Total Direct Costs: \$ 328,832  
 Principal Investigator: **C. Hendrix**  
 Role: Principal investigator of investigator-initiated single site pharmacokinetic-pharmacodynamic drug interaction study; developed protocol collaboratively with sponsor; responsible execution, analysis.  
 Effort: 10%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 02/01/99-01/31/00  
Title: Methadone in combination with amprenavir in opiate abusers.  
Grant Number: M01 RR000052; COL30330  
Sponsor: NIH; Glaxo  
Total Direct Costs: \$ 252,561  
Principal Investigator: **C. Hendrix**  
Role: Protocol design, single site principal investigator, and data analysis for investigator-initiated drug interaction study with pharmacokinetic and pharmacodynamic endpoints.  
Effort: 10%

Dates: 09/01/98-08/31/99  
Title: Phase I/II study of the pharmacokinetic of efavirenz when added to a ritonavir-saquinavir-containing an antiretroviral regimen in HIV.  
Grant Number: NIH M01 RR000052; DMP 266-046  
Sponsor: NIH; DuPont-Merck  
Total Direct Costs: \$ 284,618  
Principal Investigator: **C. Hendrix**  
Role: Principal investigator, protocol design, execution, and data analysis of investigator-initiated single site of antiretroviral drug interactions.  
Effort: 10%

Dates: 09/01/98-07/01/99  
Title: Safety, pharmacokinetics, and tolerability of intravenously administered AMD 3100 in normal healthy volunteers.  
Grant Number: M01 RR000052; 98-01  
Sponsor: NIH; AnorMED  
Total Direct Costs: \$ 72,644  
Principal Investigator: **C. Hendrix**  
Role: Principal investigator responsible for study design, execution, and data analysis of first-in-human study of novel CXCR-4 receptor inhibitor.  
Effort: 10%

Dates: 07/01/98 – 06/30/99  
Title: Phosphorylation of Nucleoside Analogs: Treatment-Experienced  
Total Direct Costs: \$ 259,211  
Grant Number: M01 RR000052; Glaxo Contract  
Sponsor: NIH; Glaxo  
Principal Investigator: C. Flexner  
Role: Analysis for clinical study of antiretroviral intracellular phosphorylation.  
Effort: 5%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 06/01/98-12/31/98  
 Title: Safety of orally administered SP303 for the treatment of AIDS diarrhea.  
 Grant Number: M01 RR000052; 37,554-210  
 Sponsor: NIH; Shaman Pharmaceuticals  
 Total Direct Costs: \$ 173,995  
 Principal Investigator: **C. Hendrix**  
 Role: Site principal investigator of multi-center, industry-sponsored study of novel natural product to reduce AIDS-related diarrhea.  
 Effort: 1%

Dates: 01/01/98-06/30/99  
 Title: Fluconazole prophylaxis in the surgical intensive care unit.  
 Grant Number: Unrestricted Educational Grant  
 Sponsor: Pfizer  
 Total Direct Costs: \$ 825,104  
 Principal Investigator: **C. Hendrix**  
 Role: Principal investigator, clinical trial design, study management, execution, data analysis for phase III randomized clinical trial.  
 Effort: 35%

Dates: 01/01/98 – 02/28/99  
 Title: A Phase I/II Study of the Potential Interaction Between S-1153 and the Protease Inhibitors Nelfinavir and Indinavir in HIV-1 Infected Adults Treated with 3TC and ZDV or D4T.  
 Grant Number: M01 RR000052; AG1549-535  
 Sponsor: NIH; Agouron Pharmaceuticals  
 Total Direct Costs: \$ 186,127  
 Principal Investigator: **C. Hendrix**  
 Role: Protocol development and site principal investigator for 3 site dose escalation study of novel antiretroviral agent (capravirine).  
 Effort: 10%

Dates: 01/01/98-12/31/98  
 Title: A phase I trial to evaluate the intravitreal penetration of 1263W94 after multiple-dose oral administration in AIDS patients with CMV retinitis  
 Grant Number: M01 RR000052; CMAA1004  
 Sponsor: NIH; Glaxo  
 Total Direct Costs: \$ 56,651  
 Principal Investigator: **C. Hendrix**  
 Role: Protocol design assistance, site principal investigator, data analysis, intravitreal and blood pharmacokinetics of anti-CMV drug.  
 Effort: 10%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 01/01/98-02/28/98  
 Title: Utilization of PK/PD model to optimize 1263W94 dosing against CMV.  
 Grant Number: Contract  
 Sponsor: Glaxo  
 Total Direct Costs: \$ 33,714  
 Principal Investigator: F. Hamzeh  
 Role: Surrogates of blood contamination of sampling in vitrectomy.  
 Effort: 1%

Dates: 07/01/97-06/30/00  
 Title: Faculty Development Award  
 Sponsor: Pharmaceutical Research and Manufacturer's Association.  
 Total Direct Costs: \$ 120,000  
 Principal Investigator: **C. Hendrix**  
 Role: Leadership and management of reorganized Drug Development Unit to provide complete phase I study services as a core faculty resource.  
 Effort: 10%

Dates: 01/01/97-12/31/01  
 Title: International Military Prevention Research.  
 Grant Number: Contract  
 Sponsor: Department of Defense (through Henry M. Jackson Foundation)  
 Total Direct Costs: \$ 191,000  
 Principal Investigator: **C. Hendrix**  
 Role: HIV prevention program development and process research among foreign military leadership in coordination with the UNAIDS, UNDPKO, and the Civil-Military Alliance to Combat HIV/AIDS.  
 Effort: 35%

Dates: 01/01/97 - 12/31/00  
 Title: AIDS Clinical Trials Group Advanced Technology Laboratory, Pharmacology Research Resource Unit.  
 Grant Number: U01 AI27668-PP003  
 Sponsor: NIH  
 Total Direct Costs: \$ 66,964  
 Principal Investigator: C. Flexner  
 Role: Clinical trial design, execution, and data analysis for antiretroviral drug development studies, principal investigator for multi-center studies.  
 Effort: 10%

**FUNDING****Extramural Funding (current, pending, previous)***Previous*

Dates: 01/01/97-12/31/97  
 Title: Candida/VRE Surveillance in the Intensive Care Unit.  
 Grant Number: Unrestricted Educational Grant.  
 Sponsor: Pfizer  
 Total Direct Costs: \$ 100,000  
 Principal Investigator: **C. Hendrix**  
 Role: Principal Investigator, study management, data analysis of pilot study to develop sample size estimates for prophylactic interventions in the ICU  
 Effort: 10%

Dates: 01/01/97-12/31/97  
 Title: Pharmacokinetics and safety of lobucavir in subjects with hepatic impairment.  
 Grant Number: M01 RR000052  
 Sponsor: NIH; Bristol-Myers Squibb  
 Total Direct Costs: \$ 400,319  
 Principal Investigator: **C. Hendrix**  
 Role: Site principal investigator of multi-center pharmacokinetic study.  
 Effort: 10%

Dates: 01/01/97 - 12/31/97  
 Title: Phase I/II randomized double blind placebo controlled study of the safety, tolerance and pharmacokinetics and antiretroviral activity of PMPA Prodrug in HIV-infected patients.  
 Grant Number: NIH M01 RR000052; Gilead contract  
 Sponsor: NIH; Gilead Pharmaceuticals  
 Total Direct Costs: \$ 268,239  
 Principal Investigator: P. Barditch-Crovo  
 Role: Data analysis of single center antiretroviral pharmacokinetic study.  
 Effort: 1%

Dates: 01/01/97 - 10/30/97  
 Title: Clinical Pharmacology of generic and antiviral drugs.  
 Grant Number: Cooperative Agreement  
 Sponsor: FDA  
 Total Direct Costs: \$ 1,981,673  
 Principal Investigator: P. Lietman  
 Role: Data analysis of several investigator-initiated clinical studies of drug interactions and toxicity.  
 Effort: 10%

## **CLINICAL ACTIVITIES**

### **Certification**

#### ***Medical Licensure***

State of Maryland, issued 10/1/94, # D46682 (current)

Commonwealth of Pennsylvania, issued 12/2/92, MD 043514 L, (inactive 12/31/94)

#### ***Medical Boards or Other Specialty Certification***

National Board of Medical Examiners, Parts I-III, 6/85

American Board of Internal Medicine, 9/87

American Board of Internal Medicine, Infectious Diseases, 11/1990-11/2000, #116631

American Board of Clinical Pharmacology, 10/2016

#### ***Membership in or Examiner for Specialty Board***

2018-present Board of Directors, American Board of Clinical Pharmacology

**EDUCATIONAL ACTIVITIES****Teaching***Classroom Instruction*School of Medicine

Physician and Society (medical student curriculum)

“Scientific Misconduct” 2001

Medical Pharmacology (medical student curriculum)

*Lectures*

“Pharmacokinetics I: Introduction, Membranes, Bioavailability” 1995-present

“Pharmacokinetics II: Volume, Clearance, Half-life” 1995-present

“Pharmacokinetics III: Dosing Regimens” 1995-present

“Pharmacokinetics IV: Mixed Order Kinetics, Applications” 2000-present

“Pharmacokinetic Clinical Problem Solving I and II” eLectures 2015-present

“Introduction to Antibiotics” 1998-present

“Cell wall active antibiotics I: Penicillins” 1998-present

“Cell wall active antibiotics I: Cephalosporins, Vancomycin” 1998-present

“Ribosomal inhibiting antibiotics I: Aminoglycosides” 1998-present

“Ribosomal inhibiting antibiotics II: Others” 1998-present

“Antifungal Drugs” 2001

“Pharmacokinetics of anti-seizure drugs” 1995-1999

“Pharmacology of immunotherapeutics in neurology” 2000

“Aspirin and NSAIDs” 1998-2004, 2017

“Opiates” 1994-2004

“Quinolones” 2007

*Small group/tutorials*

Intersession Small Group Co-Leader (Clinical-Basic Science correlations) 2011-present

Pharmacokinetics problem-solving (2, 2-hour sessions) 1995-present

Infectious Diseases small group discussion (4, 2-hour sessions) 1994-2003

Pharmacology tutorial “Clinical Investigation” (5, 2-hour sessions) 1994-2012

Vaccine small group discussion (1, 2-hour session) 1997-2000

Metabolism small group 2012-2015

Pharmacology medical student journal club 2012-2015

Tutorial “My Favorite Drug (Drug Development)” 2016

Rational Therapeutics (created course; required 4th year medical student course)

“Practical Pharmacokinetics” 1995-2004

“Drug Interactions” 2004

“Rational Use of Antibiotics” 2005-2006

Pharmacology (Pharmacology Graduate Students):

“Pharmacokinetics I: Introduction, Membranes, Bioavailability” 2000-present

“Pharmacokinetics II: Volume, Clearance, Half-life” 2000-present

“Pharmacokinetics III: Mixed Order Kinetics” 2000-present

“Antibiotics” 2000-2006

“Aspirin and NSAIDs” 2000-2004

Pharmacology tutorial “Clinical Investigation” (5, 2-hour sessions) 2010-present

## EDUCATIONAL ACTIVITIES

### Teaching

#### *Classroom Instruction- continued*

Analytical Methods of Clinical Pharmacology (Fellowship 24-hour curriculum) 2000-present

“Principles of PK/PD in Drug Development”

“Curve Stripping”

“Non-Compartmental Analysis”

“Compartmental Analysis”

“Pharmacodynamic Studies”

“Pharmacodynamic Data Analysis”

“PK/PD Linkage Analysis”

“Population PK Analysis Overview”

“Clinical Trial Simulation Overview”

Laboratory Science of the Clinical Investigator – Short Course 2017-present

Course creator and co-director with S. Nimmagadda

Osler House Staff Noon Teaching Conference 2004 - 2012

“Practical Pharmacokinetics for the House Officer” 2004-2012

“Pharmacokinetics in Special Populations” 2004-2012

“Rational Therapeutics of COX-2 Selective and Non-selective NSAIDs” 2004-2010

“Making Drugs Safer” 2005-2012

“Aminoglycoside Dosing Strategies” 2007-2012

“Integrating HIV Prevention into an Internal Medicine Practice”, 2011-2012

#### School of Nursing

“Pharmacology of Immune Suppressive Drugs”, Graduate Student Curriculum, 1998-9

#### School of Public Health

Principles of Drug Development, (required GTPCI Course) 1994-2003

“Overview of the drug development process” 1999-2003

“Pharmacokinetics for Drug Development” 1999-2003

“Pharmacokinetic and Safety Studies” 1994-2003

“Pharmacokinetic and Safety Studies - practicum” 1999-2003

“Pharmacokinetic and Safety Studies – student project critique” 1999-2003

“Learning vs. Confirming Studies” 1999-2003

“Learning vs. Confirming Studies - practicum” 1999-2003

“Learning vs. Confirming Studies - student project critique” 1999-2003

“Clinical Trial Simulation” 2001-2003

## **EDUCATIONAL ACTIVITIES**

### **Teaching**

#### *Classroom Instruction - continued*

Analytical Methods in Clinical Investigation (required GTPCI Course),

“Databases: How to use and abuse them I: Principles” 1997-2002

“Databases: How to use and abuse them II: Applications” 1997-2002

Topics in Clinical Investigation (required GTPCI Course)

“Scientific Misconduct” 1995-present

Epidemiology and Natural History of Human Viral Infections

“Antiviral Therapy” 1997 - present

Epidemiology and Public Health Impact of HIV and AIDS

“Antiretroviral Therapy” 2004 - present

Graduate Summer Institute of Epidemiology and Biostatistics, Advanced Issues in HIV/AIDS Course, “HIV Chemoprevention Drug Development Issues”, 2005 – present

Advanced Topics on the Control and Prevention of HIV/ AIDS

“HIV Chemoprevention” 2006 - present

Epidemiology of Infectious Disease Journal Club, Faculty discussant, 2007

Doctoral Seminar in International Health, “Pharmacology in Public Health”, 2009-2011

#### *Clinical Instruction*

Clinical Skills (required 2nd year Course), Preceptor, 1997

Internal Medicine Inpatient Service, Teaching Attending, 1995-1996

#### *PerdanaUniversity Graduate School of Medicine (Kuala Lumpur, Malaysia)*

*Scientific Foundations of Medicine Course*

*Introduction to Pharmacology Section (2013-present)*

“Receptors and Enzymes”

“Drug Metabolism”

“Pharmacokinetics I-IV”

“Pharmacokinetic Case Studies – Problem Solving”

“Autonomic Pharmacology I-II”

“Drug Safety”

“Drug Development”

“Complementary and Alternative Medicine”

“Drug Resistance”

## **EDUCATIONAL ACTIVITIES**

### **Teaching**

#### ***Continuing Medical Education – Military***

US Air Force Annual HIV/AIDS Train-the-trainer Short Course 1991-1999  
Course Director, Instructor 1991-1999

International Military HIV/AIDS Education (in collaboration with UNAIDS)

Harare, Zimbabwe, Regional Training Seminar, 6 East and Southern African National Delegations, Speaker/Facilitator, 1995

Cha-Am, Thailand, Regional Training Seminar, 7 South and Southeast Asian National Delegations, Speaker/Facilitator, 1995

Kampala, Uganda, Regional Training Seminar, West African National Delegations, Presentation provided, 1996

Windhoek, Namibia, Regional Training Seminar, 14 East and Southern African National Delegations, Speaker/Facilitator, 1997

Hanoi, Republic of Vietnam, Country Site Visit Team, Speaker, Military Consultant, 1998

Moscow/Saint Petersburg, Russian Federation, Country Site Visit, Speaker, Military Consultant, 1998

“HIV Military Threat Assessment and Response.” Annual HIV Prevention Education Train-the-Trainer Course, San Antonio, Texas. May 1999.

#### ***Continuing Medical Education- Civilian***

“Clinical Pharmacology of Antiretroviral Drugs.” Curriculum Review Course, American Society of Clinical Pharmacology and Therapeutics, New Orleans, Louisiana. March 1998. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Clinical Pharmacology of Antiretroviral Drugs.” Curriculum Review Course, American Society of Clinical Pharmacology and Therapeutics, San Antonio, Texas. March 1999. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“New Antibacterial Drugs.” Pediatric Trends Course, Johns Hopkins University School of Medicine, Office of Continuing Medical Education. Baltimore, Maryland. April 1999. JHMI. Clinical faculty and post-doctoral trainees.

“New Antiviral Drugs”. Pediatric Trends Course. Johns Hopkins University School of Medicine, Office of Continuing Medical Education. Baltimore, Maryland. April 1999. JHMI. Clinical faculty and post-doctoral trainees.

**EDUCATIONAL ACTIVITIES****Teaching*****Continuing Medical Education – Civilian continued***

“COX-2 Inhibitors: New NSAIDs on the Block.” Conjoint Clinic, Johns Hopkins University School of Medicine, Office of Continuing Medical Education. Baltimore, Maryland. May 1999. JHMI. Clinical faculty and post-doctoral trainees.

“New Drugs for HIV Infection.” Clinical Care of the Patient with HIV Infection. Baltimore, Maryland. April 1999. JHMI. Clinical faculty and post-doctoral trainees.

“New Drugs for HIV.” The Johns Hopkins AIDS Service HIV Management Preceptorship Program, Baltimore, Maryland. April 1999. JHMI. Clinical faculty and post-doctoral trainees.

“Databases and Clinical Research: How to Use and Abuse Them.” Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Baltimore, Maryland. May 1999. JHMI. Clinical faculty and post-doctoral trainees.

“New Drugs for HIV Infection.” Clinical Care of the Patient with HIV Infection. Baltimore, Maryland. April 2000. JHMI. Clinical faculty and post-doctoral trainees.

“Databases and Clinical Research: How to Use and Abuse Them.” Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Baltimore, Maryland. May 2000. JHMI. Clinical faculty and post-doctoral trainees.

“NSAIDs and COX-2 Inhibitors: Current Status.” Conjoint Clinic, Johns Hopkins University School of Medicine, Office of Continuing Medical Education. Baltimore, Maryland. February 2001. JHMI/Regional. Clinical faculty and post-doctoral trainees.

“Databases and Clinical Research: How to Use and Abuse Them.” Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Baltimore, Maryland. April 2001. JHMI. Clinical faculty and post-doctoral trainees.

“Tools for Pre-Approval Drug Safety Evaluation”, Academics to CDER Series: Annual Continuing Medical Education Course May 2003. Regional. FDA Professional Staff Development.

“Aminoglycoside and Vancomycin Therapeutic Drug Monitoring.” Johns Hopkins Distance Learning (Bermuda Site), Office Of Continuing Medical Education, Baltimore, Maryland. May 2005. JHMI/Regional. Clinical faculty and post-doctoral trainees.

“Practical Pharmacokinetics for Primary Care.” Anne Arundel Community College, Physician Assistant Curriculum, Arnold, Maryland, 2005. Regional. Physician Assistant candidates.

## EDUCATIONAL ACTIVITIES

### Teaching

#### *Continuing Medical Education – Civilian continued*

“Relationships between Academia and the Pharmaceutical Industry.” American Medical Student Association (Johns Hopkins University Chapter), November 2006. JHMI. Medical Students.

“Development of Topical HIV Microbicides.” Division of Infectious Diseases, Fellows’ Conference, December 2006. JHMI. Clinical faculty and post-doctoral trainees.

“Clinical Pharmacology of Antiretroviral Drugs.” Curriculum Review Course, American Society of Clinical Pharmacology and Therapeutics, Anaheim, California. March 2007. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Pharmacodynamics of Antibiotics.” Division of Infectious Diseases, Fellows’ Conference, November 2007. JHMI. ID faculty and post-doctoral fellows.

“Pharmacological Principles of Antiretroviral Drugs” Curriculum Review Course. ASCPT, March 2009. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Pharmacological Principles of Antiretroviral Drugs” Curriculum Review Course. ASCPT, March 2013. International. Audience: Clinical Pharmacologists faculty and post-doctoral trainees.

“Pharmacogenomics: One Aspect of Precision Medicine in Primary Care” Curriculum Review Course. American Medical Forum. Washington, DC. November 2017. National. Audience: Internal Medicine & Primary Care Physicians.

“Pharmacogenomics: One Aspect of Precision Medicine in Primary Care” Curriculum Review Course. American Medical Forum. Washington, DC. June 2018. National. Audience: Internal Medicine & Primary Care Physicians.

“HIV Prevention with Drugs: Pre-Exposure Prophylaxis (PrEP) in Primary Care.” Curriculum Review Course. American Medical Forum. Washington, DC. June 2018. National. Audience: Internal Medicine & Primary Care Physicians.

“HIV Prevention with Drugs: Pre-Exposure Prophylaxis (PrEP) in Primary Care.” Curriculum Review Course. American Medical Forum. Washington, DC. November 2017. National. Audience: Internal Medicine & Primary Care Physicians.

## EDUCATIONAL ACTIVITIES

### Mentoring

#### *Principal Mentor*

Stephen P. Blatt, M.D., 1990-1991

Infectious Disease Fellow, Wilford Hall USAF Medical Center  
Current position: Private Practice, Dayton, OH (1994-present)

Janet M. J. Hammond, M.D., Ph.D., 1995-1998

Clinical Pharmacology Fellow; Graduate Training Program in Clinical Investigation,  
Johns Hopkins University School of Hygiene and Public Health  
Thesis "Emerging Pathogens in Intensive Care"; Sc.M. granted 5/25/99.  
Current Position: Vice President of Infectious Diseases Development, AbbVie, Lake  
Forest, IL.

Robert Pelz, M.D., 1997-2000

Infectious Diseases Fellow  
Graduate Training Program in Clinical Investigation, Ph.D. 2000  
Research: Epidemiology and treatment of ICU infections  
Awards: Infectious Diseases Society of America 1998 Fellows Award for Scientific  
Excellence. "Do surveillance cultures predict fungal infection in critically ill pts?"  
Society of Critical Care Medicine 2000 In-training Fellow Award. "A double blind  
placebo controlled trial of prophylactic fluconazole to prevent Candida  
infections in critically ill surgical patients"  
Society of Critical Care Medicine 2000 Educational Scholarship Award  
"Fluconazole blood concentrations after enteral administration in critically ill  
surgical patients exceed most Candida minimal inhibitory concentrations in a  
double-blind, placebo-controlled trial in which fluconazole prevented Candidal  
infections."  
Johns Hopkins University Helen B. Taussig Young Investigators Award.  
"Nosocomial Fungal Infections in the Critically Ill: Dx and Prevention."  
Current Position: Clinical Assistant Professor of Medicine, Oregon Health and Science  
University, School of Medicine, Portland, OR

Thomas Ndovi, M.D., 1999-2005

Clinical Pharmacology Fellow  
Graduate Training Program in Clinical Investigation, 1999-2005, Ph.D. 2005  
Fogarty International Fellow 1999-2001, 2003-2004  
Merck International Fellow in Clinical Pharmacology 2001-2003  
Research: Pharmacology of antiretroviral drugs in genital compartments  
Awards: Department of Medicine Research Retreat Clinical Fellow Poster Finalist 2005  
British Journal of Clinical Pharmacology Prize 2007  
Last Position: Assistant Professor of Medicine, University of Malawi; Director, Johns  
Hopkins-Malawi Clinical Research Unit, Blantyre, Malawi (Deceased 2007)

## EDUCATIONAL ACTIVITIES

### Mentoring

#### *Principal Mentor - continued*

Shelley Sylvester Magill, M.D., 2000-2007

Infectious Diseases Fellow/Assistant Professor

Graduate Training Program in Clinical Investigation, Ph.D. 2007

Awards: Pfizer Mycology Fellowship Award Recipient 2001-2003;

Clinical Scientist Award 2003 (Johns Hopkins University, declined)

Research: Ecology and prevention of fungal infections in the ICU

Position: Assistant Professor, Division of Infectious Diseases, Johns Hopkins University School of Medicine 2004 - 2007

Current Position: Medical Officer, Mycotic Diseases Branch, CDC, Atlanta, GA (2007-present)

Lewis Radonovich, M.D., 2000-2002

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, Ph.D. Candidate

PhRMA Fellowship in Pharmacology 2001-2002

Research: Chemoprophylaxis of adenoviral infections

Previous Position: Assistant Professor of Medicine, University of Florida, Gainesville FL (2002-2015)

Current Position: Centers for Disease Control, NIOSH, Pittsburgh, PA (2015-present)

Thanyawee Puthanakit, M.D., 2001-2002

International Fogarty Fellow; Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation; MHS degree 2002

Research: Pharmacokinetics of Antiretroviral Drugs, Drug interactions in the ICU

Assistant Professor, Chiang Mai University Medical Faculty, 2002-2005

Current Position: Associate Professor, Department of Pediatrics, Chulalongkorn University, Bangkok, Thailand; The HIV Netherlands Australia Thailand Research Collaborative.(2002-present)

Nimalie Stone, M.D., 2003-2004

Clinical Pharmacology Fellow

Research: Chemokine receptor inhibition phase I studies; Anti-infective drug utilization

Current Position: Medical Officer, CDC, Atlanta, Georgia

Wasif Khan, M.D., 2003-2005

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, M.H.S. 2005

Merck International Fellow in Clinical Pharmacology 2003-2005

Research: Pharmacology of antiretroviral drugs, microbicide distribution

Current Position: Research Physician, International Center for Diarrheal Disease Research, Dhaka, Bangladesh. (2005-present)

## EDUCATIONAL ACTIVITIES

### Mentoring

#### *Principal Mentor – continued*

Ying-Jun Cao, M.D., 2004-2007

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, Ph.D. 2007

Research in Progress: Development of methods to describe pharmacokinetics in the male genital tract; Quantitative methods to assess colon microbicide and HIV distribution

Awards: Department of Medicine Research Retreat Clinical Fellow Poster Finalist 2005;

American Society for Clinical Pharmacology and Therapeutics Young Investigator Award 2006-7;

Conference Retroviruses and Opportunistic Infections, Young Investigator Award 2007

British Journal of Clinical Pharmacology Prize 2012

Positions: Assistant Professor of Medicine, Division of Clinical Pharmacology, Johns Hopkins University School of Medicine. 2007-2008; 2008-present (Adjunct).

Director Science, Global Clinical Pharmacology & Exploratory Development, Astellas Pharmaceuticals, 2008-present.

Sridhar Nimmagadda, Ph.D., 2005-2008

Post-doctoral Fellow in Pharmacology and Radiology (Martin Pomper co-mentor)

Research: Quantitative luminal and tissue distribution of HIV and CD4 cells in the human vagina and colon following simulated receptive intercourse

Positions: Associate Professor of Radiology, Johns Hopkins University School of Medicine, 2009-present.

Kelly Brungardt Stein, MD, 2006-2007

Joint Clinical Pharmacology – Infectious Diseases Fellow

Graduate Training Program in Clinical Investigation, ScM 2009

Research: Protein binding of antiretrovirals in semen; vaginal distribution of HIV & CD4 cells.

Current Position: Instructor, Rush University Medical Center 2008-present

Nicolette Louissaint, PhD, 2006-2013

Pharmacology Training Program, Department of Pharmacology (2006 – 2010)

Ph.D. Candidate (PhD conferred May 2010), Post-doctoral fellow (May 2010-present)

Research in Progress: Quantitative luminal and tissue distribution of HIV and CD4 cells in the human vagina and colon following simulated receptive intercourse

Awards: Keystone Symposia Minority Scholarship, 2008

Department of Medicine Research Retreat Clinical Research Fellow Poster Finalist, 2009

American Society for Clinical Pharmacology and Therapeutics (ASCPT) Presidential Trainee Award 2010

ASPET Integrative Research in Pharmacology Awards 2012

AAAS Fellow – US Department of State 2013-2014

Current Position: Director of Healthcare Ready, AAAS Science and Technology Policy Fellow, Foreign Affairs Officer, US Department of State, 2014 - present

## EDUCATIONAL ACTIVITIES

### Mentoring

#### *Principal Mentor - continued*

Lindsay Brooke Avery, BS, 2008-2012

Pharmacology Training Program, Department of Pharmacology

Ph.D. Candidate; PhD conferred August 2012

Research: Efavirenz protein binding, compartmental distribution, and antiviral effect

Awards: American Society for Clinical Pharmacology and Therapeutics (ASCPT) Presidential Trainee Award 2010

Young Investigator Award. 20th Conference on Retroviruses and Opportunistic Infections 2013

Positions: Post-doctoral fellow, Namandje Bumpus Lab, Johns Hopkins University 2012-2014;

Current position: Pharmaceutical Development, Pfizer, Inc. Boston, MA, 2014-present

Liye Li, MD, PhD. 2009-2010

Clinical Pharmacology Fellow

Research: Development of candidate topical rectal microbicides.

Current Position: Nuclear Medicine private practice 2010 - present

Francisco Leyva, Md. PhD, 2009-2013

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, M.H.S. 2012

Research: Development of candidate topical rectal microbicides.

Current Position: National Institutes of Health, Division of Microbiology and Infectious Diseases

Yanhui Lu, BS, 2010-2014

Pharmacology Training Program, Department of Pharmacology

Ph.D. Candidate; PhD conferred March 2014

Research: Identification of Novel Phase I and Phase II Metabolites of Maraviroc

Awards:

Junghea Park Memorial Travel Award 2012

Scheinberg Travel Award for spring 2011

Graduate Student Travel Award, ASPET Annual Meeting 2012

2012 Chinese Government Award for Outstanding Self-financed Students Abroad (China Scholarship Council)

2014 Bae Gyo Jung Young Investigator Day Award. Johns Hopkins University

Current Position: Office of Clinical Pharmacology, FDA 2015-present

Jenell Fenell Coleman, MD, 2010 – 2014

Assistant Professor, Department of Obstetrics and Gynecology

Harold Amos Medical Faculty Development Award

Research: Contraceptive – Antiretroviral drug interactions

Current Position: Associate Professor, Obstetrics & Gynecology, Johns Hopkins University

## EDUCATIONAL ACTIVITIES

### Mentoring

#### *Principal Mentor - continued*

Salee Parichat, MD, M.P.H. 2011-2012

International Fogarty Fellow, Thailand; Epidemiology, Masters of Public Health 2012,  
Bloomberg School of Public Health,

Research: Pre-exposure Prophylaxis adherence measured by plasma drug levels in MTN-001:  
comparison between vaginal gel and oral tablets in two geographic regions.

Current Position: RIHES, Chiang Mai University, Thailand

Hiwot Hiruy, MD, 2011-2015

Joint Clinical Pharmacology – Pediatric Infectious Diseases Fellow

Graduate Training Program in Clinical Investigation, PhD 2015

Research: Gastrointestinal tract pharmacology of topical HIV microbicides

Current Position: Medical Officer, FDA 2015-present

Jenny Robinson, MD, 2012-2014

Clinical Pharmacology Fellow

Graduate Training Program in Clinical Investigation, PhD Candidate

Research in progress: Female Genital tract pharmacology of topical HIV microbicides

Current Position: Assistant Professor, Obstetrics & Gynecology, Johns Hopkins University  
2014-present

Ethel Weld, MD, 2013-2016

Joint Clinical Pharmacology –Infectious Diseases Fellow

Graduate Training Program in Clinical Investigation, PhD Candidate

Research in progress: Gastrointestinal tract pharmacology of topical HIV microbicides

Awards:

The Pearl M. Stetler Research Fund for Women Physicians Award 2015-2016

Research Scholars Junior Faculty Award (KL2) 2017-2018

Current Position: Assistant Professor, Department of Medicine (Clinical Pharmacology), Johns  
Hopkins University, 2016-present

Funding: KL2 NCTS Johns Hopkins ICTR

Jackson Mukonzo, PhD, 2014

Fulbright Faculty Scholar

Research in progress: Polymorphisms uniquely impacting HIV treatment in African populations

Current Position: Director (Acting), Department of Pharmacology & Therapeutics, Makerere  
University, College of Health Science, Kampala, Uganda

Eugenie Shieh, MD, 2014-2017

Joint Clinical Pharmacology–Gastroenterology Fellow

Graduate Training Program in Clinical Investigation, PhD Candidate

Research in progress: Gastrointestinal tract pharmacology of topical HIV microbicides

Private practice gastroenterology, CA 2017-present

## **EDUCATIONAL ACTIVITIES**

### **Mentoring**

#### ***Principal Mentor - continued***

Victoria Ojeda, 2015-present

Associate Professor, University of California, San Diego

HIV Prevention Trials Network Scholar

Research in Progress: Impact of staff-participant relationships on adherence in randomized controlled PrEP trials

Current Position: Associate Professor, University of California at San Diego, School of Public Health, San Diego, CA

Rachel Scott, MD, 2016-present

Assistant Professor, Georgetown University

Mid Atlantic CFAR Mentoring

Research in progress: ARV & PrEP PK in pregnancy and post-partum

Current Position: Assistant Professor of Medicine, Georgetown University, Washington, DC

Funding: K23 NIMH

Zachary Janik, 2016-present

Medical Student, Research Mentor

Research in Progress: Quantitative assessment of White Coat Adherence in HIV Pre-Exposure Prophylaxis.

Katherine Huether, 2017-2018

Medical Student, Drug Development Research Rotation

#### ***Secondary Sub-Specialty Mentoring***

Normalynn Garrett, PhD candidate, Nursing; Pharmacology mentoring, 1998-1999

Andre Agthe, Neonatal Fellow, GTPCI; Pharmacology mentor, 2000-2004

Amy Ginsberg, Infectious Diseases Fellow; Pharmacology mentor, 2002-2003

#### ***Advisor (when not Primary Mentor) – GTPCI - continued***

Rodney Willoughby, MD, Pediatrics Faculty, GTPCI; Pharmacology mentor, 1999-2004

Lawrence Lee, Clinical Pharmacology Fellow; Pharmacokinetics mentor, 2003-2004

Devi Chittineni, Clinical Pharmacology Fellow; Pharmacokinetics mentor, 2004 – 2006

Myaing Nyunt, Clinical Pharmacology Fellow, GTPCI; Pharmacokinetics mentor, 2005 - 2008

Current Position: Assistant Professor of Medicine, University of Maryland Medical Center

## EDUCATIONAL ACTIVITIES

### *Advisor (when not Primary Mentor) – GTPCI - continued*

Kelly Dooley, MD, Joint Clinical Pharmacology – Infectious Diseases Fellow, GTPCI;  
Pharmacokinetics Mentor, 2006 – 2010  
Current Position: Associate Professor of Medicine, Johns Hopkins University

Sofia Perea, Pharm.D., Ph.D., 2002-2004  
Oncology Post-Doctoral Fellow  
Graduate Training Program in Clinical Investigation, Ph.D. Candidate

Kai Zhang, M.D., 2003-2004  
Post-Doctoral Fellow  
Graduate Training Program in Clinical Investigation, Ph.D. Candidate

Victor Crentsil, M.D., 2005 – 2007  
Division of Geriatric Medicine  
Graduate Training Program in Clinical Investigation, M.H.S. Degree 2007  
Current Position: FDA Medical Officer

Romanee Chaiwarith, M.D. 2006 - 2007  
Post-Doctoral Fellow  
Graduate Training Program in Clinical Investigation, M.H.S. Candidate  
Current Position: Assistant Professor, Medicine, Chiang Mai University

Tamorah Lewis, MD, Joint Clinical Pharmacology – Neonatology Fellow, GTPCI;  
Pharmacokinetics Mentor, 2010 – 2014, Fellowship Advisory Committee, 2010-2014  
Current Position: Assistant Professor, Pediatrics, Mercy Children's Hospital, Kansas City  
(2014-present)

Pranita Tamma, M.D. 2010-2011  
Post-Doctoral Fellow Pediatric Infectious Diseases  
Graduate Training Program in Clinical Investigation, M.H.S. Candidate  
Current Position: Assistant Professor, Pediatrics (Infectious Diseases), Johns Hopkins  
University (2011-present)

Berkley Limketkai MD 2011 – 2017  
Post-Doctoral Fellow Gastroenterology  
Graduate Training Program in Clinical Investigation, Ph.D. 2017  
Current Position: Assistant Professor, Medicine (Gastroenterology) Stanford University  
(2014-present)

Erica Shelton MD 2012 – 2014  
Instructor, Emergency Medicine  
Graduate Training Program in Clinical Investigation, Ph.D. Candidate

Craig W. Hendrix., MD

Curriculum Vitae

Current Position: Assistant Professor, Emergency Medicine, Johns Hopkins University  
(2014-present)

Omamah Alfarisi PharmD 2012 – present

Post-Doctoral Fellow Clinical Pharmacology

Graduate Training Program in Clinical Investigation, Ph.D. Candidate, pharmacokinetics  
mentor

Kattayoun Kordy MD, 2014-2016

Clinical Pharmacology UCLA, F32, Pharmacokinetics mentor

Current Position: Assistant Professor, Medicine (Gastroenterology) University of Southern  
California (2016-present)

**EDUCATIONAL ACTIVITIES*****Mentoring Committees***

Adriana Andrade, MD 2007-2018

Associate Professor of Medicine (Infectious Diseases)

Research in Progress: HIV Clinical Pharmacology, Drug interactions with complementary medicine products and antiretroviral drugs, Adherence to therapeutic regimens.

Myaing Nyunt, MD, PhD 2008-2013

Assistant Professor of International Health (School of Public Health)

Research in Progress: Clinical pharmacology of malaria therapeutics and prevention

Previous Position: Assistant Professor, Medicine, University of Maryland, Baltimore, MD (2014-2017)

Current Position: Assitant Professor, Medicine, Duke University, Durham, NC (2017-present)

**Mentoring*****Thesis/Oral Examination Committees***

Janet Hammond, “Emerging Pathogens in Intensive Care”, M.H.S. thesis, Graduate Training Program in Clinical Investigation, School of Hygiene and Public Health, Thesis advisor, Thesis Committee Member 1996-1999.

Normalynn Garrett, “Effects of LY235959 on surgery-induced immunosuppression and increased metastasis in rats”, Ph.D. thesis, School of Nursing, Thesis Committee Member, 1998-9.

Robert Pelz, “Prophylaxis of invasive fungal infections in the Surgical Intensive Care Unit: Efficacy, Pharmacology, and Cost Analysis”, Ph.D. thesis, Graduate Training Program in Clinical Investigation, School of Hygiene and Public Health, Thesis advisor, Thesis Committee Member, 1997-2001.

Rodney Willoughby, “Developmental Kinetics of Cytokines in Cerebral Palsy”, Ph.D. thesis, Graduate Training Program in Clinical Investigation, School of Hygiene and Public Health, Thesis Committee Member, 1999-2008.

Claudine Woo, “Subgroup analyses in clinical trials”, PhD thesis; Ph.D. 2006, Clinical Trials Program, Department of Epidemiology. School of Public Health, Preliminary Oral Examination Committee Member, 2001; Thesis Committee Member, 2003 - 2006.

Leena Choi, “Modeling biomedical data and the foundations of bioequivalence”, Ph.D. Thesis, Department of Biostatistics, School of Public Health, Preliminary Oral Examination Committee Chairman, 2001; Thesis Committee Chairman, 2005.

Elizabeth Lowe, “Phase I and Pharmacokinetic Study of Liposomal Doxorubicin (TLC D-99) in Pediatric Patients with Refractory Solid Tumors”, M.H.S. thesis, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Reader, 2002.

Melanie Rusch, “Were Sexual Risk Behaviors Changing in Injection Drug Users in the ALIVE Cohort Before HAART was Readily Available in this Population”, M.H.S. Candidate, Department of Epidemiology, School of Public Health, Thesis reader, 2002.

**EDUCATIONAL ACTIVITIES****Mentoring*****Thesis/Oral Examination Committees – continued***

Alex Agthe, “Clonidine and opiates in the treatment of neonatal abstinence syndrome”, Ph.D. candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee, 2002 Thesis Committee Member, 2007-2008.

Thomas Ndovi, “Compartmental Kinetics of Antiretroviral Drugs (ARVs) in the human Male Genital Tract”, PhD Thesis, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee Member, 2003; Thesis Committee Member, 2003-2005.

Michael Gibson, Ph.D. candidate, Department of Oncology, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2002-2007.

Ricardo Carvalho, “Unidirectional Transscleral Delivery from Episcleral Implants”, Sc.M. Thesis, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2003-2006, Thesis Reader 2006.

Shelley Sylvester Magill, PhD Candidate, Department of Medicine, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee Member 2004, Thesis Committee member, 2004-2007.

Courtney Silverthorn, Ph.D. Candidate, Department of Pharmacology, School of Medicine, Preliminary Oral Exam Committee Member, 2004.

Lawrence Soon-U Lee, “Antioxidant and phase 2 enzyme induction activity of ginseng in humans”, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Oral Examination Committee, 2005; Thesis Committee, 2007.

Moiria McMahon, Ph.D. Candidate, Department of Pharmacology, School of Medicine, Preliminary Oral Exam Committee Member, 2006.

Ying-Jun Cao, “Antiretroviral Drug Penetration into the Male Genital Tract,” PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Examination Committee Member, 2006; Thesis Defense Committee, 2007.

Lijuan Deng, “Spline Based Curve Fitting with Application to Kinetic Imaging M.S.” Candidate, Department of Biostatistics, Bloomberg School of Public Health, Thesis Reader 2006.

AeRang Kim, Ph.D. candidate, Department of Oncology, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2006-2009.

Michael Yu, Ph.D. candidate, Department of Oncology, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2006-2010.

Susanna Nazarian, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2008-2009.

**EDUCATIONAL ACTIVITIES****Mentoring*****Thesis/Oral Examination Committees – continued***

Jean Wang, “Predicting Cancer in Barrett's Esophagus”, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2008-2009.

Nicolette Louissaint, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2008-2010.

Benjamin Jilek, PhD candidate, Biochemistry, Cellular and Molecular Biology (BCMB) Graduate Program, School of Medicine, Thesis Committee Member, 2008-2011.

Jonathan Neiswinger, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Oral Examination Committee Member, 2009.

Ying-Chun Lo, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Oral Examination Committee Member, 2009.

Meng-Jung Chiang, PhD candidate, Pharmacology and Molecular Sciences, School of Medicine, Oral Examination Committee Member (Alternate), 2009.

Jeff Goldsmith, PhD candidate, Biostatistics, Bloomberg School of Public Health, Oral Examination Committee member. 2010. Thesis Committee member, 2011-2012.

Lindsay B. Avery, PhD Candidate. Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2011-2012.

Salee Parichat, MD, M.P.H. Candidate. Epidemiology, Bloomberg School of Public Health, Thesis Committee, 2011-2012.

Ryan Westergaard, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2012.

Melissa Zarr, PhD Candidate. Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2012 – 2014. Thesis Reader 2014.

Laura Ensign, PhD candidate, Chemical and Biomolecular Engineering, School of Engineering, Thesis Committee, 2012.

Tamara Lewis, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2012-2015.

Jenny Robinson, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2013-present.

Yanhui Lu, PhD Candidate, Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, Thesis Advisor, 2012-2014.

Berkeley Limetkai, PhD candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2013; Thesis Committee Member, 2013-2017.

**EDUCATIONAL ACTIVITIES****Mentoring***Thesis/Oral Examination Committees – continued*

Elaine To, PhD candidate, Department of Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee, 2013-2014.

Chen Yue, PhD candidate, Biostatistics, Bloomberg School of Public Health, Oral Examination Committee member. 2013. Thesis Committee member, 2013-2016.

Evelyn Eisele, PhD Candidate, Pharmacology and Molecular Sciences, School of Medicine, Thesis Committee Member, 2013-2016.

Katharina Maisel, PhD Candidate, Biomedical Engineering, School of Engineering, Thesis Committee Member, 2013-2014.

Kai Deng, PhD Candidate, Biochemistry, Cellular and Molecular Biology (BCMB) Graduate Program, Thesis Committee Member, 2013-2014.

Christopher Saeui, PhD candidate, Biomedical Engineering. Oral exam committee. 2014

Julie Lade, PhD Candidate, Pharmacology and Molecular Sciences. Thesis Committee. 2014-2016

Ethel Weld, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2015; Thesis Committee Member, 2015-present

Dominique Figueroa, PhD Candidate, Pharmacology and Molecular Sciences. Thesis Committee. 2015-2016

Clare Ruberman, PhD Candidate, Biostatistics. Oral Examination Committee, Member 2015. Thesis Committee Chair 2015-2018

Hugh Giovinazzo, PhD Candidate, Pharmacology and Molecular Sciences. Oral Examination Committee. 2015

Eugenie Shieh, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2016; Thesis Committee Member, 2015-present

Thuy Huang, PhD Candidate, Pharmacology and Molecular Sciences. Oral Examination Committee. 2015-present

Matthew Ippolito, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Preliminary Oral Exam Committee Member, 2016; Thesis Committee Member, 2017-present

Taarika Babu, PhD Candidate, Pharmacology and Molecular Sciences. Thesis Committee Member. 2017-present

Omamah Alfarisi, PhD Candidate, Graduate Training Program in Clinical Investigation, School of Public Health, Thesis Committee Member, 2018-present

## **EDUCATIONAL ACTIVITIES**

### **Mentoring**

#### *Thesis/Oral Examination Committees – continued*

Huilei Wang, PhD Candidate, Biomedical Engineering. Oral Exam Committee (Alternate) 2018.

Christy Pickering, PhD Candidate, Biomedical Engineering. Oral Exam Committee Chair 2018.

Inez Lam, PhD Candidate, Biomedical Engineering. Oral Exam Committee Chair 2018.

## **EDUCATIONAL ACTIVITIES**

### **Mentoring**

#### ***Training Grant Participation***

Grant #: 4T32GM066691

Title: Clinical Pharmacology Training Program

Principal Investigator: C. Hendrix (as of 2016 multi-PI with K. Dooley)

Date: 07/01/08-06/30/2023

Award: \$196,485 current year direct costs

Role: Mentor Clinical Pharmacology Fellows in clinical research; pharmacokinetics teaching

Grant #: 1UL1TR001079-01

Title: Institutional Clinical and Translational Science Award

Principal Investigator: D. Ford

Dates: 9/17/07 – 4/30/18

Award: \$\$7,485,218

Role: Mentor post-doctoral fellows in Graduate Training Program in Clinical Investigation

Grant #: 5T32GM08763-14

Title: Pharmacology Training Grant

Principal Investigator: J. Liu

Date: 07/01/00 – 06/30/20

Award: \$312,004

Role: Train graduate students in clinical pharmacology teaching and research.

Grant #: 2T32AI007291-21

Title: Research Training in Microbial Diseases

Principal Investigator: K. Gebo

Date: 08/01/01 – 08/31/16

Award: \$267,125 current year direct costs

Role: Mentor Infectious Diseases Fellows in clinical research

Grant #: 5R25DA021630

Title: Pediatric Training Grant: Immersion in Drug Abuse Research

Principal Investigator: E. Gauda

Dates: 07/01/07-04/30/13

Award: \$301,715

Role: Johns Hopkins/Morgan State University research training aspects of illicit drug use.

Grant #: 5D43TW00010

Title: Fogarty AIDS International Training & Research Program

Principal Investigator: C. Beyrer

Dates: 07/01/07-05/31/13

Award: \$695,000

Role: Mentoring of international post-doctoral clinical research fellows.

## **EDUCATIONAL ACTIVITIES**

### **Educational Program Building / Leadership / Administration**

#### ***School of Medicine***

Educational Policy and Curriculum Committee (EPCC), Student Assessment and Program Evaluation (SAPE) Subcommittee, member 2015-present

Medical Pharmacology (2<sup>nd</sup> year medical school)

Course Co-Director 1997-2001

Sectional Focus Group Leader (Introduction, Infectious Diseases, Rheumatology, Hepatology, Pain) 1997- 2003

Rational Therapeutics (4th year medical school, required course)

Initial Course Developer 1995

Course Director 1995-2004

Sessions jointly taught by experienced clinician and clinical pharmacologist to emphasize rational approach to therapeutic problems; focus on topics of keen interest to soon-to-be interns.

Analytical Methods in Clinical Pharmacology (Fellowship training curriculum, required course)

Initial Course Developer 2000

Course Director 2000-present

Cognitive and skill-based curriculum introduces quantitative aspects of clinical pharmacology in small-group problem-solving sessions.

Laboratory Science for the Clinical Investigator (Fellowship training curriculum, required course)

Initial Course developer 2017

Designed to provide an overview to clinical post-doctoral fellows and junior faculty planning clinical research studies that will rely on laboratory collaboration to support the clinical research. Curriculum covers a broad array of laboratory methods that describe quantitative laboratory methods, process of validation, quality control, and culture of laboratory-clinical interactions.

#### ***School of Public Health***

Principles of Drug Development, (required GTPCI Course)

Course Director 1999-2003

Curriculum oriented around small-group “pharmaceutical team” skill-building exercises supplemented by didactic sessions (course director, industry and FDA medical reviewers) to provide fundamentals of the drug development process. Final exam includes visiting senior leadership from FDA to hear fully developed drug development plans designed by student teams.

## **EDUCATIONAL ACTIVITIES**

### **Educational Program Building / Leadership - continued**

#### ***US Air Force***

US Air Force HIV Force wide Base Level Prevention & Education Program

Initial Program Development 1991

Course director 1991-1999

Lecturer/ Small Group leader 1991-1999

US Air Force wide HIV prevention program implemented based on identification and training of small multi-disciplinary base-level HIV prevention teams comprised of physician, nurse educator, public health officer and other health professionals who develop a local prevention plan tailored to meet local needs. Team building and training carried out initially and sustained over time at annual HIV/AIDS Train-the-trainer Short Course (24 hour CME units).

#### ***National***

“Principles and Practice of Drug Development”

Sanctioned by Institute of Medicine, concept developed at Institute of Medicine Forum

Sponsored by Stanford University, The Burroughs Wellcome Fund, and The Doris Duke Charitable Foundation

2006 - Curriculum development consultant

2006 - Lectures (delivered at Stanford University and internet broadcast to dozens of registered U.S. university campuses via the Stanford University Center for Professional Development)

“Role of pharmacokinetics-pharmacodynamics in drug development”

“Pharmacokinetics bridging process and practice in drug development”

“Pharmacokinetic-Pharmacodynamic models in drug development”

#### ***Food and Drug Administration***

“Academics to CDER” Annual CME Curriculum Development

Jointly developed curriculum between FDA Center for Drug Evaluation and Research Office of Training and Communication staff and Baltimore-Washington area academics

Target audience Baltimore-Washington Clinical Pharmacology Programs and FDA staff

2001-2004 Curriculum Development Committee

2003 “Tools for Pre-Approval Drug Safety Evaluation”, Course Director, Session Moderator, Lecturer

## **RESEARCH ACTIVITIES**

### **Research Program Building / Leadership**

Dates, name of research / basic science program, role

- 1989 – 1994 US Air Force/Henry M. Jackson Foundation HIV Research Program. Transitioned and substantially expanded existing observational database focused research program to integrated interventional clinical research organization collaborating in tri-service military medical consortium. Provided leadership and management of program during growth from initial staff of 4 to over 50 FTEs in clinical research program. Served initially as Research and Evaluation Unit Director (1989-1992), then Program Director (1992-1994).
- 1997 – Present Drug Development Unit (Division of Clinical Pharmacology) Reorganization. Reorganized existing clinical research unit, which focused on internal pharmaceutical industry-funded studies, to expand capacity to support investigator-initiated studies for faculty throughout the School of Medicine and refocused internal research portfolio to a primarily federally-funded clinical research enterprise. Served initially as Clinical Director (1997-1998), then overall Director (1998-Present).

## **ORGANIZATIONAL ACTIVITIES**

### **Institutional Administrative Appointments** (committees, dates)

#### *Johns Hopkins University School of Medicine Committees:*

Johns Hopkins Medicine Institutional Review Board (JHM IRB)

Member 2001- present

Co-Chairman IRB #2 – 2001 - 2007

Pharmacy & Therapeutics Liaison to JHM IRB 2001-present

Selection Committee, David S. Levine Award for Excellence in Mentoring, Department of Medicine, 2008

Department of Medicine, Appointment and Promotion Committee, 2009-present

Student Promotions Committee – Third and Fourth Years, 1996-2004

Student Promotions Committee – Second Year, 2000-2001

Joint Committee on Clinical Investigations, 1998-2001

Subcommittee (Pharmacy & Therapeutics Representative) 1998-2001

Graduate Training Program in Clinical Investigation,

Research Review Committee, 2/00-9/2006

Search Committee, Chief, Division of Infectious Diseases, Department of Medicine, 2004-2005

Search Committee, Clinical Pharmacology Faculty, Department of Medicine, 2004-2005

Search Committee, Pharmacology Faculty, Department of Pharmacology, 2004

#### *The Johns Hopkins Hospital Committees:*

Pharmacy and Therapeutics Committee, 1995-present

Joint Antibiotic Subcommittee, Chairman, 1998-2002

## **Editorial Activities**

### ***Journal Editorial Board***

Clinical Pharmacology and Therapeutics (2005 – 2008)

Clinical and Translational Science (2007 – 2015)

Pharmacology Research & Perspectives (2017-present)

## **ORGANIZATIONAL ACTIVITIES**

### ***Journal Peer Review Activities***

AIDS Research and Human Retroviruses (2006 – present)  
Antiviral Research (2001 – present)  
Clinical Drug Investigation (2006 – present)  
Clinical Infectious Diseases (2006 – present)  
Clinical Pharmacokinetics (2014-present)  
Clinical Pharmacology and Therapeutics (2002 – present)  
Clinical and Translational Science (2007 – present)  
Contraception (2006 – present)  
International Journal of STD & AIDS (2014-present)  
Journal of Acquired Immune Deficiency Syndromes (2003 – present)  
Journal of Antimicrobial Chemotherapy (2014-present)  
Journal of Clinical Pharmacology (2014-present)  
Journal of Infectious Diseases (2006 – present)  
Journal of Pharmacology and Experimental Therapeutics (2002 – present)  
Lancet HIV (2016 – present)  
Medicine (2009 – present)  
Neurology (2011 – present)  
PLOS One (2014 – present)

### **Advisory Committees, Review Groups/Study Sections** (sponsor, role, date)

Office of AIDS Research Advisory Committee, National Institutes of Health, *ex officio* member  
Department of Defense, 1995-1999

AIDS Clinical Trials Group IBT RAC, General Immune Modulation Subcommittee, National  
Institutes of Health, 1997-1998

General Clinical Research Centers, Division of Research Resources, National Institutes of Health;  
Study Section, Site Reviewer, 1998

Therapeutics Research Working Group, Office of AIDS Research Advisory Committee, National  
Institutes of Health, 1999-present

General Clinical Research Centers, Division of Research Resources, National Institutes of Health;  
Study Section, Site Reviewer, 2002

Institute of Medicine, Panel Member, Panel on “Institutional Review Boards: Health Services  
Research Data Privacy Protection”, 2000

U.S. Dept. of Agriculture, National Organic Standards Board, Technology Advisory Panel,  
Reviewer, 2002

## **ORGANIZATIONAL ACTIVITIES**

### **Advisory Committees, Review Groups (sponsor, role, date) – continued**

Centers for Disease Control and Prevention, Chairman, Special Grant Review Panel, PA “Clinical Evaluation and Testing of Vaginal Microbicide Candidates.” August 2003

National Institutes of Health, NIAID special review meeting PAR 03-138 entitled "Novel HIV Therapies: Integrated Preclinical/Clinical Program" March 2004

National Institutes of Health, NIGMS, Clinical Pharmacology Training Grant (T32), Special Emphasis Panel; Site Visit team. July 2004

National Institutes of Health, NIAID Special Emphasis Panel RFA-AI 04-047 "Partnership for Topical Microbicides" Review Committee, April 2005

National Institutes of Health, NIGMS, Clinical Pharmacology Training Grant (T32), Special Emphasis Panel. June 2005

Centers for Disease Control and Prevention (CDC), Board of Scientific Counselors, National Center for Infectious Diseases, March 2005 – 2007

Medical Research Council of Ireland, Clinical Research Infrastructure Grant Reviewer, 2006

American Foundation for AIDS Research (amfAR), Rectal HIV Transmission Targeted RFP, Scientific Reviewer, August 2006

SyNCH Trial (Single and Multiple Dose Escalation Phase I Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Orally Administered Silymarin (Legalon®) in Non-Cirrhotic Subjects with Chronic Hepatitis C or Non-Alcoholic Fatty Liver Disease), Safety Monitor, 2006

Food and Drug Administration (FDA),  
Antiviral Drugs Advisory Committee, 2007 – 2010  
Oncology Drugs Advisory Committee 2017

National Institutes of Health, NIAID Special Emphasis Panel RFA-AI-07-019 "Novel HIV Therapies: Integrated Preclinical/Clinical Program (U19)" Review Committee, October 2007

Population Council Microbicides Scientific Advisory Board, 2009 – present

National Institutes of Health, NIGMS, Clinical Pharmacology Training Grant (T32), Special Emphasis Panel; Study Section, Site Visit team. July 2014, July 2015

PREVENT U19 Program Project Grant, University of Louisville, KY, Scientific Advisory Board (2017-present)

UNC Chapel Hill Center for AIDS Research Scientific Advisory Board (2016-present)

## **ORGANIZATIONAL ACTIVITIES**

### **Professional Societies (membership, committees, dates, role)**

Alpha Omega Alpha Honor Medical Society 1983-present

Infectious Diseases Society of America 1989-1998

Civil-Military Alliance to Combat HIV/AIDS, 1996-2002; Steering Committee, 1999-2002

Armed Forces Infectious Diseases Society, 1997-1999

International Society of Antiviral Research  
Scientific Program Committee Reviewer 2001

International AIDS Society 1997 - present  
Industry Liaison Forum 2005

American Society for Clinical Pharmacology and Therapeutics (ASCPT) 1997 – present  
Board of Directors, 2010 – 2012  
Coordinating Committee on Scientific Sections, 2004-2010  
Chairman 2010-2012  
Vice Chairman 2008 – 2010  
Infectious Diseases and Antimicrobial Agents Section, 1997-present  
Chairman 2005 – 2008  
Vice Chairman 2004 – 2005  
Steering Committee 2018-present  
Scientific Program Committee, 1998-2002, 2005-2008  
ASCPT Nominating Committee, 2004-2005, 2014-2015  
Education Committee-1999-2002, 2015-present  
Social Media Task Force 2014-2015  
Mentor Task Force 2015-present  
Career Development Committee 2016-present  
Webinar Committee 2017

International Society of Pharmacometrics 2011 – 2015

American College of Clinical Pharmacology 2018-present

**ORGANIZATIONAL ACTIVITIES****Conference Organizer, Session Chair** (sponsor, date, role) - continued

Thirty-First International Congress of Military Medicine, “Medical Response to Chemical Warfare”, Beijing, People’s Republic of China, Symposium Co-Chair, December 1996.

Third Congress on AIDS in Asia and the Pacific, “Military AIDS Symposium”, Manila, Philippines, December 1997, Symposium Co-chair.

American Society for Clinical Pharmacology and Therapeutics, “Post-Marketing Surveillance”, San Antonio, Texas March 1999, Symposium Co-Chair.

American Society for Clinical Pharmacology and Therapeutics, “Novel Pharmacokinetic Methods for Developing HIV Chemoprevention Strategies”, Orlando, Florida March 2005, Workshop Organizer, Co-Chair.

American Society for Clinical Pharmacology and Therapeutics, “Pharmacokinetics and Clinical Applications”, Baltimore, Maryland, March 2006, Session Co-Chair.

Microbicides 2012, “Can we determine who uses? Self reports and objective measures of adherence in microbicide & PrEP trials”. Sydney. April 2012. Symposium committee.

American College of Clinical Pharmacology. “Symposium VII: Adherence: Missing Link in the Puzzle of Clinical Pharmacology”. Bethesda, MD. September 2013. Session Co-Chair.

HIV Research for Prevention (HIVR4P). “Long-acting Drug Release Systems for PrEP and Treatment.” Chicago, IL. October 2016. Session Co-Chair.

HIV Research for Prevention (HIVR4P). “Choosing ARVs for Prevention: Ensuring and Measuring Effective Tissue Delivery” Chicago, IL. October 2016. Session Co-Chair.

Conference on Retroviruses and Opportunistic Infections (CROI). “Of Mice, Monkeys, and Men: Prep from Preclinical to Population Level Impact”. Boston, MA. March 2018. Session Co-Chair.

## **RECOGNITION**

### **Awards, Honors**

Distinguished Military Graduate, Massachusetts Institute of Technology, AFROTC, 1978

Air Force Commendation Medal (USAF), 1980

Alpha Omega Alpha Honor Medical Society, 1983

Department of Medicine Award for Outstanding Academic Performance, Georgetown University, School of Medicine, 1984

Cahill Award for Academic Excellence in Surgery, Georgetown Univ., School of Medicine, 1984

*Magna cum Laude* Graduate, Georgetown University, School of Medicine, 1984

Meritorious Service Medal (USAF), 1994

Meritorious Service Medal, First Oak Leaf Cluster (USAF), 1997

Pharmaceutical Research and Manufacturers Association Faculty Development Award, 1997

Outstanding Pharmacology Professor (Basic Sciences), Medical Student Association, 2001-2002

Student Marshal, Medical School Graduation, Class of 2002

Johns Hopkins Alumni Association Excellence in Teaching Award, 2003

David M. Levine Faculty Mentoring Award (Department of Medicine) 2007

PhRMA Foundation Award in Excellence 2017

American College of Clinical Pharmacology, Distinguished Investigator Award 2018

**RECOGNITION****Invited Talks, Panels**

1. "A Risk-Benefit Perspective on Universal HIV Screening in the United States Air Force." 1991, Buenos Aires, Argentina. Invited Talk, 17th Meeting of the Committee on Medicine in the Air Forces in the Americas. Sponsor: Committee on Medicine in the Air Forces in the Americas.
2. "International Security Impact of the HIV/AIDS Epidemic". 1995. Kampala, Uganda. Invited Talk, Africa Regional AIDS Conference, Military AIDS Symposium. Sponsor: UNAIDS.
3. "HIV Prevention Policy in Military Organizations". December 1996. Beijing, People's Republic of China. Invited Talk, Thirty-First International Congress of Military Medicine, Beijing, China. Sponsor: Peoples Liberation Army, People's Republic of China.
4. "Planning Effective HIV Prevention Interventions in the Military". October 1998. St. Petersburg, Russian Federation. Invited Talk, Kirov Military Medical Academy. Sponsor: Russian Federation Ministry of Defense.
5. "Drug Interaction Research Issues in Heavily Treated HIV-infected Patients". May 1999. Toronto, Canada. Invited Talk, International AIDS Society – Industrial Liaison Forum: The Challenge of Clinical Trial Design in Evaluating HIV Antiretroviral Use in Heavily-Pre-Treated Patients (Conference). Sponsor: International AIDS Society.
6. "Pharmacology of Antiretroviral Drugs in the Genital Tract". August 1999. Atlanta, Georgia. Invited Talk, National HIV Prevention Conference. Sponsor: CDC.
7. "COX-2 Inhibitors: Evaluation of New NSAIDs". September 1999. Towson, Maryland. Invited Talk, Arthritis Foundation of Maryland (Sponsor).
8. "Potential Drug Interactions in Antiviral Therapy". May 2000. Madrid, Spain. Invited Talk, European Congress on Chemotherapy-3 (Sponsor).
9. "Clinical Pharmacology of Rectal Microbicides". Atlanta, February 2001. Invited Talk, Centers for Disease Control (CDC) Conference on Rectal Microbicides, Sponsor: CDC.
10. "Preventing Fungal Infections". May 2001. Baltimore. Medical Grand Rounds, Johns Hopkins University School of Medicine. Sponsor: Department of Medicine.
11. "Pharmacologic Studies in the Development of Rectal Microbicides", June 2001. Baltimore. Invited Talk, Rectal Microbicide Workshop. Sponsor: NIH Office of AIDS Research.
12. "Development of Beta-Cyclodextrin as a Topical HIV Microbicide Candidate", August 2001. Rockville. Invited Talk, NIH Division of Antiviral Drug Products. Sponsor: FDA.
13. "Drug Interactions in Combined Hepatitis C-HIV Chemotherapy", April 2002. Aspen. Strategies for the Management of HIV/HCV Coinfection. Sponsor: Perspectives in Medicine.

**RECOGNITION****Invited Talks, Panels – continued**

14. “Quantitative Safety Assessment in Microbicide Development”, May 2002. Antwerp, Belgium. Invited Talk, Microbicides 2002. (Cancelled)
15. “Distribution of Candidate Microbicide Gel and Simulated Ejaculate in the Lower Gastrointestinal Tract”, June 2003. Los Angeles. Invited Talk, UCLA Center for HIV and Digestive Diseases (Sponsor).
16. “Clinical Development of a CXCR4 Chemokine Inhibitor”, June 2003. New York City. Invited Talk, Entry Inhibitor Special Issue Advisory Board. Sponsor: Glaxo-Smith-Kline.
17. "Rational Development of Rectal Microbicides: Pharmacology, Toxicity, and Acceptability", July 2003. Atlanta. Invited Talk, National HIV Prevention Conference. Sponsor: CDC.
18. “Development of a CXCR4 Chemokine Receptor Inhibitor for HIV Infection”, December 2003. Towson. Invited Talk, Towson University. Sponsor: Towson University.
19. “Distribution of Rectal Microbicide Vehicle and Simulated Ejaculate following Simulated Coital Activity” January 2004. New York City. Invited Talk, Columbia University. Sponsor: Columbia University, School of Medicine.
20. “Delivery of Microbicide to “At Risk” Intestinal Mucosa” March 2004. London. Invited Talk, Challenges to Rectal Microbicide Development (Satellite): Microbicides 2004.
21. “Critical Pharmacologic Issues in Vaginal and Rectal Microbicide Development” October 2004. Providence. Visiting Professor. Sponsor: Tufts University - Brown University Center for AIDS Research.
22. “Pharmacologic Issues in HIV Chemoprevention.” February 2005. Boston. Invited Talk, International AIDS Society - Industry Liaison Forum, 12<sup>th</sup> National Conference on Retroviruses and Opportunistic Infections. Sponsor: International AIDS Society.
23. “Clinical Pharmacokinetics and Pharmacodynamics of Chemokine Inhibitors.” February 2005. Boston. Invited Talk, 12th National Conference on Retroviruses and Opportunistic Infections. Sponsor: International AIDS Society.
24. “Adaptations of Radiologic Methods With Coital Simulations To Assess The Pharmacokinetics Of Topical Microbicides In The Vagina And Rectum”, March 2005. Orlando. Invited Talk, Workshop on “Novel Pharmacokinetic Methods for Developing HIV Chemoprevention Strategies” Sponsor: American Society for Clinical Pharmacology and Therapeutics.
25. "Microbicides for HIV Prevention: Development Challenges for Clinical Pharmacology". April 2005. Quebec City. Invited Talk, 6th International Workshop on Clinical Pharmacology of HIV Therapy (Sponsor).

**RECOGNITION****Invited Talks, Panels – continued**

26. “Pharmacological Aspects of Microbicide Development”. July 2005. Rio de Janeiro. Invited Talk, Challenges in HIV Microbicide Development. UCLA AIDS Institute and Brazilian STD/AIDS Program (Satellite Meeting): 3rd International AIDS Society Conference on HIV Pathogenesis and Treatment. Sponsor: International AIDS Society
27. “Clinical Pharmacology Challenges in Topical HIV Microbicide Development”. September 2005. Buffalo. Visiting Professor. University of Buffalo School of Pharmacy and Pharmaceutical Sciences and School of Medicine/VA Medical Center.
28. “Making Drugs Safer” November 2005. Baltimore. Invited Talk, A Woman’s Journey. Sponsor: Johns Hopkins University.
29. “HIV Chemoprevention: Evolving Approaches to Prevent HIV Infection with Drugs” Baltimore, January 2006. Invited Talk, Department of Medicine Grand Rounds (Sponsor).
30. “Rectal Microbicide Development: Measuring Gel & Virus Distribution” Web-Cast Teleconference, March 2006. Invited Talk, International Rectal Microbicides Working Group
31. “Drug Distribution & Formulation Issues in Rectal Microbicide Development” Cape Town, April 2006. Invited Talk, Rectal Microbicide Satellite Meeting. Microbicides 2006. Sponsor: UCLA AIDS Institute.
32. “Role of pharmacokinetics-pharmacodynamics in drug development”; “Pharmacokinetics bridging process and practice in drug development”; “Pharmacokinetic-Pharmacodynamic models in drug development”. Palo Alto, National Webcast, April 2006. Invited talks, Principles and Practice of Drug Development Course. Sponsor: Stanford University and Institute of Medicine
33. “Rectal Microbicide Development: Contrasts to Traditional Drug and Vaginal Microbicide Development”, Washington, D.C., May 2006. Invited Talk, Department of Health Policy, School of Public Health, George Washington University (Sponsor)
34. “Rectal HIV Microbicide Pharmacology & Drug Development” Raleigh-Durham, June 2006. Visiting Professor, Duke University Pratt School of Engineering, Department of Biomedical Engineering (Sponsor).
35. “Debate: Why Microbicides Will Fail” Arlington, September 2006. Invited Talk, Biomedical Interventions for HIV Prevention Working Group Meeting. Sponsor: Forum for Collaborative HIV Research Workshop.
36. “Topical HIV Microbicide Development: Evolving Challenges”, Baltimore, November 2006. Invited Talk, Department of Pathology Grand Rounds (Sponsor).

**RECOGNITION****Invited Talks, Panels – continued**

37. "A Phase I, Dose-Rising Study of AMD11070 in HIV-Seronegative Men to Assess the Safety and Pharmacokinetics after Single or Multiple Doses," Baltimore, December 2006. Invited Talk, Plenary session, AIDS Clinical Trials Group. Sponsor: NIH.
38. "Reporting Scientific Misconduct – Deciding When and How to Act." Washington, D.C., December 2006. Invited Talk, Panel Member. Compliance and Investigator Fraud in Clinical Trials. Sponsor: CBI.
39. "Topical HIV Microbicide Development." Philadelphia. March 2007. Visiting Professor, Thomas Jefferson University, Division of Clinical Pharmacology (Sponsor).
40. "How Does Clinical Pharmacology Enhance HIV Microbicide Development?" Boston. April 2007. Visiting Professor, Tufts University, Division of Infectious Diseases (Sponsor).
41. "Pharmacology and Comparative Properties of NSAIDs." Miami, May 2007. Invited Talk, Panel member, Osteoarthritis and NSAIDs: Scientific Expert Panel Meeting. Sponsor: MDG
43. "HIV Microbicide Development from a Clinical Pharmacology Perspective." Seattle, July 2007. Invited Talk. Center for AIDS Research Pathogenesis Seminar Series, University of Washington.
44. "Clinical Study Design in Drug Development." Chicago, September 2007. Invited Talk. Science for Managers, Kellogg School of Management, Northwestern University.
45. "Distribution of Microbicide and HIV Surrogates in the Rectum and Distal Colon to Inform Rational Rectal Microbicide Development". Durban, South Africa., October 2007. Invited Talk. Nelson R. Mandela School of Medicine, University of KwaZulu-Natal, South Africa.
46. "Sparse Sampling Strategies in the Development of Vaginal Microbicide Candidates to Relationships Between Drug Exposure and Seroconversion Outcomes". Durban, South Africa, October 2007. Invited Talk: South Africa Medical Research Council, HIV/AIDS Lead Programme and HIV Prevention Research Unit.
47. "Pharmacokinetic Issues in ARV Microbicide Resistance". New Delhi, February 2008. Invited Talk, Microbicides 2008.
48. "Methods to Develop a Rectal-Specific Microbicide". New Delhi, February 2008. Invited Talk. Microbicides 2008.
49. "New Methods in Prevention of HIV Infection". Ames, March 2008. Invited Talk. Stupka Symposium, Iowa State University.

**RECOGNITION****Invited Talks, Panels – continued**

50. “Antiretroviral -based Microbicides Pharmacokinetics-Pharmacodynamics and Resistance”. Cape Town, September 2008. Invited Talk. International Partnership for Microbicides Annual Meeting.
51. “Unique Contributions of MTN-001 to Microbicide Development Methodology”. Cape Town, September 2008. Invited Talk. Microbicide Trial Network, Regional Investigator’s Meeting.
52. “Pharmacokinetics & Future Pharmacodynamic Links”. Cape Town, September 2008. Invited Talk. Microbicide Trial Network, Regional Investigator’s Meeting.
53. “Microbicide Development Pipeline: Candidates, Mechanisms, Formulations, Clinical Phase” Cape Town September 2008. International Partnership for Microbicides Annual Meeting.
54. “Clinical Study Design in Drug Development” Chicago, September 2007. Invited Talk. Science for Managers, Kellogg School of Management, Northwestern University.
55. “Academic Contributions to Translational Drug Development”. Shanghai, September 2008. International Clinical Research and Translational Medicine Symposium, Fudan University.
56. “Clinical Pharmacology Approach to HIV Chemoprevention Drug Development”. Rochester, MN, October 2008. Invited Talk. Mayo Clinic.
57. “PK-PD in HIV Chemoprevention Studies” Atlanta. December 2008. AIDS Vaccine Advocacy Coalition (AVAC) sponsored meeting on Intermittent PrEP Development.
58. “Three-dimensional Problems in Imaging Drugs for HIV Chemoprevention” Baltimore 2008. Department of Biostatistics Grand Rounds, Johns Hopkins University School of Public Health.
59. “Drug Concentrations as an adherence biomarker in HIV prevention” New York January 2009. Quick Clinical Trials Working Group meeting on measuring adherence in HIV prevention trials.
60. “HIV Prevention with Drugs: Using Clinical Pharmacology to Put "Rational “Back in Drug Development.” Baltimore March 2009. Department of Medicine, Grand Rounds.
61. “HIV Prevention with Topical Microbicides: Using Clinical Pharmacology to Put 'Rational' Back in Drug Development” Amsterdam April 2009. 10<sup>th</sup> HIV Clinical Pharmacology Workshop.
62. “Quantitative Pharmacokinetics of the Male Genital Tract and Applications in Drug Development”. Invited Lecture. Atlanta March 2010. 111<sup>th</sup> Annual meeting of the American Society for Clinical Pharmacology and Therapeutics.

**RECOGNITION****Invited Talks, Panels – continued**

63. “HIV Prevention with Drugs”. Invited plenary speaker. Hopkins-Brazil HIV Conference, Rio de Janeiro, April 2010.
64. “Pharmacology methods in prevention trials: assessing compartments and adherence”. Invited talk, Laboratory Plenary Session, HIV Prevention Trials Network Annual Meeting. Washington, DC. April 2010.
65. “Pharmacokinetic Assessment of Adherence”. Invited Talk. Microbicides 2010, May 2010, Pittsburgh.
66. “What Role Pharmacokinetics-Pharmacodynamics?” Invited Talk. Cape Town October 2010. Africa Regional Meeting of Microbicide Trial Network.
67. “Pharmacokinetics and Adherence in PrEP Development”. Invited Talk. San Francisco. November 12, 2011 Forum for Collaborative HIV Research: 5th PrEP Working Group.
68. “The Role of Clinical Pharmacology in the Development of Topical HIV Microbicides” Visiting Professor. Pittsburgh. January 2011. University of Pittsburgh.
69. “MTN-001 Phase 2 Adherence and Pharmacokinetic Study of Oral and Vaginal Preparations of Tenofovir.” Invited Talk. Microbicide Trial Network Annual Meeting. Arlington. March 2011.
70. “Use of Pharmacokinetics for Understanding Outcomes in HIV Prevention Trials” Invited Talk. Lab Plenary HIV Prevention Trials Network Annual Meeting, Washington, DC. June 2011.
71. Pharmacological assessment of medication adherence – Oral PrEP and Microbicides”. Invited Talk. 19<sup>th</sup> International Society for STD Research. Quebec City. July 2011.
72. “Pharmacokinetics and Tissue Concentrations of Tenofovir and Emtricitabine: What is Needed to Prevent Transmission?” Invited Talk. Plenary HIV Vaccine Trials Network Annual Meeting. Seattle. November 2011.
73. “Clinical Pharmacology in HIV Pre-Exposure Prophylaxis Drug Development: Developing and Applying Tools when the Train has left the Station.” Invited Talk. FDA Office of Translational Science. Silver Spring. January 2012.
74. “Attempts to Improve the Rational Development of HIV Pre-Exposure Prophylaxis through Clinical Pharmacology”. Invited Talk. Mercer University. School of Pharmacy. Atlanta. February 2012

**RECOGNITION****Invited Talks, Panels – continued**

75. “Clinical Pharmacology in PrEP Development: Can small intensive studies inform RCTs?” Invited Talk. Microbicide Trials Network Annual Meeting. Bethesda, February 2012.
76. “Exploring Outcome Variability Across HIV Pre-Exposure Prophylaxis (PrEP) Trials”, Anti-infective Section, ASCPT Annual Meeting. National Harbor, MD March 2012.
77. “Antiretroviral Pharmacology for PrEP: Enhancing RCT Understanding with Small Intensive Studies”, Treatment as Prevention/Pre-Exposure Prophylaxis Summit. London, June 2012.
78. “Making Sense of Oral PrEP trials: Little Studies Informing Big Studies”, Plenary Session, HPTN Annual Meeting. Washington, DC, June 2012.
79. “Oral & Topical PrEP: Unifying RCT Outcomes”, Invited Talk, 7th HIV Transmission Workshop, Washington, DC. June 2012.
80. “Pharmacokinetic Assessment of PrEP Adherence”, Invited talk, NIH DAIDS Behavioral Science Working Group Data Capture Technologies Focus Group, 11 October 2012.
81. “A Pharmacological Perspective on HIV Explant Challenge”, invited talk, Biopsy Challenge meeting, NIH-Bill and Melinda Gates Foundation, Washington, DC, 29 November 2012.
82. “Genital and Anal Tract PrEP Pharmacokinetics”, Office of AIDS Research Advisory Council Annual Meeting, Washington, DC, 8 November 2012.
83. “Measuring PK & Adherence in PrEP Trials: Explanation & Prediction”, invited talk, RIHES, Chiang Mai University, Chiang Mai, Thailand, 7 January 2013.
84. "Clinical Pharmacology Approach to Rational Rectal Microbicide Development", Invited talk, Thai Red Cross/HIV-NAT, Chulalongkorn Univ, Bangkok, Thailand, 10 January 2013.
85. “Measuring PK & Adherence in PrEP Trials: Explanation & Prediction”, Invited talk, Department of Medicine, University of Malaya, Kuala Lumpur, Malaysia, 15 January 2013.
86. “Pharmacological Approach to Monitoring Drug Adherence”, Plenary Lecture, Microbicide Trials Network Annual Meeting. Bethesda, MD. February 2013.
87. “Enriching the design of clinical PK/PD studies of novel drug delivery systems”, Invited Talk, Bill & Melinda Gates Foundation – NIH Think Tank on HIV Prevention Drug Delivery Systems. Washington, DC. February 2013.
88. “PK Assessment of Adherence in PrEP Trials” Pharmacometrics in Antiviral Drug Development Symposium, Annual Meeting of ASCPT, Indianapolis, 8 March 2013.

**RECOGNITION****Invited Talks, Panels – continued**

89. “Pharmacometric approaches to adherence assessment in HIV prevention trials.” Mercer University Invited talk. Atlanta, 5 March 2013.
90. “How PK (could) inform PrEP Trials”. Invited Talk, NIH, Division of AIDS Seminar, Bethesda, 15 March 2013.
91. “Pharmacological Aspects of PrEP”, Invited Talk, Hopkins-Brazil HIV conference, Rio de Janeiro, Brazil 19 April 2013.
92. “Pharmacological Challenges for Next Generation PrEP”, Invited Talk, 14th International Workshop on Clinical Pharmacology of HIV Therapy, Amsterdam, Netherlands, 23 APR 2013.
93. “Making sense out of oral and topical PrEP trials: Using little studies to understand big studies,” Invited Talk, Annual Meeting of HIV Prevention Trials Network, Washington, DC, 6 May 2013.
94. “Scientific Misconduct”. Invited Talk. FDA Office of Criminal Investigations. Charleston, SC, 18 June 2013.
95. “Exploring concentration-response in HIV Pre-Exposure Prophylaxis to optimize clinical care and trial design.” Cell-Lancet Conference “What will it take for an AIDS Free World”. San Francisco, 4 November 2013.
96. “HIV Pre-Exposure Prophylaxis: Clinical Pharmacology Insights”. Invited Talk, 21st Conference on Retroviruses and Opportunistic Infections, Boston, Mar 4, 2014.
97. “Adherence : Impact on Study Results” CONRAD/AVAC Adaptive Trial Designs Conference. Washington, DC. June 23, 2014.
98. “The Role of Pharmacokinetics in selecting PrEP strategies”. Invited Talk, 54<sup>th</sup> Interscience Conference on Antibiotics and Antimicrobial Therapy. Washington, D.C. September 9, 2014.
99. “HIV Pre-exposure Prophylaxis (PrEP) Trials: Making the Complex Simpler through Clinical Pharmacology”. Invited Talk, Medical Grand Rounds, Western Ontario University, London, Ontario, September 17, 2014.
100. “Combining Pharmacology and Behavioral Science to Develop a Rectal Microbicide for HIV PrEP that People will Enjoy Using”. Invited talk, Columbia University. Sponsor: Columbia University, School of Medicine. December 18, 2014.

**RECOGNITION****Invited Talks, Panels – continued**

101. “HIV Pre-Exposure Prophylaxis: Clinical Pharmacology Enriching Drug Development”. Invited Talk, Dartmouth University, Division of Clinical Pharmacology. Lebanon, NH 23 June 2015.
102. “Pharmacokinetics in Microbicide Development”. Invited Talk. NIH/DAIDS MTN Conference, “The Use of Mucosal Assays in Microbicide Trials” Arlington, VA 25-26 August 2015.
103. “Real-Time” Pharmacologically-based Adherence Testing”. Invited Talk. NIH/DAIDS Conference “Optimizing Adherence Post-VOICE”, Rockville, MD 2-3 September 2015.
104. “HIV Pre-Exposure Prophylaxis (PrEP) & Development of Microbicides”. Invited Talk. American College of Clinical Pharmacology Annual Meeting, “An Update on HIV Treatment, Prevention and Drug Development Symposium”, San Francisco, CA 28 September 2015.
105. “HIV Pre-Exposure Prophylaxis (PrEP) & Development of Microbicides”. Invited Talk. University of California at San Diego Center for AIDS Research, San Diego, CA 23 October 2015.
106. “HIV Pre-Exposure Prophylaxis Drug Development”. Invited Talk. Medical Grand Rounds, General Hospital, Tijuana, Mexico, 26 October 2015.
107. “Pharmacologic Adherence Assessment & Application in PrEP”. Invited Talk. 2015 Center for AIDS Research (CFAR) Social and Behavioral Sciences Research Network Conference, Baltimore, MD 29 October 2015.
108. “Developing Behaviorally-Congruent Rectal Microbicides: A Clinical Pharmacology Approach”. US-Japan Conference USAID, Bethesda, MD. 12 January 2016.
109. “Lessons Learned from Antiretroviral Testing”. Invited Talk . UCLA CFAR-Sponsored Substance Use Meeting: Advancing the Field of Biobehavioral Substance Use Measurement for HIV Positive and At-risk Populations. Los Angeles, CA. 1 February 2016.
110. “Development of HIV Pre-exposure Prophylaxis: A Clinical Pharmacologist’s Inside View”. Invited Talk. University of North Texas Health Science Center. Fort Worth, TX. 8 April 2016
111. “Building on Oral PrEP Success: Rectal Microbicide Development”. Invited Talk. DC Center for AIDS Research, Howard University, Washington, DC. 4 May 2016.
112. “HIV Pre-Exposure Prophylaxis Development: A Clinical Pharmacologist’s Inside View”. Invited Talk. KU Leuven, Leuven, Belgium. 17 May 2016.

**RECOGNITION****Invited Talks, Panels – continued**

113. “PK-PD Data to Advance Topical PrEP Products to Phase III”. Invited Talk. Clinical Trial Evaluation Workshop for MPTs. Initiative for Multipurpose Prevention Technologies (IMPT). Washington, DC. 13 September 2016.
114. “Rectal vs. Vaginal Compartment Pharmacology.” Invited talk. Contribution of Sexual Behaviour in the Global Heterosexual HIV Epidemic Workshop. NIH/DAIDS. Bethesda, MD. 15 September 2016.
115. “Pharmacologic Considerations for HIV Prevention Strategies”. Invited talk. Western New York HIV Prevention Network Meeting. University of Buffalo, Buffalo, NY. 19 September 2016
116. “HIV Pre-exposure Prophylaxis Development: A Clinical Pharmacologist’s Inside View”. Invited talk. Combating HIV/AIDS: Tx, PGx and PrEP Workshop, ACCP Annual Meeting. HIV symposium. San Diego, CA. 24 September 2016.
117. “Quantitative Assessment of Adherence: Experiences in HIV Prevention”. Invited Talk. National Institute of Drug Abuse, Baltimore, MD 20 December 2016.
118. “Rectal Microbicide Development & DREAM Progress”. Invited talk. Tenofovir Development Meeting, MTN Annual Meeting. Bethesda, MD. 20 March 2017.
119. “Developing Alternatives to Oral HIV PrEP: Rectal Microbicides & Long-Acting Formulations”. Invited Talk. University of Texas Health Science Center, Galveston. April 2017.
120. “For Something Completely Different: Development of a Rectal Enema as Microbicide”. Invited Talk. Oak Crest Institute of Science, Monroeville, CA May 2017.
121. “Rectal Microbicide Development: How Did We Get Here? What Have we Learned?” Invited webinar talk. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). August 2017.
122. “Rectal Microbicides: Where We’re Heading”. Invited webinar talk. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). August 2017.
123. “Impact of adherence on the development of HIV Pre-exposure Prophylaxis” Invited Symposium Talk (delivered Mark Sales), American College of Clinical Pharmacology Annual Meeting. San Diego, CA. September 2017.

**RECOGNITION****Invited Talks, Panels – continued**

124. “Advances in Formulations in HIV PrEP: Topical Products - Rings, Gels, Implants, etc.”  
Invited Symposium talk (delivered Marc Baum), American College of Clinical Pharmacology Annual Meeting. San Diego, CA. September 2017.
125. “Review of the Current Rectal Microbicide Context”. Invited Talk. Reboot the Booty Think Tank. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). New York, NY. September 2017.
126. “Lube Safety 101”. Symposium on Lubricant Safety, US Conference on AIDS. Washington, DC. September 2017.
127. “Next Generation PrEP? Injectable & Implantable ARVs”. Plenary Talk. Microbicide Trial Network Regional Meeting, Cape Town, RSA. September 2017.
128. “The Path Ahead for Rectal Microbicides”. Plenary Talk. Microbicide Trials Network Regional Meeting, Cape Town, RSA. September 2017.
129. “DREAM Program for Rectal Microbicide Prevention”. Invited talk. PREVENT Program Project Annual Meeting. Louisville, KY. October 2017.
130. “Promise & Progress of Rectal Microbicides for HIV Pre-Exposure Prophylaxis”. Invited Talk. Center for AIDS Research. University of Alabama, Birmingham, AL. November 2017.
131. “Microbicides: Where We’re Heading” Invited Talk. Second Annual Biomedical HIV Prevention Summit (NMAC). New Orleans, LA. December 2017
132. “Clinical Pharmacology of HIV Pre-Exposure Prophylaxis (PrEP) – Where are we now?”  
Visiting Professor. University of Liverpool. Liverpool, UK. February 2018.
133. “Beyond Oral PrEP: Promise and Challenges of Alternative Antiviral Dosing Methods for PrEP”. Invited Lecture. Office of AIDS Research Brown Bag Seminar. Brockville, MD. February 2018.
134. “Beyond Oral PrEP: Promise and Challenges of Alternative Antiviral Dosing Methods for PrEP” Invited Talk. 8th International Workshop on HIV & Women. Boston, MA. March 2018.
135. “Proof-of-Concept for On Demand, Behaviorally-Congruent Rectal Microbicide Douche”.  
Plenary Lecture. MTN Annual Meeting. Bethesda, MD March 2018.
136. “Success, Disappointment, & *Hope* in the Development of HIV Pre-Exposure Prophylaxis”.  
Invited Talk. Walter Reed Army Institute of Research, Silver Spring, MD. April 2018.

## **RECOGNITION**

### **Invited Talks, Panels – continued**

137. “Rectal Microbicide Product Development”. Invited talk. Oak Crest Institute of Science Program Project Annual Meeting. Monrovia, CA. May 2018.

138. “Pharmacology Lab Contributions to PrEP Product Development”. Invited Talk. HPTN Annual Meeting. Washington, DC. May 2018.

139. “Clinical Pharmacology of HIV Pre-Exposure Prophylaxis (PrEP) – Where are we now?” Invited Talk. International Workshop on Clinical Pharmacology of Antiviral Therapy. Baltimore, MD. May 2018.

140. “DREAM Program: On Demand, Behaviorally-Congruent Rectal Microbicide Douche”. Invited webinar talk. Sponsored by AIDS Vaccine Advocacy Coalition (AVAC) and International Rectal Microbicide Advocates (iRMA). June 2018.

# EXHIBIT G

**BY ORDER OF THE  
SECRETARY OF THE AIR FORCE**

**AIR FORCE INSTRUCTION 44-178**



**4 MARCH 2014**

Certified Current 28 June 2016

**Medical**

**HUMAN IMMUNODEFICIENCY VIRUS  
PROGRAM**

**COMPLIANCE WITH THIS PUBLICATION IS MANDATORY**

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(Brig Gen Charles E. Potter)

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This instruction implements AFPD 44-1, *Medical Operations*, and Department of Defense (DoD) Instruction 6485.01, *Human Immunodeficiency Virus*, June 7, 2013. It outlines the Air Force Human Immunodeficiency Virus (HIV) Program including responsibilities and procedures for identification, surveillance, and administration of Active Duty Air Force personnel. The Air National Guard (ANG) and Headquarters Air Force Reserve Command (HQ AFRC) utilize this instruction along with supplements to provide specific guidelines for the administration of Air Reserve Component (ARC) personnel infected with HIV. Headquarters Air Reserve Personnel Center (HQ ARPC) utilizes AFI 44-175 as guidance for Individual Mobilization Augmentees (IMAs), with local MTFs as the notifying agent. This instruction requires collecting and maintaining information protected by the Privacy Act of 1974. This is authorized by 10 U.S.C., Chapter 55, *Medical and Dental Care*, 10 U.S.C., Sec. 8013, *Power and Duties of the Secretary of the Air Force*, and Executive Order 9397 (SSN) as amended by Executive Order 13478, Amendments to Executive Order 9397 Relating to Federal Agency Use of Social Security Numbers, November 18, 2008. Systems Record Notices F044 AF SG E, *Electronic Medical Records System*, and R, *Reporting of Medical Conditions of Public Health and Military Significance*, apply. Ensure that all records created as a result of processes prescribed in this publication are maintained IAW Air Force Manual (AFMAN) 33-363, Management of Records, and disposed of IAW Air Force Records Information Management System (AFRIMS) Records Disposition Schedule (RDS).

Send comments and suggested improvements on AF Form 847, **Recommendation for Change of Publication**, through channels, to AFMSA/SG3PM. See **Attachment 1** for a glossary of

references, abbreviations, acronyms, and terms. This publication may be supplemented at any level, but all direct Supplements must be routed to the OPR of this publication for coordination prior to certification and approval. The authorities to waive wing/unit level requirements in this publication are identified with a Tier ("T-0, T-1, T-2, T-3") number following the compliance statement. See AFI 33-360, Publications and Forms Management, for a description of the authorities associated with the Tier numbers. Submit requests for waivers through the chain of command to the appropriate Tier waiver approval authority, or alternately, to the Publication OPR for non-tiered compliance items.

**SUMMARY OF CHANGES**

This document has been substantially revised and must be completely reviewed. Major changes include condensed sections describing the requirements for a positive HIV test and algorithms for determining HIV infection which reference current guidelines by the American Public Health Laboratories (APHL) and Centers for Disease Control (CDC). The location of the USAF HIV Medical Evaluation Unit was updated to San Antonio Military Medical Center (SAMMC) and the location of HIV laboratory testing was updated to the USAF School of Aerospace Medicine (USAFSAM) HIV Testing Services, Wright-Patterson Air Force Base. The clinical evaluation visit structure was modified, with HIV evaluations performed at SAMMC for initial visits, followed by a second visit in 6 months, then yearly thereafter while the patient remains on active duty (AD) status. Interim clinical visits will be performed as necessary in the local area based on recommendations from the USAF HIV Medical Evaluation Unit. The sections detailing the components of HIV clinical evaluations have been condensed with all elements of HIV clinical evaluations to be performed according to current clinical guidelines.

<b>Chapter 1—ROLES AND RESPONSIBILITIES</b>	<b>4</b>
1.1. HQ USAF/SG. ....	4
1.2. HQ AFRC/SG. ....	4
1.3. HQ ANG/SG. ....	4
1.4. HQ AFMC/SG. ....	4
1.5. HQ AETC/SG. ....	4
1.6. USAF HIV MEDICAL EVALUATION UNIT. ....	4
<b>Chapter 2—HIV PROGRAM</b>	<b>5</b>
2.1. General. ....	5
2.2. Populations Tested. ....	5
2.3. Initial Procedures for Positive Tests. ....	5
2.4. Clinical Evaluation, to Include Evaluation for Continued Military Service. ....	5
2.5. Limitations of Use of Information. ....	6
2.6. Public Health. ....	6

<b>AFI44-178 4 MARCH 2014</b>	<b>3</b>
2.7. USAFSAM. ....	6
2.8. AF Blood Centers. ....	6
2.9. Combat Zone Procedures. ....	7
2.10. Work Restrictions. ....	7
<b>Chapter 3—HIV TESTING MEASUREMENT</b>	<b>8</b>
3.1. HIV Testing Measurement. ....	8
<b>Chapter 4—FORMS</b>	<b>9</b>
4.1. Forms. ....	9
<b>Attachment 1—GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION</b>	<b>10</b>
<b>Attachment 2—PROCEDURES FOR SCREENING APPLICANTS</b>	<b>15</b>
<b>Attachment 3—AIR FORCE HIV TESTING PROCEDURES</b>	<b>17</b>
<b>Attachment 4—COMPLETION OF FORMS FOR REQUESTING HIV TESTING AND SPECIMEN TRANSMITTAL</b>	<b>22</b>
<b>Attachment 5—HIV TESTING AND INTERPRETATION OF RESULTS</b>	<b>29</b>
<b>Attachment 6—HIV TESTING OF DOD CIVILIAN EMPLOYEES</b>	<b>31</b>
<b>Attachment 7—GUIDELINES FOR ADMINISTERING THE ORDER TO FOLLOW PREVENTIVE MEDICINE REQUIREMENTS TO INDIVIDUALS INFECTED WITH HIV</b>	<b>33</b>
<b>Attachment 8—STANDARD CLINICAL PROTOCOL</b>	<b>34</b>
<b>Attachment 9—RETENTION AND SEPARATION</b>	<b>36</b>
<b>Attachment 10—LIMITATIONS ON THE USE OF INFORMATION FROM EPIDEMIOLOGICAL ASSESSMENTS</b>	<b>37</b>
<b>Attachment 11—PERSONNEL NOTIFICATION, MEDICAL EVALUATION, AND EPIDEMIOLOGICAL INVESTIGATION</b>	<b>39</b>
<b>Attachment 12—PROCEDURE FOR EVALUATING T-HELPER CELL COUNT</b>	<b>41</b>
<b>Attachment 13—ORDER TO FOLLOW PREVENTIVE MEDICINE REQUIREMENTS</b>	<b>43</b>

## Chapter 1

### ROLES AND RESPONSIBILITIES

**1.1. HQ USAF/SG.** Provides facilities, manpower, and funds to collect HIV testing specimens of Air Force (AF) personnel, to medically evaluate all HIV positive AD members including IMAs, and to ensure spouses and contacts of HIV infected AD members are notified, counseled, and tested appropriately.

**1.2. HQ AFRC/SG.** Ensures reserve personnel are HIV tested and spouses and contacts of HIV infected reserve personnel are notified appropriately.

**1.3. HQ ANG/SG.** Ensures ANG personnel are HIV tested and spouses and contacts of HIV infected ANG personnel are notified appropriately.

**1.4. HQ AFMC/SG.** Provides facilities, funds, and manpower to the USAFSAM HIV Testing Services to perform HIV testing and epidemiological analysis of all HIV tests performed on ADAF personnel and their dependents. Provides support to the DoD Serum Repository.

**1.5. HQ AETC/SG.** Provides facilities, funds, and manpower to medically evaluate all HIV positive ADAF members.

**1.6. USAF HIV MEDICAL EVALUATION UNIT.** Located in the Joint Infectious Disease Service at SAMMC, medically evaluates all ADAF HIV positive members initially, at 6 months, and then every 12 months thereafter while on active duty. (T-1)

## Chapter 2

### HIV PROGRAM

**2.1. General.** The AF tests all members for human immunodeficiency virus, medically evaluates all AD infected members, and educates members on means of prevention.

**2.2. Populations Tested.**

2.2.1. Accessions. All applicants for enlistment or appointment to the ADAF or ARC are screened for evidence of HIV infection (**Attachment 3**). Applicants infected with HIV are ineligible for enlistment or appointment to the ADAF and the ARC. Waiver for HIV infection is not authorized.

2.2.2. ADAF personnel. All ADAF personnel are screened for serological evidence of HIV infection every two years, preferably as part of their Preventive Health Assessment (PHA). They are also tested for clinically indicated reasons, when newly diagnosed with active tuberculosis, during pregnancy, when diagnosed with a sexually transmitted infection (STI), upon entry to drug or alcohol treatment programs, or prior to incarceration. HIV testing is conducted IAW **Attachment 3**. (T-1)

2.2.3. ARC personnel. Air Force Reserve personnel are screened for serological evidence of HIV infection every two years, preferably during their PHA (Preventive Health Assessment). ARC members will have a current HIV test within two years of the date on which they are called to active duty for 30 days or more. HIV testing is conducted IAW **Attachment 3**. (T-1)

2.2.4. DoD Civilians. DoD Civilian employees are tested for serological evidence of HIV to comply with host nation requirements for screening of DoD employees (**Attachment 6**) and after occupationally related exposures. (T-1)

**2.3. Initial Procedures for Positive Tests.** All ADAF personnel testing positive are counseled by a physician regarding the significance of a positive test. They are given information on modes of transmission, appropriate precautions to mitigate transmission, and prognosis. ADAF members are administered an order to follow preventive medicine requirements as described in **Attachment 7**. ARC members will also be administered this order. The preventive medicine requirements/order will not be delayed pending any administrative action. All eligible beneficiaries are offered counseling. Contacts of HIV-infected members are notified of potential exposure to HIV infection according to state or local law. (T-0)

**2.4. Clinical Evaluation, to Include Evaluation for Continued Military Service.** All ADAF members, as well as ARC members on extended active duty, who test positive for HIV are referred to SAMMC for medical evaluation. Per AFI 48-123 and AFI 41-210, HIV-positive personnel must undergo medical evaluation for the purpose of determining status for continued military service. ARC members who are not on extended active duty or who are not on full-time National Guard duty, and who show serologic evidence of HIV infection, will be referred for a medical evaluation of fitness for continued service in the same manner as service members with other chronic or progressive illnesses in accordance with DoDI 1332.38. In the case of an ANG member, it is only required if the state identifies a nonmobility, nondeployable position in which the member can be retained. All ADAF members will have an initial evaluation at SAMMC, followed by a visit at 6 months, then yearly thereafter while remaining on AD status. ARC and

ANG members whose condition is determined to meet Line of Duty requirements may have initial and/or annual HIV evaluations performed at regional military facilities. ARC and ANG members not meeting Line of Duty requirements will have an initial evaluation by a civilian HIV specialist. The medical evaluation follows the standard clinical protocol outlined in [Attachment 8](#) and utilizes procedures for evaluating T-helper cell counts described in [Attachment 12](#). ARC members not on extended active duty must obtain a medical evaluation that meets the requirements of [Attachment 8](#) from their civilian healthcare provider (in the case of the ANG, only if the state identifies a nonmobility, nondeployable position in which the member can be retained). An epidemiological assessment (including sexual contacts and history of blood transfusions or donations) is conducted to determine potential risk of HIV transmission (see [Attachment 11](#)). (T-1)

2.4.1. Outcome of Evaluation for Continued Military Service. HIV seropositivity alone is not grounds for medical separation or retirement for ADAF members. Members shall be retained or separated as outlined in [Attachment 9](#). (T-1)

2.4.2. Periodic Re-evaluation. HIV infected ADAF members retained on active duty and ARC members retained in the Selected Reserve must be medically evaluated annually at SAMMC. Such personnel must be assigned within the continental United States (CONUS). Alaska, Hawaii, and Puerto Rico are also acceptable. ARC HIV infected members may not be deployed outside of CONUS (except for Alaska, Hawaii, and Puerto Rico). HIV-infected members shall not be assigned to OCONUS mobility positions, and those on flying status must be placed on Duty Not Including Flying (DNIF) status pending medical evaluation/waiver determination. Waivers are considered using normal procedures established for chronic diseases. Aeromedical waivers are considered according to the Aerospace Medicine Waiver Guide. Members on the Personnel Reliability Program (PRP) or other security sensitive positions shall be evaluated for suspension or temporary decertification during medical evaluation, as determined by their Certifying Official/Unit Commander on the advice of a Competent Medical Authority. The Secretary of the Air Force may, on a case-by-case basis, further limit duties and assignment of members to protect the health and safety of the HIV-infected member or other members. Submit such requests to Office of the Secretary of the Air Force, Air Force Pentagon, Washington, DC 20330-1670. (T-1)

**2.5. Limitations of Use of Information.** Commanders and other personnel comply with limitations on the use of information obtained during the epidemiological assessment of HIV-infected members as outlined in [Attachment 10](#). (T-1)

**2.6. Public Health.** Provides HIV education to all ADAF members, offers education to other eligible beneficiaries, maintains a list of HIV positive personnel to be gained, reports to gaining bases departing HIV positive personnel, and educates HIV positive members and their dependents. (T-1)

**2.7. USAFSAM.** USAFSAM performs HIV testing (PHE) of submitted specimens and conducts epidemiological surveillance (PHR) of HIV infection in Air Force members and dependents. (T-1)

**2.8. AF Blood Centers.** AF Blood Centers follow policies of the Armed Services Blood Program Office, Food and Drug Administration (FDA), and the accreditation requirements of the American Association of Blood Banks (AABB). (T-0)

**2.9. Combat Zone Procedures.** Routine HIV testing is suspended in declared combat zones, defined as those areas where hostile pay is authorized.

**2.10. Work Restrictions.** Force-wide, HIV-infected employees are allowed to continue working as long as they are able to maintain acceptable performance and do not pose a safety or health threat to themselves or others in the workplace. If performance or safety problems arise, managers and supervisors address such problems using existing personnel policies and instructions. HIV-infected healthcare workers, however, should be relieved from patient care responsibilities until an expert review panel has met to advise the healthcare worker on work restrictions. Recommendations to the panel will be made by HIV treatment experts during the individual's initial HIV evaluation at SAMMC in accordance with the most recent guidelines from the Centers for Disease Control and Society for Health Care Epidemiology of America. The panel should be encouraged to contact SAMMC for advice (via telephone conference call) to ensure organizational consistency. (T-1)

### Chapter 3

#### HIV TESTING MEASUREMENT

**3.1. HIV Testing Measurement.** The AF's goal is to reduce the incidence of HIV infection in its personnel. USAFSAM tracks trends of HIV incidence in AF members. AF labs that do their own HIV testing must communicate test results and ship corresponding serum specimens to USAFSAM so they may ship samples to the DoD serum repository, and track trends. (T-1)

## Chapter 4

### FORMS

**4.1. Forms.** AF Form 1762, *HIV Log/Specimen Transmittal*, will be used for requesting HIV testing and specimen transmittal for those sites that do not have CHCS access (see [Attachment 4](#)). AF Form 3844, *HIV Testing Notification Form*, will be used to notify personnel of required HIV testing. AF Form 3845, *Preventive Medicine Counseling Record*, will be used to record counseling provided for HIV positive individuals. AF Form 74, *Communication Status Notice/Request*, is sent to MTF/CCs and Reserve Medical Unit (RMU)/CCs along with a copy of the patient's positive HIV testing screen and confirmation testing results. The MTF/CC and RMU/CC will document on AF Form 74 that the patient has been notified of the positive HIV results, then return the form to USAFSAM. Positive HIV results will not be finalized until USAFSAM/PHE receives the AF Form 74. (T-1)

THOMAS W. TRAVIS  
Lieutenant General, USAF, MC, CFS  
Surgeon General

## Attachment 1

## GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

*References.*

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AFI 48-123, *Medical Examination and Standards, GM1*, 31 January 2011

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*Adopted Forms.*

AF Form 1762, HIV Log/Specimen Transmittal  
AF Form 3844, HIV Testing Notification Form  
AF Form 3845, Preventive Medicine Counseling Record  
AF Form 74, Communication Status Notice/Request

*Abbreviations and Acronyms.*

**AABB**—American Association of Blood Banks  
**ADAF**—Active Duty Air Force  
**AETC**—Air Education and Training Command  
**AFMC**—Air Force Materiel Command  
**AFMOA**—Air Force Medical Operations Agency  
**AFMOA/SGOC**—Air Force Medical Operations Agency, Surgeon General’s Office of Consultants  
**AFPC**—Air Force Personnel Center  
**AFPC/DPANM**—Air Force Personnel Center/Medical Retention Standards Branch  
**AFPD**—Air Force Policy Directive  
**AFRC**—Air Force Reserve Command  
**AIDS**—Acquired Immunodeficiency Syndrome  
**ANGB**—Air National Guard Bureau  
**APHL**—American Public Health Laboratories  
**ARC**—Air Reserve Component (Air Force Reserve and Air National Guard)  
**ASD**—Assistant Secretary of Defense  
**CDC**—Centers for Disease Control and Prevention  
**CHCS**—Composite Healthcare System  
**CHN**—Community Health Nurse  
**CONUS**—Continental United States  
**COT**—Consecutive Overseas Tour  
**CPO**—Civilian Personnel Office  
**DAF**—Department of the Air Force  
**DBMS**—Director, Base Medical Services  
**DoD**—Department of Defense  
**DoDSR**—Department of Defense Serum Repository

**DNIF**—Duty Not Including Flying  
**DSN**—Defense Switched Network  
**FDA**—Food and Drug Administration  
**FM**—Flight Medicine  
**FM & P**—Force Management and Personnel  
**FMP**—Family Member Prefix  
**HBV**—Hepatitis B virus  
**HIV**—Human Immunodeficiency Virus (the virus that causes AIDS)  
**HQ AETC**—Headquarters Air Education and Training Command  
**HQ AFRC/SG**—Headquarters Air Force Reserve Command Surgeon  
**HQ ANG/SG**—Headquarters Air National Guard Command Surgeon  
**HQ USAF**—Headquarters US Air Force  
**ICD-9**—International Classification of Diseases, Revision 9  
**IMA**—Individual Mobilization Augmentee  
**I-RILO**—Initial Review in Lieu of Medical Board  
**MAJCOM**—Major Command  
**MEB**—Medical Evaluation Board  
**MTF/CC**—Medical Treatment Facility Commander  
**MPF**—Military Personnel Flight  
**MTF**—Medical Treatment Facility  
**NGB**—National Guard Bureau  
**OB**—Obstetrics  
**OI**—Opportunistic Infection  
**OS**—Overseas  
**OSHA**—Occupational Safety and Health Association  
**OTS**—Officer Training School  
**PCS**—Permanent Change of Station  
**PE**—Physical Examination  
**PES**—Physical Examination Section  
**PH**—Public Health  
**PQAM**—Program Quality Assurance Monitor  
**PRP**—Personnel Reliability Program

**ROTC**—Reserve Officer Training Corps

**SAF**—Secretary of the Air Force

**SAMMC**—San Antonio Military Medical Center

**SF**—Standard Form

**SG**—Surgeon General

**SHEA**—Society for Healthcare Epidemiology of America

**SSN**—Social Security Number

**STI**—Sexually Transmitted Infection

**TDY**—Temporary Duty

**USA**—United States Army

**USCG**—United States Coast Guard

**USMC**—United States Marine Corps

**USN**—United States Navy

**UCMJ**—Uniform Code of Military Justice

**USAFSAM**—United States Air Force School of Aerospace Medicine

**USUHS**—Uniformed Services University of the Health Sciences

*Terms.*

**Air Reserve Component**—Air Force Reserve and Air National Guard components of the Air Force

**Department of Defense Civilian Employees**—Current and prospective DoD US civilian employees. Does not include members of the family of DoD civilian employees, employees of, or applicants for, positions with contractors performing work for DoD, or their families.

**Enzyme Linked Immunosorbent Assay**—A screening test read as ‘reactive’ if the results are above a calculated cutoff.

**Epidemiological Assessment**—The process by which personal and confidential information on the possible modes of transmission of HIV are obtained from an HIV-infected person. This information is used to determine if previous, present, or future contacts of the infected individual are at risk for infection with HIV and to prevent further transmission of HIV.

**Host Nation**—A foreign nation to which DoD US civilian employees are assigned to perform their official duties.

**Human Immunodeficiency Virus**—The virus that causes AIDS.

**Positive**—A true positive test is an indicator of a condition being present

**Reactive**—Reacts with the reagent antibody test to produce a visible result

**Serologic Evidence of HIV Infection**—A reactive result given by a FDA approved serologic test for HIV detection, such as an enzyme-linked immunosorbent assay (ELISA) or

Chemiluminescent Immunoassay (ChLIA) that is confirmed in by additional testing in a validated testing algorithm, for example by a diagnostic HIV Western Blot immunoelectrophoresis. For Western Blot tests with indeterminate results, an alternative FDA approved test can be used to resolve indeterminates such as a viral load-based assay (APTIMA).

**Western Blot Test**—A qualitative assay for the detection and identification of antibodies of HIV-1 contained in human serum. It is intended for use with persons of unknown risk as an additional more specific test on human serum specimens found to be repeatedly reactive using a screening procedure such as ELISA.

## Attachment 2

### PROCEDURES FOR SCREENING APPLICANTS

**A2.1.** Screen applicants to the USAF or ARC for serologic evidence of HIV infection. Test and interpret results, using the procedures in **Attachment 3**. Counsel applicants on the significance of test results and the need to seek treatment from a civilian physician. (T-1)

**A2.2.** Screen applicants for enlisted service at the Military Entrance Processing Stations (MEPS) or the initial point of entry to military service. Applicants who enlist under a delayed enlistment program who exhibit serologic evidence of HIV infection before entry on active duty may be discharged due to erroneous enlistment. (T-1)

**A2.3.** Screen applicants accepted for the Air Force Academy as part of the processing for entry into the Academy and again as part of their medical screening prior to appointment as officers. Screen other officer candidates during their preappointment or precontracting physical examination. (T-1)

**A2.4.** Screen applicants for ARC during the normal entry physical examinations or in the preappointment programs established for officers. Those individuals with serologic evidence of HIV infection, who must meet accession medical fitness standards to enlist or be appointed, are not eligible for service with the ARC. (T-1)

**A2.5.** Take the following actions on officer applicants who are ineligible for appointment due to serologic evidence of HIV infection:

A2.5.1. Disenroll enlisted members who are candidates for appointment through Officer Training School (OTS) programs immediately from the program. If OTS is the individual's initial entry training, discharge the individual. If the sole basis for discharge is serologic evidence of HIV infection, issue an honorable or entry-level discharge, as appropriate. A candidate who has completed initial entry training during the current period of service before entry into candidate status shall be administered in accordance with Service directives for enlisted personnel. (T-1)

A2.5.2. Disenroll individuals in preappointment programs, such as Reserve Officer Training Corps (ROTC) and Health Professions Scholarship Program (HPSP) participants. The head of the Military Service concerned, or the designated representative, may delay disenrollment until the end of the academic term in which serologic evidence of HIV infection is confirmed. Disenrolled participants retain any financial support through the end of the academic term in which the disenrollment takes place. Financial assistance received in these programs is not subject to recoupment, if the sole basis for dis-enrollment is serologic evidence of HIV infection. (T-1)

A2.5.3. Separate Air Force Academy cadets and personnel attending the Uniformed Services University of the Health Sciences (USUHS) from the Academy or USUHS and discharge them. The superintendent of the Academy may delay separation to the end of the current academic year. A cadet granted such a delay in the final academic year, who is otherwise qualified, may graduate without commission and then is discharged. If the sole basis for discharge is serologic evidence of HIV infection, issue an honorable discharge. (T-1)

A2.5.4. Disenroll commissioned officers in DoD-sponsored professional education programs leading to appointment in a professional military specialty (including medical, dental, chaplain, and legal or judge advocate) from the program at the end of the academic term in which serologic evidence of HIV infection is confirmed. Except when laws specifically prohibit it, waive any additional service obligation incurred by participation in such programs; do not recoup any financial assistance received in these programs. Apply the time spent by the officers in these programs towards satisfaction of any preexisting service obligation. (T-1)

A2.5.5. Counsel people disenrolled from officer programs who are to be separated; include preventive medicine counseling and advise the individual to seek treatment from a civilian physician. (T-1)

### Attachment 3

## AIR FORCE HIV TESTING PROCEDURES

### A3.1. Responsibilities:

A3.1.1. Medical Treatment Facility Commander (MTF/CC). Is responsible for the HIV testing program. Appoints an HIV designated physician (and one or more alternates, if alternates are desired); ensures HIV positive individuals are notified and counseled as soon as possible following receipt of the positive test result; and ensures AD members are referred to SAMMC within 60 days of receipt of the HIV positive results notification from the USAFSAM HIV Testing Services to the base. Reserve medical unit commanders will immediately notify wing/unit commanders of any positive HIV test results. (T-1)

A3.1.2. Clinical Laboratory Manager. Draws, processes, and ships specimens for HIV testing. All specimens for HIV testing should be sent to USAFSAM HIV Testing Services, Epidemiology Laboratory Service, USAFSAM/PHE, 2510 Fifth Street, Bldg 20840, Wright-Patterson, OH 45433-7951 (DSN 798-4140). If, because of time considerations, local contract HIV testing is done for needlestick exposure, the laboratory manager must also ship a corresponding serum specimen, with HIV test request, to USAFSAM HIV Testing Services. If testing is done by an approved USAF laboratory, the laboratory manager must also ship corresponding serum specimen and results to USAFSAM HIV Testing Services. Upon completion of testing, USAFSAM HIV Testing Service will ship AD, Guard and Reserve samples to the Department of Defense Serum Repository (DoDSR). (T-1)

A3.1.3. Primary Care Management Team. Ensures HIV testing is accomplished in conjunction with appropriate Preventive Health Assessment or physical examinations (as described in paragraph [A3.2](#)). (T-1)

A3.1.4. Public Health (PH). Coordinates with MTF/CC's designee to ensure proper notification of the individual member. Is responsible for monitoring HIV positive ADAF members. Receives and reports to gaining public health personnel when HIV positive personnel are transferred. Informs the requesting laboratory of positive results so they can close out the test status in the computer system. The SAMMC HIV community liaison nurse performs additional case contact interviews, epidemiological follow-ups, and disease reporting procedures during SAMMC HIV evaluation visits. (T-1)

A3.1.5. HIV Testing Point of Contact. MTF shipping and receiving technician is responsible for shipping specimens; identifying supply deficiencies; maintaining results; and acting as the liaison with USAFSAM HIV Testing Services. (T-1)

A3.1.6. Civilian Personnel Office (CPO). Notifies by letter the clinical laboratory manager of any Department of the Air Force civilian employee requiring HIV testing. (T-1)

A3.1.7. Major Commands (MAJCOM). Deputy Command Surgeon (MAJCOM/SGP) or designee acts as liaison between USAFSAM HIV Testing Services and MTFs within the command.

A3.1.8. **USAFSAM**. Monitors and ensures that all active duty, guard and reserve positive HIV tests, as well as positive tests on dependants in the San Antonio area are reported to the HIV Program at SAMMC. Ensures that DoD mandated epidemiological studies are

accomplished on a periodic basis. The USAF HIV Medical Evaluation Unit Director or designee ensures that referred personnel on active orders are scheduled for evaluation within 30 days after being contacted by the referring base. (T-1)

A3.1.9. Reserve Medical Unit. Contacts the epidemiology lab to confirm positive test results before release of information, conducting counseling, or determining need for spousal or contact notification. (T-1)

**A3.2. Preventive Health Assessment (PHA):** Primary Care Manager ensures HIV testing is accomplished per the clinical testing requirements in the PHA for AD members or ARC members. (T-1)

**A3.3. Sexually Transmitted Infection (STI) Clinic Testing:**

A3.3.1. Providers counsel all STI patients regarding the need for HIV testing. Immediate HIV testing and follow-up testing IAW the most recent CDC recommendations. Informed consent laws are followed for dependents and civilians. (T-1)

A3.3.2. Providers refer all STI patients to PH for case contact interviews as soon as identified. (T-1)

A3.3.3. Test specimens IAW [A3.1.2](#) (T-1)

A3.3.4. MTF/CC or designee ensures all HIV positive individuals are properly notified and counseled, and all ADAF members are referred to the HIV Medical Evaluation Unit at SAMMC for medical evaluation. RMU/CC or designee ensures all HIV positive Reservists are properly notified and counseled, and all Reservists eligible for evaluation at the HIV Medical Evaluation Unit at SAMMC for medical evaluation are referred to the Unit for evaluation. (T-1)

**A3.4. Drug and/or Alcohol Treatment Testing:**

A3.4.1. The Alcohol and Drug Abuse Prevention and Treatment (ADAPT) Program Manager or designee notifies all AD members entering treatment programs of required HIV testing and provides the member with AF Form 3844. Local and state laws dictate availability of testing for family members and use of informed consent. Their testing is not mandatory. Individuals who are not DoD military health care beneficiaries (for example, civilian employees) are not HIV tested. (T-1)

A3.4.2. The treatment entrant reports to the MTF laboratory with AF Form 3844.

A3.4.3. Laboratory personnel obtain an HIV specimen and complete Part 2 of AF Form 3844.

A3.4.4. Accomplish the HIV testing IAW [A3.1.2](#) (T-1)

A3.4.5. The clinical laboratory manager forwards the completed AF Form 3844 to the ADAPT Program Manager or designee who ensures all AD members entering treatment have been HIV tested.

A3.4.6. MTF/CC or designee ensures all HIV positive individuals are properly notified and counseled, and all AD members are referred to the HIV Medical Evaluation Unit at SAMMC for medical evaluation. (T-1)

### **A3.5. Clinical Testing:**

A3.5.1. All health care providers order HIV testing for those patients with clinical indications of HIV related diseases (e.g. active tuberculosis, incident HBV and HCV cases) and for patients with potential exposure to the virus. A confirmed positive result on a urinalysis drug test is a clinical indication for HIV testing. Providers inform patients of HIV testing for clinical indications. Local state informed consent laws are followed for family members and other beneficiaries (for example, retirees). Informed consent is not required for AD members. (T-0)

A3.5.2. Providers ordering HIV testing ensure test results are reviewed, HIV positive patients are counseled, and HIV positive AD members are referred to the HIV Medical Evaluation Unit at SAMMC for medical evaluation. Normally, the HIV designated physician in conjunction with public health personnel, provide counseling and referral services. (T-1)

A3.5.3. Providers will not routinely order HIV testing on all patients. (T-1)

A3.5.4. Clinical testing is accomplished IAW [A3.1.2](#) (T-1)

### **A3.6. Occupational Exposure Testing.**

A3.6.1. Employees report to PH for occupational exposure testing and follow up IAW OSHA Blood-borne Pathogen Final Rule as implemented in the facility Infection Control Program/Employee Health Program. (T-0)

A3.6.2. Follow the latest CDC guidelines for blood and body fluid exposures to bloodborne pathogens as stated in the facility Infection Control Program/ Employee Health Program/Bloodborne Pathogen Program. Refer to AFI 44-108, *Infection Control Program*. (T-0)

A3.6.3. Personnel who perform exposure-prone procedures (to include, but not limited to, surgeons, pathologists, dentists, dental technicians, phlebotomists, emergency medical technicians, and physicians, nurses and technicians working in the emergency room, intensive care, surgery, and labor/ delivery) should know their HIV antibody status.

A3.6.4. Follow local state laws on HIV testing and informed consent for non-active duty individuals, including employees and patients. Informed consent is not required for active duty personnel. (T-0)

A3.6.5. Personnel testing is accomplished IAW [A3.1.2](#) (T-1)

### **A3.7. Prenatal Testing:**

A3.7.1. Screen all AD obstetrics (OB) patients for evidence of HIV infection regardless of previous testing. (T-1)

A3.7.2. Encourage nonactive duty OB patients to be tested. Follow local state laws on informed consent for nonactive duty patients.

A3.7.3. Submit additional specimens as clinical specimens, not as OB specimens.

A3.7.4. Accomplish testing IAW [A4.1.2](#) (T-1)

### **A3.8. Results Reporting:**

A3.8.1. Active Duty. The USAFSAM HIV Testing Services reports negative test results usually electronically to the submitting MTF within three workdays. First time positive notification letters are sent via FedEx Priority Overnight or by encrypted e-mail to the MTF/CC and base PH. Enclosed in each notification letter is an AF Form 74. The MTF/CC and PH officer write on their respective cards the date results were received, complete blocks (phone number, date and sign/organization/installation), document notification of the patient, and return to USAFSAM HIV Testing Services either by mail or by encrypted e-mail. Once the signed AF Form 74 is returned to the USAFSAM HIV Testing Service, the result will be certified in CHCS. Known positive patient's results are made available within 7 working days. (T-1)

A3.8.2. Air National Guard and Air Force Reserve. USAFSAM HIV Testing Services results for Air National Guard and Air Force Reserve units are reported the same as for Active Duty except that units not attached to an MTF with CHCS lab interoperability must log into the Wright-Patterson CHCS platform remotely to retrieve their results. (T-1)

A3.8.3. Clinical and Civilian Employee Samples. The USAFSAM HIV Testing Services report negative test results to the submitting MTF Laboratory Services within 3 working days. If positive, a notification letter is sent via FedEx Priority Overnight within seven workdays to PH. The letter has an AF Form 74 enclosed. The PH officer will write on AF Form 74 the date results were received, complete blocks (phone number, date and sign/organization/installation), document notification of the patient, and return to USAFSAM HIV Testing Services. (T-1)

A3.8.4. Results of HIV Testing Performed at DoD Labs Other Than Air Force. Occasionally, HIV testing will be done at Army or Navy laboratories on active duty Air Force personnel. When USAFSAM HIV Testing Services obtain first time positive results from other services, notification on AF members, USAFSAM HIV Testing Service will contact the submitting MTF's PH to ensure that notification has been performed. If notification has not been accomplished, USAFSAM HIV Testing Service will initiate notification as outlined in [A3.9.1](#). (T-1)

**A3.9. Blood Bank Testing.** If a military member is identified as HIV positive through blood donation or other blood bank or outside laboratory testing, a specimen must be sent to USAFSAM HIV Testing Services for confirmation. (T-1)

A3.9.1. All military members with a positive HIV screening test should be referred to public health for appropriate counseling and follow-up instructions regarding further testing. (T-0)

### **A3.10. Problem Resolution:**

A3.10.1. Inform USAFSAM HIV Testing Services of difficulties obtaining supplies or test results.

A3.10.2. The USAFSAM HIV Testing Services handles all test inquiries.

**NOTE:** Assess HIV risk at every preventive health assessment (PHA) and screen for serologic evidence of HIV infection during their PHA as required (minimum testing every 2 years). ARC personnel are screened during their periodic long flying physical every three years or nonflying physical every five years or as per the PHA clinical testing requirements. DoD mandated testing continues to include sexually transmitted disease (STI) clinic patients, drug and alcohol treatment entrants, prior to PCS OS assignments, prenatal patients, and host country requirements before deployment. (T-1)

## Attachment 4

### COMPLETION OF FORMS FOR REQUESTING HIV TESTING AND SPECIMEN TRANSMITTAL

#### A4.1. Composite Healthcare System.

A4.1.1. Submitting labs with Composite Healthcare System (CHCS) have the capability to create and send a list of specimens which can be sent to the receiving lab.

A4.1.1.1. Create a shipping/transmittal list in Composite Healthcare System (CHCS).

A4.1.1.2. Include a copy of the shipping/transmittal list in each specimen package sent to the receiving lab.

A4.1.1.3. Send the shipping/transmittal list electronically (if applicable) to the receiving lab through CHCS.

#### A4.2. AF FORM 1762 Completion (to be used ONLY by sites without CHCS access):

A4.2.1. AF Form 1762 is used to request HIV Screen Testing when CHCS is not available. The following information is mandatory: the facility/organization and address at the top of each form submitted. If not, specimens will be processed as NBI (no base identification) which will delay results until submitting activity can be ascertained. (T-1)

A4.2.2. For each request, the Full Name (last name, first name, middle initial) not nick-names, Full SSN (not last 4) with an FMP, Date of Birth (dates are to be entered as DD-  
MMM-YY, e.g., October 19, 1948 = 19 Oct 48), Duty Code (see [A5.3](#)) and Source Code (see [A5.4](#)). [Force Testing no longer exists. All periodic testing is done in conjunction with “P” (physicals) unless meeting one of the other source codes. See [A5.4](#) Source Codes.] (T-1)

A4.2.3. Testing will not proceed until all information is provided. Additionally, the individual being tested will not receive a test date in the master AFPC records if the name, FMP/SSN, or date of birth, do not match. (T-1)

A4.2.4. Fill out forms LEGIBLY. If entered by hand, the individual responsible for verifying the identity of personnel being screened, not the person being drawn, will print the information. Typewritten or computer generated forms are preferred. If you have computer support, call USAFSAM HIV Testing Services for available software programs to help produce a computer generated AF Form 1762. The AF Form 1762 is available through e-Publishing (<http://www.e-publishing.af.mil/shared/media/epubs/af1762.xfd>).

A4.2.5. At the bottom of the form, fill in date shipped, name of shipping person, or someone USAFSAM HIV Testing Services can contact if there are problems, and a DSN phone number or commercial number only if DSN is unavailable.

A4.2.6. MTF's that use the Composite Healthcare System (CHCS), refer to ADHOC A98 1011, Automated HIV Shipping Form, which can be downloaded from the Brooks web site: <http://www.tmsc.brooks.af.mil>.

A4.2.7. Guard and Reserve bases not utilizing CHCS can use developed software from US AFI HIV Testing Service (phone number DSN 240-8934). Guard and Reserve sites that access the Wright-Patterson CHCS remotely will use the CHCS ad hoc “ASL” (USAFSAM (Epi) Lab Referral Shipping List) function to generate their shipping list(s). This ad hoc

function is given to all Guard and Reserve users who request CHCS access through the Epidemiology Laboratory Information Systems Department.

A4.2.8. Common Errors in filing out AF Form 1762:

A4.2.8.1. Not putting Base ID/Submitting Activity at the top of each form

A4.2.8.2. Name - incomplete or not legible. Has name recently changed or is there a suffix (e.g. "Jr." or "III") after the name?

A4.2.8.3. SSN - more or less than 9 digits; not legible. Failure to include FMP with SSN.

A4.2.8.4. No Duty Code, no Source Code, or entry of unauthorized code.

A4.2.8.5. No Date or Shipping official to contact in case of problems.

A4.2.8.6. No DSN phone or commercial number if DSN unavailable.

A4.2.8.7. Failure to retain copy of AF Form 1762. A4.2.9. Forward the first two copies of the AF Form 1762 to USAFSAM HIV Testing Services along with the specimens. Keep the third copy in the laboratory for MTF record keeping purposes to track timely return of results. If test results have not been received within three days, contact USAFSAM HIV Testing Services for assistance.

A4.2.8.8. The MTF/CC reviews the reports and provides copies of positive results to the physician designated to advise and counsel HIV antibody positive individuals. (T-1)

A4.2.8.9. DoD laboratories authorized to perform HIV antibody clinical screening in-house use AF Form 1762 as a log for all HIV antibody ELISA screenings performed. All five items of information are to be completed. By the fifth working day of the month, forward all results from the previous month electronically or by floppy disc to USAFSAM HIV Testing Services. Forward specimens tested negative to USAFSAM HIV Testing Services marked "DoDSR" for placement in the DoDSR. Forward a specimen from each individual who screens positive for HIV in local testing to USAFSAM HIV Testing Services for confirmatory testing. (T-1)

**A4.3. AF Form 4 is used only to request Western Blot Confirmation Testing.** Do not use this form for HIV screening requests; use an AF Form 1762 as required in section [A5.1.1](#) For bases who perform local clinical testing and MTF Blood Banks that screen donors, all specimens that screen positive must be sent to the HIV Testing Services for FDA confirmation algorithm testing. Complete the form as follows: Fill out the top of the form with **all** required information. Blocks 13 and 14 must be completed with Duty Code and Source Code or testing will be delayed until information is obtained.

**A4.4. Duty Codes:** To obtain the most accurate information possible, submitting laboratories must use the patient category code (pat cat code) from CHCS for duty codes on the AF Form 1762 to identify the status of the individual being tested. This is an Alpha, two numeric code which is a mandatory field when registering members into CHCS. Therefore, this information should be available to download to an ADHOC report when computer generating the CHCS AF Form 1762. These codes closely emulate the DEERS codes for status of individual member being tested. For submitting activities not on CHCS, use the Pat Cat that closely defines the status of the individual. The following are the most commonly used:

**PAT CATs DEFINITION.**

A11 Army, Active Duty A12 Army, Reserve A13 Army, Recruits A14 Army, Academy Cadet  
A15 Army, National Guard

**PAT CATs DEFINITION.**

A21 Army, ROTC A23 Army National Guard A26 Army, Applicants-Enlistment's A31 Army,  
Retired A41 Army, Dependent of Active Duty A43 Army, Dependent of Retiree A45 Army,  
Dependent of Deceased Active Duty A47 Army, Dependent of Deceased Retiree A48 Army,  
Unmarried former Spouse

F11 Air Force, Active Duty F12 Air Force, Reserve F13 Air Force, Recruits F14 Air Force,  
Academy Cadet F15 Air Force, National Guard F21 Air Force, ROTC F23 Air Force National  
Guard F26 Air Force, Applicants-Enlistment's F31 Air Force, Retired F41 Air Force, Dependent  
of Active Duty F43 Air Force, Dependent of Retiree F45 Air Force, Dependent of Deceased  
Active Duty F47 Air Force, Dependent of Deceased Retiree F48 Air Force, Unmarried former  
Spouse M11 Marine Corps, Active Duty M12 Marine Corps, Reserve M13 Marine Corps,  
Recruits M14 Marine Corps, Academy-midshipmen M21 Marine Corps, ROTC M26 Marine  
Corps, Applicants-Enlistment's M31 Marine Corps, Retired M41 Marine Corps, Dependent of  
Active Duty M43 Marine Corps, Dependent of Retiree M45 Marine Corps, Dependent of  
Deceased Active Duty M47 Marine Corps, Dependent of Deceased Retiree M48 Marine Corps,  
Unmarried former Spouse

N11 Navy, Active Duty N12 Navy, Reserve N13 Navy, Recruits N14 Navy, Academy-  
Midshipmen N21 Navy, ROTC N26 Navy, Applicants-Enlistment's N31 Navy, Retired N41  
Navy, Dependent of Active Duty N43 Navy, Dependent of Retiree N45 Navy, Dependent of  
Deceased Active Duty N47 Navy, Dependent of Deceased Retiree N48 Navy, Unmarried former  
Spouse

C11 Coast Guard, Active Duty C12 Coast Guard, Reserve

**PAT CATs DEFINITION**

C31 Coast Guard, Retired C41 Coast Guard, Dependent of Active Duty C43 Coast Guard,  
Dependent of Retiree

P11 Public Health Svs, Active Duty P12 Public Health Svs, Reserve P31 Public Health Svs,  
Retired P41 Public Health Svs, Dependent of Active Duty P43 Public Health Svs, Dependent of  
Retiree

K53 Civil Service Employee/Other Federal Agencies K57 Civilian Employee, Occupational

AFI44-178 4 MARCH 2014

25

Health K59 Federal Government Employees, Overseas K61 VA Sharing Agreement/VA beneficiary K64 Other Federal Agency (DAF employee) K66 Federal Prisoners

**Table A4.1. PAT CATs Definition.**

A11	Army, Active Duty
A12	Army, Reserve
A13	Army, Recruits
A14	Army, Academy Cadet
A15	Army, National Guard
A21	Army, ROTC
A23	Army National Guard
A26	Army, Applicants-Enlistment's
A31	Army, Retired
A41	Army, Dependent of Active Duty
A43	Army, Dependent of Retiree
A45	Army, Dependent of Deceased Active Duty
A47	Army, Dependent of Deceased Retiree
A48	Army, Unmarried former Spouse

F11	Air Force, Active Duty
F12	Air Force, Reserve
F13	Air Force, Recruits
F14	Air Force, Academy Cadet
F15	Air Force, National Guard
F21	Air Force, ROTC
F23	Air Force National Guard
F26	Air Force, Applicants-Enlistment's
F31	Air Force, Retired
F41	Air Force, Dependent of Active Duty
F43	Air Force, Dependent of Retiree
F45	Air Force, Dependent of Deceased Active Duty
F47	Air Force, Dependent of Deceased Retiree
F48	Air Force, Unmarried former Spouse

M11	Marine Corps, Active Duty
M12	Marine Corps, Reserve
M13	Marine Corps, Recruits
M14	Marine Corps, Academy -midshipmen
M15	Marine Corps, National Guard
M21	Marine Corps, ROTC
M23	Marine Corps National Guard
M26	Marine Corps, Applicants-Enlistment's
M31	Marine Corps, Retired
M41	Marine Corps, Dependent of Active Duty
M43	Marine Corps, Dependent of Retiree
M45	Marine Corps, Dependent of Deceased Active Duty
M47	Marine Corps, Dependent of Deceased Retiree
M48	Marine Corps, Unmarried former Spouse

N11	Navy, Active Duty
N12	Navy, Reserve
N13	Navy, Recruits
N14	Navy, Academy Cadet
N15	Navy, National Guard
N21	Navy, ROTC
N23	Navy National Guard
N26	Navy, Applicants-Enlistment's
N31	Navy, Retired
N41	Navy, Dependent of Active Duty
N43	Navy, Dependent of Retiree
N45	Navy, Dependent of Deceased Active Duty
N47	Navy, Dependent of Deceased Retiree
N48	Navy, Unmarried former Spouse

C11	Coast Guard, Active Duty
C12	Coast Guard, Reserve
C31	Coast Guard, Retired
C41	Coast Guard, Dependent of Active Duty
C43	Coast Guard, Dependent of Retiree

K53	Civil Service Employee/Other Federal Agencies
K57	Civilian Employee, Occupational Health
K59	Federal Government Employees, Overseas
K61	VA Sharing Agreement/VA beneficiary
K64	Other Federal Agency (DAF employee)
K66	Federal Prisoners

P11	Public Health Svs, Active Duty
P12	Public Health Svs, Reserve
P31	Public Health Svs, Retired

P41	Public Health Svs, Dependent of Active Duty
P43	Public Health Svs, Dependent of Retiree

**A4.5. Source Code.** The only authorized codes used in the appropriate block on the AF Form 1762 are listed below. These codes identify the reason that the individual is being screened. They were adopted for use throughout DoD by the Reportable Disease Data Base (RDDDB) Working Group. A single code is entered on the AF Form 1762. Multiple codes for an individual are not authorized:

**Table A4.2. Source Codes.**

A	Alcohol and Drug Treatment
B	Blood Donor (Authorized for use on specimens or confirmation specimens)
C	Contact Testing (Referral)
F	Force Screening (routine screening of personnel)
I	Indicated for Clinical Reasons
J	Prisoners or Detained Persons
M	Medical Admissions (Including Psychiatric)
N	Pre-deployment
O	OB Clinic/Pregnancy Related
P	Physical Examinations
R	Requested by Individual
S	Surgical Admission (Including Invasive Procedures and ER)
T	Post-deployment
V	STI Clinic Visit
X	Any Other Source (used only in extremely rare cases)

**A4.6. Shipment of Specimen Requirements.**

A4.6.1. Ship specimens using instructions provided by USAFSAM HIV Testing Services. It is very important that the MTFs follow these instructions. Deviation could cause rejection of a shipment and necessitate redrawing each individual.

A4.6.2. USAFSAM HIV Testing Services will only accept 12x75 mm polypropylene tubes. If the whole shipment arrives in anything other than these type tubes, the shipment will be returned to the submitting MTF at their expense to process in the correct tubes. Single specimens will have to be redrawn. Tubes and caps can be ordered from most laboratory supply catalogues (see below) or can be obtained by completing a supply order form and submitting to our Customer Service Team via email at [usafsam.phe.cst@wpafb.af.mil](mailto:usafsam.phe.cst@wpafb.af.mil). This order form can be found on our website at <https://kx.afms.mil/epi.calling> the Epidemiology Laboratory Services at DSN 240-8751 or 8378. If the submitting MTF's stock runs out, it will have to hold specimens until a supply of the correct tubes are received.

**AFI44-178 4 MARCH 2014**

**27**

Test Tubes, 12x75 mm, polypropylene, round bottom

FSN 6640-01-264-2362

Curtin-Matheseon Scientific (CMS) #289-657

S/P-Baxter T-1226-12

Plug Cap for 12x75 test tubes

FSN 6640-01-2222963

CMS #148-346

S/P-Baxter T1226-32

Tubes and caps in one order

S/P-Baxter T1226-42

Double sided Plastic Bags

Fisher Cat #01-824 Lab Safety Supply Cat #TL-23805

VWR Cat #11216-783

A4.6.3. Label tubes with a CHCS generated label. If CHCS is unavailable, write FULL NAME (Last name, first name, middle initial), and the FULL SSN with FMP, and collection date on label, then place label long-wise without covering the bottom of tube. (Pre/Post deployment specimens need draw date). Secure with a plastic plug cap. DO NOT USE PARAFILM.

A4.6.4. Place patient samples in a foam tube rack in the order listed on the shipping/transmittal list or AF Form 1762. Wrap foam tube rack containing specimens in absorbent material and place in a large plastic shipping bag. Place patient samples (amount for 1 AF Form 1762/no more than 22) with absorbent material in large portion of plastic shipping bag. Place one copy of the shipping/transmittal list or one copy and original of AF Form 1762. Place original and one copy of AF Form 1762 inside the outer pouch of the shipping bag corresponding to samples and tear off plastic strip covering the adhesive and to SEAL THE BAG. If foam tube racks are not available, place no more than 10 specimens in a small plastic shipping bag containing absorbent material. Place one copy of the shipping/transmittal list or one copy and original of AF Form 1762 in the outer pouch of the shipping bag and SEAL THE BAG. Repeat for each batch of 10 specimens. In shipping

HIVs specimens with other EPI specimens, place HIV specimens in a separate ziplock plastic shipping bag marked: "HIV"

A4.6.5. The following common errors could be avoided if a quality control program exists.

A4.6.6. Common errors in Specimen Preparation:

A4.6.6.1. Not spinning specimen down causing hemolyzed specimens

A4.6.6.2. Putting specimens in the wrong tubes; only polypropylene 12x75 mm will be accepted.

A4.6.6.3. Over-filling tubes, causing tube cap to come off when the specimen is frozen.

A4.6.6.4. Not putting tube caps on tightly.

A4.6.6.5. Tape or parafilm around the cap of the tube.

A4.6.6.6. Omitting the individual's full name/full SSN on tube

A4.6.6.7. Only last four of SSN on the transport tube.

A4.6.6.8. Name on tube does not match name on shipping/paperwork transmittal list or AF Form 1762.

A4.6.6.9. No shipping/transmittal list or AF Form 1762 accompanying the specimen tube.

A4.6.7. Common Errors in Specimen Packaging:

A4.6.7.1. Not wrapping tubes with absorbent paper material.

A4.6.7.2. Not maintaining a cold environment (use ice, cold packs, or dry ice as appropriate).

A4.6.7.3. Not separating shipping/transmittal lists or AF Forms 1762 from specimens, causing forms to get wet if leakage occurs.

A4.6.7.4. Not sealing the shipping bag completely causing specimens to be lost in transit.

A4.6.7.5. Not packing specimens in foam shipping rack or separating them into batches of ten.

## Attachment 5

### HIV TESTING AND INTERPRETATION OF RESULTS

#### A5.1. Laboratories:

A5.1.1. Use only approved MTF laboratories or the USAFSAM HIV Testing Services to perform the initial screening test on specimens collected from Service members. (T-1)

A5.1.2. All approved Air Force MTF laboratories that perform in-house HIV testing must send a serum sample for testing to USAFSAM HIV Testing Services IAW [A3.1.2](#) This sample will be forwarded to the DoD serum repository after testing by the USAF HIV Testing Service. (T-1)

A5.1.3. The USAFSAM HIV Testing Services, USAFSAM, Wright-Patterson Air Force Base, maintains specimens for seven days after testing then discarded. Specimens from Reserve and Guard units are sent to the DoD serum repository. (T-1)

#### A5.2. Specimen Collection and Handling:

A5.2.1. Collect blood samples with appropriate vacutainer tubes.

A5.2.2. Label tubes with a CHCS generated label. As a minimum, each sample is labeled with three unique patient identifiers such as; the individual's full name, FMP/SSN, date of birth or a laboratory assigned number. Also include the date and time of collection.

A5.2.3. Samples are centrifuged and serum separated within six hours of collection.

A5.2.4. Specimens should be refrigerated before the initial test. If the initial test is cannot be conducted within seven days, or the date at which the sample was collected is unknown, the specimen must be frozen ( $\leq -20^{\circ}\text{C}$ ).

A5.2.5. Use cold packs to keep specimens at refrigerated temperatures ( $2 - 8^{\circ}\text{C}$ ) or shipped on dry ice if the samples are frozen ( $\leq -20^{\circ}\text{C}$ ) during transit between laboratories.

A5.2.6. Ship specimens according to US (or foreign) biological agent shipping requirements.

#### A5.3. Initial Test:

A5.3.1. Conduct the initial test using a FDA-approved screening test. Interpret results according to the manufacturer's package insert.

A5.3.2. The laboratory establishes an internal quality control program.

A5.3.3. All controls will be 100 percent correct before the entire batch results are considered acceptable.

#### A5.4. Supplemental/Confirmatory Tests:

A5.4.1. All HIV testing will follow an APHL/CDC-approved algorithm. (T-0)

A5.4.2. Perform a FDA-approved confirmatory test, such as a Western Blot (WB) test. For Western Blot tests with indeterminate results, an alternative FDA approved test can be used to resolve indeterminates such as a viral load-based assay (APTIMA) or other FDA approved testing platform. (T-0)

A5.4.3. The laboratory validates its procedure using a protocol that establishes accuracy, precision, and reproducibility.

## Attachment 6

### HIV TESTING OF DOD CIVILIAN EMPLOYEES

**A6.1.** Direct requests for authority to screen DoD civilian employees for HIV to the Assistant Secretary of Defense (ASD)/Force Management and Personnel (FM&P). Only requests that are based on a host nation HIV screening requirement are accepted. Requests based on other concerns, such as sensitive foreign policy or medical health care issues, are not considered under this instruction. Approvals are provided in writing by the ASD/FM&P and apply to all the DoD Components that may have activities located in the host nation. (T-0)

**A6.2.** Specific HIV screening requirements may apply to DoD civilian employees currently assigned to positions in the host nation and to prospective employees. When applied to prospective employees, HIV screening is considered a requirement imposed by another nation, that must be met before the final decision to select the individual for a position, or before approving temporary duty or detail to the host nation. Individuals who refuse to cooperate with HIV screening requirements or those who cooperate and are diagnosed as HIV seropositive, may not be considered further for employment in host nations with HIV screening requirements. (T-0)

**A6.3.** DoD civilian employees who refuse to cooperate with the screening requirements are treated, as follows:

A6.3.1. Those who volunteered for the assignment, whether permanent or temporary, are retained in their official position without further action and without prejudice to employee benefits, career progression opportunities, or other personnel actions to which those employees are entitled under applicable law or instruction.

A6.3.2. Those who are obligated to accept assignment to the host nation under the terms of an employment agreement, regularly scheduled tour of duty, or similar and/or prior obligation may be subjected to an appropriate adverse personnel action under the specific terms of the employment agreement or other authorities that may apply.

A6.3.3. Host nation screening requirements, which apply to DoD civilian employees currently located in that country, must be observed. Appropriate personnel actions may be taken, without prejudice to employee rights and privileges to comply with the requirements. (T-0)

**A6.4.** Individuals who are not employed in the host nation, who accept the screening, and who are evaluated as HIV seropositive shall be denied the assignment on the basis that evidence of seronegativity is required by the host nation. If denied the assignment, such DoD employees shall be retained in their current positions without prejudice. Appropriate personnel actions may be taken, without prejudice to employee rights and privileges, on DoD civilian employees currently located in the host nation. In all cases, employees shall be given proper counseling and shall retain all the rights and benefits to which they are entitled, including accommodations for the handicapped as in the applicable ASD/FM&P Memorandum, and for employees in the United States (29 U.S.C. 794). Non-DoD employees are referred to appropriate support service organizations. (T-0)

**A6.5.** Some host nations may not bar entry to HIV seropositive DoD civilian employees, but may require reporting of such individuals to host nation authorities. In such cases, DoD civilian employees who are evaluated as HIV seropositive shall be informed of the reporting

requirements. They shall be counseled and given the option of declining the assignment and retaining their official positions without prejudice or notification to the host nation. If assignment is accepted, the requesting authority shall release the HIV seropositive result, as required. Employees currently located in the host nation may also decline to have seropositive results released. In such cases, they may request and shall be granted early return at government expense or other appropriate personnel action without prejudice to employee rights and privileges. (T-0)

**A6.6.** A positive HIV screening test must be confirmed by an FDA approved confirmatory test according to an APHL/CDC approved algorithm. A civilian employee may not be identified as HIV antibody positive, unless the confirmatory test is positive. The clinical standards in this instruction shall be observed during initial and confirmatory testing. (T-0)

**A6.7.** Provide tests at no cost to the DoD civilian employees, including applicants. (T-0)

**A6.8.** Counsel DoD civilian employees infected with HIV. (T-0)

## Attachment 7

### GUIDELINES FOR ADMINISTERING THE ORDER TO FOLLOW PREVENTIVE MEDICINE REQUIREMENTS TO INDIVIDUALS INFECTED WITH HIV

**A7.1.** After the member is notified by a health care provider that he or she has tested positive for HIV infection, and the significance of such a test, the MTF/CC expeditiously notifies the member's unit commander of the positive test results. For active duty members, the member's unit commander issues an order to follow preventive medicine requirements. For unit assigned reservists, this order is issued only after their immediate commander determines the member will be retained in the Selected Reserve. When the order is given, a credentialed provider is present to answer any medical concerns of the member. Use the order at [Attachment 13](#). It is signed and dated by the commander and member. If the member refuses to sign, the commander notes that the member refused to sign in the acknowledgment section. The order is securely stored to protect the member's privacy and confidentiality. A copy of the order is provided to the member. Upon the individual's reassignment, the unit commander forwards the order in a sealed envelope to the gaining commander. The envelope is marked "To Be Opened By Addressee Only." Upon the individual's separation from the Air Force, the order is destroyed. (T-1)

**A7.2.** AD members testing positive for HIV infection undergo a complete medical evaluation at SAMMC. Upon arrival, all HIV positive members are counseled by a health care provider or by the HIV Community Health Nurse (CHN) assigned to the HIV Medical Evaluation Unit at SAMMC. Use AF Form 3845, **Preventive Medicine Counseling Record**, or similar form. The CHN signs the form. The member signs the counseling record acknowledging receipt of the counseling. One copy of the record is given the member and one copy filed in the records of the HIV CHN. (T-1)

**A7.3.** If the member is returned to duty from the HIV Medical Evaluation Unit to a different unit from which he or she came, the gaining unit commander issues an additional order to follow preventive medicine requirements to the member. A copy of this order is given to the member. Use the order at [Attachment 13](#). The commander may request the MTF/CC or other health care provider is present when the order is administered to answer any medical concerns of the member. The commander and member sign and date the order. If the member refuses to sign, the commander notes the member refused to sign in the acknowledgment section. Securely store the order to protect the member's privacy and confidentiality. (T-1)

**A7.4.** It is unnecessary to recall members issued orders under former procedures. HIV seropositive members, who have not been previously issued preventive medicine requirement orders, must be counseled by a health care provider assigned to the local medical facility on AF Form 3845 and issued an order ([Attachment 13](#)) by his or her unit commander. (T-1)

**NOTE:** DoD requested the Military Departments standardize the administration of the order to follow preventive medicine requirements to individuals infected with HIV. The guidelines above standardize and simplify procedures.

## Attachment 8

### STANDARD CLINICAL PROTOCOL

#### **A8.1. Medical Evaluation:**

A8.1.1. Accomplish a complete medical evaluation of AF personnel with HIV infection with an initial visit, a second visit at 6 months, and subsequent visits every 12 months at SAMMC as long as the member is retained on active duty. HIV disease will be staged according to current CDC guidelines for every clinical visit. Interim medical visits will be performed as necessary in the member's local area in accordance with current DHHS Guidelines for Management of Adult HIV Infections. For unit assigned reservists not on extended active duty, this evaluation is not accomplished until after the commander's decision to retain the member. If the member is retained, the evaluation must be accomplished and documented IAW AFI 48-123, AFI 41-210, and AFRC medical guidance on nonduty related medical conditions. (T-1)

A8.1.2. Maintain a frozen serum specimen on all HIV positive individuals at a central serum bank for at least three years at -70 degrees Celsius. (T-1)

A8.1.3. Seek psychiatric consultation if there are concerns about fitness for duty or if the screening evaluation suggests more detailed psychiatric evaluation is needed. If the patient has persistent evidence of diminished intellectual skills, personality changes, and motor impairment, more specialized studies (neurologic studies, computed tomography or magnetic resonance imaging, lumbar puncture, psychiatric examination, and neuropsychiatric testing) may be required to evaluate the possible presence of a HIV-related mental or neurological syndrome. (T-1)

A8.1.4. Perform additional testing in both initial and follow-up epidemiologic/clinical assessments as indicated to maintain compliance with changes in accepted standards of care for management of HIV infection. (T-1)

**A8.2. Medical Record Coding of HIV-1 Infections.** Follow current ICD CM coding guidelines for medical record coding of HIV infection.

#### **A8.3. Disposition of Members Infected:**

A8.3.1. DoD Directive 1332.18, Separation From the Military Service by Reason of Physical Disability, November 4, 1996, and AFI 41-210, Medical Evaluations Boards (MEB) and Continued Military Service, provides guidelines for fitness for duty determinations. However, MEB pre-screening will occur with an Initial Review in Lieu of an MEB (I-RILO) under the guidelines of AFI 41-210, chapter 4, section 4k. This guidance provides I-RILO screening procedures for both ADAF members Air Reserve Component members. (T-0)

A8.3.2. Refer AD members infected with HIV for I-RILO in accordance with AFI 41-210, immediately following the initial evaluation. However, while I-RILOs usually require a letter from the member's Commander indicating the impact of a member's condition upon his/her duty performance, such a letter is not required in the case of HIV seropositive members because of the risk of Privacy Act violations while routing such letters through the Commander's support staff. I-RILOs will only be submitted from the HIV Medical

**AFI44-178 4 MARCH 2014**

**35**

Evaluation Unit at SAMMC and individual home bases are not to submit I-RILOs or annual ALC-C RILOs for HIV infection. (T-1)

## Attachment 9

### RETENTION AND SEPARATION

#### A9.1. Retention:

A9.1.1. Members with laboratory evidence of HIV infection who are able to perform the duties of their office, grade, rank and/or rating, may not be separated solely on the basis of laboratory evidence of HIV infection. (T-0)

A9.1.2. HIV-infected members who have been evaluated for continued military service and are retained will receive an Assignment Limitation Code (ALC-C). Please refer to AFI 41-210 for ALC-C stratifications and for a list of waiver authorities for OCONUS TDY and/or assignment. (T-1)

#### A9.2. Separation:

A9.2.1. AFI 36-3212, *Physical Evaluation for Retention, Retirement, and Separation*, provides guidance for separation or retirement of AD members who are determined to be unfit for further duty.

A9.2.2. AD and Reserve members with laboratory evidence of HIV infection found not to have complied with lawfully ordered preventive medicine procedures are subject to administrative and disciplinary action, which may include separation.

A9.2.3. Separation of AD members with laboratory evidence of HIV infection under the plenary authority of the Secretary of the Air Force, if requested by the member, is permitted.

A9.2.4. The immediate commander of ARC members not on extended active duty who show serologic evidence of HIV infection will determine if the member can be utilized in the Selected Reserve. If the member cannot be utilized, he/she may be transferred involuntarily to the Standby Reserve or separated. If separated, the characterization of service shall never be less than that warranted by the member's service record. (T-1)

A9.2.5. Air Force members determined to have been infected with HIV at the time of enlistment or appointment are subject to discharge for erroneous enlistment or appointment. (T-1)

## Attachment 10

### LIMITATIONS ON THE USE OF INFORMATION FROM EPIDEMIOLOGICAL ASSESSMENTS

#### A10.1. Limitations of Results:

A10.1.1. Laboratory tests results performed under this instruction may not be used as the sole basis for separation of a member. The results may be used to support a separation based on physical disability or as specifically authorized by any section in this instruction. This instruction shall not preclude use of laboratory test results in any other manner consistent with law or instruction. (T-1)

A10.1.2. Laboratory test results confirming evidence of HIV infection may not be used as an independent basis for any adverse administrative action or any disciplinary action, including punitive actions under the Uniform Code of Military Justice (UCMJ) (10 U.S.C. 47, reference [j]). (T-1) However, such results may be used for other purposes including, but not limited to, the following:

A10.1.2.1. Separation under the accession testing program.

A10.1.2.2. Voluntary separation for the convenience of the Government.

A10.1.2.3. Other administrative separation action authorized by Air Force policy.

A10.1.2.4. In conducting authorized Armed Services Blood Program Look Back activities.

A10.1.2.5. Other purposes (such as rebuttal or impeachment) consistent with law or instruction (e.g., the Federal or Military Rules of Evidence or the Rules of Evidence of a State), including to establish the HIV seropositivity of a member when the member disregards the preventive medicine counseling or the preventive medicine order or both in an administrative or disciplinary action based on such disregard or disobedience.

A10.1.3. HIV infection is an element in any permissible administrative or disciplinary action, including any criminal prosecution (e.g., as an element of proof of an offense charged under the UCMJ or under the code of a State or the United States).

A10.1.4. HIV infection is a proper ancillary matter in an administrative or disciplinary action, including any criminal prosecution (e.g., as a matter in aggravation in a court-martial in which the HIV positive member is convicted of an act of rape committed after being informed that he or she is HIV positive).

#### A10.2. Limitations on the Use of Information Obtained in the Epidemiological Assessment Interview:

A10.2.1. Information obtained from a member during, or as a result of, an epidemiological assessment interview may not be used against the member in the following situations:

A10.2.1.1. A court-martial.

A10.2.1.2. Line of duty determination.

A10.2.1.3. Nonjudicial punishment.

A10.2.1.4. Involuntary separation (other than for medical reasons).

A10.2.1.5. Administrative or punitive reduction-in-grade.

A10.2.1.6. Denial of promotion.

A10.2.1.7. An unfavorable entry in a personnel record.

A10.2.1.8. A denial to reenlistment.

A10.2.1.9. Any other action considered by the Secretary of the Air Force concerned to be an adverse personnel action.

A10.2.2. The limitations in paragraph [A10.2.1](#) do not apply to the introduction of evidence for appropriate impeachment or rebuttal purposes in any proceeding, such as one in which the evidence of drug abuse or relevant sexual activity (or lack thereof) has been first introduced by the member or to disciplinary or other action based on independently derived evidence.

A10.2.3. The limitations in paragraph [A10.2.1](#) do not apply to nonadverse personnel actions on a case-by-case basis, such as: A10.2.3.1. Reassignment. A10.2.3.2. Disqualification (temporary or permanent) from a personnel reliability program. A10.2.3.3. Denial, suspension, or revocation of a security clearance. A10.2.3.4. Suspension or termination of access to classified information.

A10.2.4. Removal (temporary or permanent) from flight status or other duties requiring a high degree of stability or alertness, including explosive ordnance disposal or deep-sea diving.

**A10.3. Entries in Personnel Records:** Except as authorized by this instruction, if any such personnel actions are taken because of, or are supported by, serologic evidence of HIV infection or information described in paragraph [A10.1.2](#), no unfavorable entry may be placed in a personnel record for such actions. Recording a personnel action is not an unfavorable entry in a personnel record. Additionally, information reflecting an individual's serologic or other evidence of infection with HIV is not grounds for an unfavorable entry in a personnel record.

**Attachment 11****PERSONNEL NOTIFICATION, MEDICAL EVALUATION, AND  
EPIDEMIOLOGICAL INVESTIGATION****A11.1. Personnel Notification:**

A11.1.1. Once a health care authority has been notified of an individual with serologic or other laboratory/clinical evidence of HIV infection, public health and or the HIV designated physician shall undertake preventive medicine intervention. The CHN and physician staff at the SAMMC HIV Medical Evaluation Unit will assist military and civilian blood bank organizations and preventive medicine authorities with blood donor look back tracing and referral and refer case-contact information to the appropriate military or civilian health authority. (T-0)

A11.1.2. All individuals with serologic evidence of HIV infection who are military healthcare beneficiaries shall be counseled by a physician or a designated healthcare provider on the significance of a positive antibody test. They shall be advised as to the mode of transmission, the appropriate precautions and personal hygiene measures required to minimize transmission through sexual activities and/ or intimate contact with blood or blood products, and of the need to advise any past or future sexual partners of their infection. Women shall be advised of the risk of perinatal transmission during past, current, and future pregnancies. The individuals shall be informed that they are ineligible to donate blood, sperm, organs or tissues and shall be placed on a permanent donor deferral list. (T-0)

A11.1.3. Service members identified to be at risk shall be counseled and tested for serologic evidence of HIV infection. Other DoD beneficiaries, such as retirees and family members, identified to be at risk, shall be informed of their risk and offered serologic testing, clinical evaluation, and counseling. The names of individuals identified to be at risk who are not eligible for military healthcare shall be referred to civilian health authorities in the local area where the index case is identified, unless prohibited by the appropriate State or host-nation civilian authority. Anonymity of the HIV index case shall be maintained, unless reporting is required by civil authorities. (T-0)

A11.1.4. Blood donors who demonstrate repeatedly reactive screening tests for HIV, but for whom confirmatory test(s) are negative or indeterminate are not eligible for blood donor pool, shall be appropriately counseled. (T-0)

**A11.2. Medical Evaluation:**

A11.2.1. Active duty personnel and ARC members on extended active duty who have tested positive for HIV shall be sent to the HIV Medical Evaluation Unit at SAMMC for medical evaluation. All DoD directed evaluations will be completed as an outpatient, coordinated by the HIV Evaluation Unit staff. All Active Duty HIV patients undertaking their initial evaluation will undergo mental health status screening by a SAMMC mental health provider. (T-1)

A11.2.2. Physically or mentally unstable HIV patients should have their conditions addressed and stabilized sufficiently for outpatient management prior to transport. Upon arrival, those patients exhibiting an active process requiring physician attention during non-duty hours will be admitted to the appropriate inpatient service. (T-1)

A11.2.3. SAMMC HIV Medical Evaluation Unit staff will conduct a confidential patient epidemiologic interview, repeat the contact notification process, and verify blood donation “lookback” process. The HIV Evaluation Unit CHN or designee will provide the disease education and risk reduction counseling during the patient interview, and complete two copies of the standardized medical counseling form (“Prevention Medicine Counseling Record”). One copy is given to the patient, and the other copy maintained in the HIV CHN’s confidential patient files. If the patient refuses to sign, SAMMC Directorate of Medical Law will be notified. The “Order to Follow Preventive Medicine Requirements” is issued by the unit commander of an HIV infected person prior to the patient’s initial evaluation by the HIV unit. (T-1)

A11.2.4. All HIV infected active duty and TDRL personnel arriving at SAMMC will receive medical evaluation and staging of their HIV disease by an assigned HIV unit staff physician. The physician will also provide disease specific patient education and appropriate treatment recommendations, and serve as liaison with consulting or inpatient services when necessary. The HIV unit physician will be available to the patient’s primary care provider for ongoing patient management and any issues concerning scheduled reevaluations. (T-1)

### **A11.3. Epidemiological Investigation:**

A11.3.1. Epidemiological investigation shall attempt to determine potential contacts of patients who have serologic or other laboratory or clinical evidence of HIV infection. The patient shall be informed of the importance of case-contact notification to interrupt disease transmission and shall be informed that contacts shall be advised of their potential exposure to HIV. Individuals at risk of infection include sexual contacts (male or female); children born to infected mothers; recipients of blood, blood products, organs, tissues, or sperm; and users of contaminated intravenous drug paraphernalia. At risk individuals who are eligible for healthcare in the military medical system shall be notified. The Secretaries of the Military Departments shall designate all spouses (regardless of the Service affiliation of the HIV infected Reservist) who are notified under this provision to receive serologic testing and counseling on a voluntary basis from MTFs under the Secretaries’ of the Military Departments jurisdiction. (T-0)

A11.3.2. Communicable disease reporting procedures shall be followed consistent with this Directive through liaison between the public health authorities and the appropriate local, State, Territorial, Federal, or host-nation health jurisdiction. (T-0)

## Attachment 12

### PROCEDURE FOR EVALUATING T-HELPER CELL COUNT

#### A12.1. Analytical Procedure:

A12.1.1. Determine the percentage of CD4+ and CD3+ positive lymphocytes by immunophenotyping blood cells using flow-cytometry instrumentation per applicable CDC guidelines. Each laboratory performing T-helper cell counts maintains a current and complete standard operating procedure manual. The absolute T-helper cell count is a product of the percentage of T-helper cells (defined as CD4+ and CD3+ positive lymphocytes) and the absolute lymphocyte level.

#### A12.2. Internal Quality Control Program:

A12.2.1. Each laboratory maintains a comprehensive internal quality control program. Minimally, on each day of operation monitor the following flow-cytometry procedures or reagents:

A12.2.1.1. Optical focusing and alignment of all lenses and light paths for forward-angle light scatter, right-angle light scatter, red fluorescence, and green fluorescence if these functions are adjustable on the instrument.

A12.2.1.2. Standardize fluorescent intensity beads, particles, or cells with fluorescence in the range of biological samples.

A12.2.1.3. Verify fluorescent compensation beads, particles, or cells with fluorescence in the range of biological samples.

A12.2.1.4. A human blood control sample or equivalent.

A12.2.2. Each laboratory establishes tolerance limits for each of the procedures or reagents in paragraph [A12.1](#). Take corrective action and document when any quality control reagent exceeds established tolerance limits. Accomplish routine maintenance and function verification checks. The laboratory director regularly reviews corrective and quality control records.

**A12.3. External Quality Control Program:** The Army establishes and operates an external quality control program to evaluate the results reported by the flow-cytometry laboratories. The external quality control program includes a hematology survey to monitor the performance of the absolute lymphocyte count and a flow-cytometry survey to monitor the performance of each immunophenotyping procedure.

**A12.4. Recording and Reporting Data:** The laboratory director reviews and verifies the reported results. The laboratory report contains data from which absolute and relative values may be calculated for each lymphocyte subpopulation along with locally derived normal ranges inclusive of the fifth and ninety-fifth percentiles. The laboratory maintains permanent files of patient reports, internal and external quality control records, and instrument maintenance and performance verification checks.

#### A12.5. Personnel Qualifications:

A12.5.1. Properly train all personnel involved with the flow-cytometry instrumentation.

A12.5.2. Director of the flow-cytometry laboratory holds a doctoral degree in a biologic science or is a physician and possesses experience in immunology or cell biology.

A12.5.3. Technical supervisor holds a bachelor's degree in a biological science and has at least two years of experience in flow-cytometry.

**A12.6. Safety:** All laboratories comply with the CDC biosafety level 2 standards. All procedures having the potential to create infectious aerosols shall be conducted within the confines of a Class II biological safety cabinet. Although certain specimen processing procedures may inactivate infectious agents, all material is treated as infectious throughout all procedures. Decontaminate all material generated in the processing and evaluation of blood specimens and dispose of using established hazardous waste disposal policies.

**Attachment 13**

**ORDER TO FOLLOW PREVENTIVE MEDICINE REQUIREMENTS**

Because of the necessity to safeguard the overall health, welfare, safety, and reputation of this command and to ensure unit readiness and the ability of the unit to accomplish its mission, certain behavior and unsafe health procedures must be proscribed for members who are diagnosed as positive for HIV infection.

As a military member who has been diagnosed as positive for HIV infection, you are hereby ordered:

- (1) to verbally inform sexual partners that you are HIV positive prior to engaging in sexual relations. This order extends to sexual relations with other military members, military dependents, civilian employees of DoD components or any other persons;
- (2) to use proper methods to prevent the transfer of body fluids during sexual relations, including the use of condoms providing an adequate barrier for HIV (e.g. latex);
- (3) in the event that you require emergency care, to inform personnel responding to your emergency that you are HIV positive as soon as you are physically able to do so.
- (4) when seeking medical care, you may wish to inform the provider that you have HIV so that the provider can use that information to optimize your evaluation and treatment;
- (5) not to donate blood, sperm, tissues, or other organs.

Violating the terms of this order may result in adverse administrative action or punishment under the Uniform Code of Military Justice for violation of a lawful order.

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Signature of Commander and Date

### ACKNOWLEDGMENT

I have read and understand the terms of this order and acknowledge that I have a duty to obey this order. I understand that I must inform sexual partners, including other military members, military dependents, civilian employees of DoD components, or any other persons, that I am HIV positive prior to sexual relations; that I must use proper methods to prevent the transfer of body fluids while engaging in sexual relations, including the use of condoms providing an adequate barrier for HIV; that if I need emergency care I will inform personnel responding to my emergency that I am HIV positive as soon as I am physically able to do so; that when I seek medical or dental care I may wish to inform the provider that I have HIV in order to optimize my evaluation and treatment; and that I must not donate blood, sperm, tissues, or other organs. I understand that violations of this order may result in adverse administrative actions or punishment under the Uniform Code of Military Justice for violation of a lawful order.

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Signature of Member and Date

# EXHIBIT H



# Department of Defense INSTRUCTION

NUMBER 6490.07  
February 5, 2010

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USD(P&R)

SUBJECT: Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees

References: See Enclosure 1

1. PURPOSE. In accordance with the authority in DoD Directive (DoDD) 5124.02 (Reference (a)) and the guidance in DoDDs 6200.04 and 1400.31 (References (b) and (c)), this Instruction establishes policy, assigns responsibilities, and provides procedures for ensuring that Service members and DoD civilian employees, including Coast Guard Service members and civilian employees at all times, including when the Coast Guard is a Service in the Department of Homeland Security by agreement with that Department, (hereafter referred to collectively as “DoD personnel”) deployed and deploying on contingency deployments are medically able to accomplish their duties in deployed environments.

2. APPLICABILITY. This Instruction:

a. Applies to:

(1) OSD, the Military Departments (including the Coast Guard at all times, including when it is a Service in the Department of Homeland Security by agreement with that Department), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the “DoD Components”).

(2) DoD personnel deployed and deploying on contingency deployments consistent with DoD and Service-specific guidance, including Reference (c) and DoD Instruction (DoDI) 1400.32 (Reference (d)).

b. Does not apply to contingency contractor personnel, who shall comply with the guidance in DoDI 3020.41 (Reference (e)), or to shipboard operations that are not anticipated to involve operations ashore, which shall follow Service-specific guidance.

*DoDI 6490.07, February 5, 2010*

c. Shall be used as a minimum medical standard for all deploying and deployed DoD personnel, BUT does not alter or replace:

(1) With respect to military personnel, the accession, retention, and general fitness for duty standards previously established by the Department of Defense, including those described in DoDI 6130.4, DoDD 6130.3, Under Secretary of Defense for Personnel and Readiness (USD(P&R)) Memorandum, Assistant Secretary of Defense for Health Affairs (ASD(HA)) Memorandum, and DoDI 6485.01 (References (f) through (j), respectively).

(2) With respect to civilian employees covered by sections 791 and 794a of title 29, United States Code (also known and hereafter referred to as “The Rehabilitation Act of 1973, as amended” (Reference (k))), the legal obligations of a DoD Component as an employer pursuant to that Act.

(3) More stringent individual Military Department policy guidance or Service-specific readiness requirements.

3. DEFINITIONS. These terms and their definitions are for the purpose of this Instruction.

a. contingency. A situation requiring military operations in response to natural disasters, terrorists, subversives, or as otherwise directed by appropriate authority to protect US interests.

b. contingency deployment. A deployment that is limited to outside the continental United States, over 30 days in duration, and in a location with medical support from only non-fixed (temporary) military medical treatment facilities. It is a deployment in which the relocation of forces and materiel is to an operational area in which a contingency is or may be occurring.

c. deployment. The relocation of forces and materiel to desired operational areas. Deployment encompasses all activities from origin or home station through destination, specifically including intra-continental United States, inter-theater, and intra-theater movement legs, staging, and holding areas.

d. medical assessment. The total of the pre-deployment activities described in section 1 of Enclosure 2 of this Instruction and those listed in paragraph E4.A1.1 of DoDI 6490.03 (Reference (l)).

e. trained DoD health-care provider. A physician, physician assistant, nurse practitioner, advanced practice nurse, independent duty corpsman, independent duty medical technician, or special forces medical sergeant.

4. POLICY. It is DoD policy that:

a. The medical standards in this Instruction are mandatory for contingency deployments, and permissible for any other deployment, based on the commander’s decision.

*DoDI 6490.07, February 5, 2010*

b. DoD personnel with existing medical conditions may deploy based upon a medical assessment as described in Enclosure 2 and subparagraph E4.A1.1.1. of Reference (l), which for civilian employees shall be consistent with subparagraph 4.g.(3)(c) of DoDD 1404.10 (Reference (m)), and the requirements of The Rehabilitation Act of 1973, as amended, when such civilian employees are covered by that Act, if all of these conditions are met:

(1) The condition is not of such a nature or duration that an unexpected worsening or physical trauma is likely to have a grave medical outcome or negative impact on mission execution.

(2) The condition is stable and reasonably anticipated by the pre-deployment medical evaluator not to worsen during the deployment in light of physical, physiological, psychological, and nutritional effects of the duties and location.

(3) Any required, ongoing health care or medications anticipated to be needed for the duration of the deployment are available in theater within the Military Health System. Medication must have no special handling, storage, or other requirements (e.g., refrigeration, cold chain, or electrical power requirements). Medication must be well tolerated within harsh environmental conditions (e.g. heat or cold stress, sunlight) and should not cause significant side effects in the setting of moderate dehydration.

(4) There is no need for routine evacuation out of theater for continuing diagnostics or other evaluations. (All such evaluations should be accomplished before deployment.)

(5) In the case of civilian employees covered by The Rehabilitation Act of 1973, as amended, it is determined, based upon an individualized assessment, that the employee can perform the essential functions of the position in the deployed environment, with or without a reasonable accommodation, without causing undue hardship. In evaluating undue hardship, the nature of the accommodation and the location of the deployment must be considered. Further, the employee's medical condition must not pose a significant risk of substantial harm to the employee or others taking into account the condition of the relevant deployed environment.

c. Individuals with the conditions in Enclosure 3, based on medical assessments in accordance with Enclosure 2 and Reference (l), shall not deploy unless a waiver can be granted according to the procedures in section 3 of Enclosure 2.

d. If a Service member is found qualified for retention with no limitations on assignments or deployments following evaluation of a medical condition by competent medical and personnel authority of his or her respective Service, and if the condition remains stable, a deployment waiver of that same condition is not required by this Instruction.

e. Deploying commanders may add additional medical requirements to the standards in this Instruction based upon the demands of a specific deployment. Commanders may apply these medical standards to other deployments based on the health risk, physical demands, and medical

*DoDI 6490.07, February 5, 2010*

capabilities of the deployment. These additional standards must be consistent with The Rehabilitation Act of 1973, as amended, when applied to civilian employees covered by that Act.

f. Protected health information collected, used, and released in the execution of this Instruction shall be protected as required by DoD 6025.18-R (Reference (n)) and DoD 8580.02-R (Reference (o)).

5. RESPONSIBILITIES. See Enclosure 4.

6. PROCEDURES. See Enclosure 2.

7. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the DoD Issuances Web Site at <http://www.dtic.mil/whs/directives>.

8. EFFECTIVE DATE. This Instruction is effective immediately.



Gail H. McGinn  
Deputy Under Secretary of Defense (Plans)  
Performing the Duties of the  
Under Secretary of Defense for  
Personnel and Readiness

Enclosures:

1. References
2. Procedures
3. Medical Conditions Usually Precluding Contingency Deployment
4. Responsibilities

TABLE OF CONTENTS

REFERENCES .....6

PROCEDURES.....7

    PERFORMANCE OF MEDICAL ASSESSMENTS .....7

    DETERMINATIONS OF DEPLOYABILITY .....7

    WAIVERS .....8

    ROLES AND RESPONSIBILITIES .....8

MEDICAL CONDITIONS USUALLY PRECLUDING CONTINGENCY DEPLOYMENT ....10

RESPONSIBILITIES .....13

    ASD(HA) .....13

    SECRETARIES OF THE MILITARY DEPARTMENTS, COMMANDANT OF THE  
    COAST GUARD, AND THE DIRECTORS OF THE DEFENSE AGENCIES  
    AND THE DoD FIELD ACTIVITIES .....13

    CHAIRMAN OF THE JOINT CHIEFS OF STAFF .....13

    COMBATANT COMMANDERS.....14

    COMMANDER, UNITED STATES SPECIAL OPERATIONS COMMAND  
    (CDRUSSOCOM) .....14

*DoDI 6490.07, February 5, 2010*

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
- (b) DoD Directive 6200.04, "Force Health Protection (FHP)," October 9, 2004
- (c) DoD Directive 1400.31, "DoD Civilian Work Force Contingency and Emergency Planning and Execution," April 28, 1995
- (d) DoD Instruction 1400.32, "DoD Civilian Work Force Contingency and Emergency Planning Guidelines and Procedures," April 24, 1995
- (e) DoD Instruction 3020.41, "Contractor Personnel Authorized to Accompany the U.S. Armed Forces," October 3, 2005
- (f) DoD Instruction 6130.4, "Medical Standards for Appointment, Enlistment, or Induction in the Armed Forces," January 18, 2005
- (g) DoD Directive 6130.3, "Physical Standards for Appointment, Enlistment, and Induction," December 15, 2000
- (h) Under Secretary of Defense for Personnel and Readiness Memorandum, "Policy Guidance for Medical Deferral," February 9, 2006
- (i) Assistant Secretary of Defense for Health Affairs Memorandum, "Policy Guidance for Deployment-Limiting Psychiatric Conditions and Medications," November 7, 2006
- (j) DoD Instruction 6485.01, "Human Immunodeficiency Virus," October 17, 2006
- (k) Sections 791 and 794a of title 29, United States Code (also known as "The Rehabilitation Act of 1973, as amended")
- (l) DoD Instruction 6490.03, "Deployment Health," August 11, 2006
- (m) DoD Directive 1404.10, "DoD Civilian Expeditionary Workforce," January 23, 2009
- (n) DoD 6025.18-R, "DoD Health Information Privacy Regulation," January 24, 2003
- (o) DoD 8580.02-R, "DoD Health Information Security Regulation," July 12, 2007

*DoDI 6490.07, February 5, 2010*

ENCLOSURE 2

PROCEDURES

1. PERFORMANCE OF MEDICAL ASSESSMENTS. All DoD personnel serving in a contingency deployment as defined in section 3 of the front matter of this Instruction must undergo a medical assessment prior to deployment in accordance with subparagraph E4.A1.1.1. of Reference (I). The mandatory portions of the assessment are:

a. Completion of DD Forms 2795, "Pre-Deployment Health Assessment," and 2766, "Adult Preventive and Chronic Care Flowsheet" (available on the Internet at <http://www.dtic.mil/whs/directives/infomgt/forms/formsprogram.htm>). Except for Coast Guard personnel, completed copies of both of these forms must be submitted to the Defense Medical Surveillance System and included in DoD personnel deployment paperwork, and shall serve as the deployment medical record. For Coast Guard personnel, the DD Form 2766 shall be placed in the member's health record, but all other procedures for Coast Guard personnel shall be as described in this Instruction for DoD personnel.

b. Medical record review.

c. Current periodic health assessment (Service members only).

d. Physical exam within 1 year of deployment (DoD civilian employees only).

2. DETERMINATIONS OF DEPLOYABILITY. A trained DoD health-care provider must make a provisional determination on DD Form 2795 as to the deployability of DoD personnel. This decision should be based on all of the information obtained in the medical assessment described in section 1 of this enclosure.

a. In general, DoD personnel with any of the medical conditions in Enclosure 3, and based on a medical assessment, shall not deploy unless a waiver is granted. Consideration should be made for the nature of the disability and if it would put the individual at increased risk of injury or illness, or if the condition is likely to significantly worsen in the deployed environment.

(1) For civilian employees covered by The Rehabilitation Act of 1973, as amended, it must be determined, before deployment and based upon an individualized assessment, that the employee can perform the essential functions of the position in the deployed environment, with or without a reasonable accommodation, without causing undue hardship. In evaluating undue hardship, the nature of the accommodation and the location of the deployment must be considered. Further, the employee's medical condition must not pose a significant risk of substantial harm to the employee or others taking into account the condition of the relevant deployed environment.

*DoDI 6490.07, February 5, 2010*

(2) The requirement to provide reasonable accommodations for disabilities does not apply to deployment of military members, nor to civilian employees not covered by The Rehabilitation Act of 1973, as amended.

b. All individuals deemed not deployable at the deployment processing center shall be returned to their originating unit with a DD Form 2795 and a summary of their non-deployable medical condition to provide to the unit medical personnel. The civilian supervisor shall also be notified if the individual is deemed not deployable.

3. WAIVERS. If a commander or supervisor of DoD personnel (except for SOF personnel) wishes to deploy an individual with a medical condition that could be disqualifying (see Enclosure 3, the commander or supervisor must request a waiver. The waiver request shall be submitted to the applicable Combatant Commander through the individual's servicing military medical unit in the case of a Service member, or through the individual's personnel office in the case of a civilian employee, with medical input provided by the individual's medical provider.

a. Requests for a waiver shall include a summary of a detailed medical evaluation or consultation concerning the medical condition(s). Maximization of mission accomplishment and the protection of the health of personnel are the ultimate goals. Justification shall include statements indicating service experience, position to be placed in, any known specific hazards of the position, anticipated availability and need for care while deployed, the benefit expected to accrue from the waiver, the recommendation of the commander or supervisor, and the reasonable accommodations that can be provided for civilian employees covered by The Rehabilitation Act of 1973, as amended. For all DoD personnel, the factors listed in subparagraphs 4.b.(1) through 4.b.(4), (and subparagraph 4.b.(5) for civilian employees only) of the front matter shall be discussed.

b. For SOF personnel with any of the conditions listed in Enclosure 3, medical clearance may be granted by the CDRUSSOCOM, subject to the approval of the Combatant Commander under which the Service member is deployed or will deploy.

c. In the case of civilian employees covered by The Rehabilitation Act of 1973, as amended, a waiver must be granted if it is determined, based upon an individualized assessment, that the employee can perform the essential functions of the position in the deployed environment, with or without a reasonable accommodation, without causing undue hardship. In evaluating undue hardship, the nature of the accommodation and the location of the deployment must be considered. Further, the employee's medical condition must not pose a significant risk of substantial harm to the employee or others taking into account the condition of the relevant deployed environment.

#### 4. ROLES AND RESPONSIBILITIES

a. Commanders and Supervisors. Commanders and supervisors shall:

*DoDI 6490.07, February 5, 2010*

(1) Ensure deploying DoD personnel are appropriately assessed by competent medical authority before deployment, in accordance with Reference (1).

(2) Request waivers for DoD personnel they wish to deploy who have the medical conditions described in Enclosure 3.

(3) Ensure that DoD personnel under their command meet the medical standards of the gaining commander when individuals and their leaders deploy in support of other DoD Components. As these standards may differ by assignment, they must be coordinated separately for each deployment.

b. Supervisors. Supervisors shall additionally:

(1) Identify medical and physical requirements for deployable positions designated for fill by DoD civilian employees.

(2) Ensure that such requirements are documented in position descriptions, vacancy announcements, and other appropriate sources.

(3) Ensure that DoD civilian employees meet such requirements; take appropriate action when employees no longer meet identified requirements.

c. DoD Personnel

(1) DoD personnel in deployable positions shall be responsible for meeting the medical and physical requirements of their deployment-specific tasks.

(2) DoD personnel who are civilian employees selected for deployment opportunities outside their chain of supervision shall be responsible for meeting and maintaining the medical standards identified for the deployment by the responsible commanding officer.

*DoDI 6490.07, February 5, 2010*ENCLOSURE 3MEDICAL CONDITIONS USUALLY PRECLUDING CONTINGENCY DEPLOYMENT

This list of conditions is not intended to be all-inclusive. A list of all possible diagnoses and their severity that may cause an individual to be potentially non-deployable, pending further evaluation, would be too extensive. Medical evaluators must consider climate, altitude, rations, housing, duty assignment, and medical services available in theater when deciding whether an individual with a specific medical condition is deployable. In general, individuals with the conditions in paragraphs a. through h. of this enclosure, based upon a medical assessment as described in Enclosure 2 and Reference (1), shall not deploy unless a waiver is granted.

a. Conditions Affecting Force Health Protection

(1) Physical or psychological conditions resulting in the inability to effectively wear personal protective equipment, including protective mask, ballistic helmet, body armor, and chemical and/or biological protective garments, regardless of the nature of the condition that causes the inability to wear the equipment if wearing such equipment may be reasonably anticipated or required in the deployed location.

(2) Conditions that prohibit immunizations or the use of force health protection prescription products (FHPPPs) required for the specific deployment. Depending on the applicable threat assessment, required FHPPPs may include atropine, epinephrine, and/or pralidoxime chloride (2-PAM chloride) auto-injectors; certain antimicrobials and antimalarials; and pyridostigmine bromide.

b. Unresolved Health Conditions Requiring Care or Affecting Performance

(1) Any chronic medical condition that requires frequent clinical visits, fails to respond to adequate conservative treatment, or necessitates significant limitation of physical activity.

(2) Absence of a dental exam within the last 12 months or presence of the likelihood that dental treatment or reevaluation for oral conditions will result in dental emergencies within 12 months. Individuals being evaluated by a non-DoD civilian dentist should use DD Form 2813, "DoD Active Duty/Reserve Forces Dental Examination," as proof of dental examination (available on the Internet at <http://www.dtic.mil/whs/directives/infomgt/forms/formsprogram.htm>).

(3) Pregnancy.

(4) Any medical condition that requires either durable medical equipment or appliances, or periodic evaluation or treatment by medical specialists that is not readily available in theater.

(5) Any unresolved acute or chronic illness or injury that would impair duty performance in a deployed environment during the duration of the deployment.

*DoDI 6490.07, February 5, 2010*

(6) Cancer that requires continuing treatment or specialty medical evaluations during the anticipated duration of the deployment.

(7) Precancerous lesions that have not been treated and/or evaluated and that require treatment and/or evaluation during the anticipated duration of the deployment.

(8) Any medical condition that requires surgery or for which surgery has been performed that requires rehabilitation or additional surgery to remove devices.

(9) Any musculoskeletal condition that significantly impairs performance of duties in a deployed environment.

(10) An acute exacerbation of a physical or mental health condition that could significantly affect duty performance.

c. Conditions That Could Cause Sudden Incapacitation

(1) Recurrent loss of consciousness for any reason.

(2) Any medical condition that could result in sudden incapacitation including a history of stroke within the last 24 months, seizure disorders, and diabetes mellitus type I or II treated with insulin or oral hypoglycemic agents.

d. Pulmonary Disorders. Asthma that has a forced expiratory volume-1 (FEV-1) of less than or equal to 60 percent of predicted FEV-1 despite appropriate therapy and that has required hospitalization at least 2 times in the last 12 months, or that requires daily systemic (not inhalational) steroids.

e. Infectious Disease

(1) Active tuberculosis or known blood-borne diseases that may be transmitted to others in a deployed environment.

(2) A diagnosis of human immunodeficiency (HIV) antibody positive with the presence of progressive clinical illness or immunological deficiency. The cognizant Combatant Command surgeon shall be consulted in all instances of HIV seropositivity before medical clearance for deployment.

f. Sensory Disorders

(1) Hearing Loss. The requirement for use of a hearing aid does not necessarily preclude deployment. However, the individual must have sufficient unaided hearing to perform duties safely.

*DoDI 6490.07, February 5, 2010*

(2) Vision Loss. Best corrected visual acuity must meet job requirements to perform duties safely.

g. Cardiac and Vascular Disorders

(1) Hypertension not controlled with medication or that requires frequent monitoring.

(2) Symptomatic coronary artery disease.

(3) History of myocardial infarction within 1 year of deployment.

(4) History of coronary artery bypass graft, coronary artery angioplasty, carotid endarterectomy, other arterial stenting, or aneurysm repair within 1 year of deployment.

(5) Cardiac dysrhythmias or arrhythmias, either symptomatic or requiring medical or electrophysiologic control (presence of an implanted defibrillator and/or pacemaker).

(6) Heart failure.

h. Mental Health Disorders

(1) Psychotic and/or bipolar disorders. (See Reference (i) for detailed guidance on deployment-limiting psychiatric conditions or psychotropic medications.)

(2) Psychiatric disorders under treatment with fewer than 3 months of demonstrated stability.

(3) Clinical psychiatric disorders with residual symptoms that impair duty performance.

(4) Mental health conditions that pose a substantial risk for deterioration and/or recurrence of impairing symptoms in the deployed environment.

(5) Chronic medical conditions that require ongoing treatment with antipsychotics, lithium, or anticonvulsants.

*DoDI 6490.07, February 5, 2010*

ENCLOSURE 4

RESPONSIBILITIES

1. ASD(HA). The ASD(HA), under the authority, direction, and control of the USD(P&R), shall review and issue to the Secretaries of the Military Departments and the Directors of the Defense Agencies and the DoD Field Activities technical adjustments to the deployment standards in Enclosure 3 as needed, based on changing conditions or additional unanticipated difficulties encountered in the in-theater management of medical conditions.

2. SECRETARIES OF THE MILITARY DEPARTMENTS, COMMANDANT OF THE COAST GUARD, AND DIRECTORS OF THE DEFENSE AGENCIES AND THE DoD FIELD ACTIVITIES. The Secretaries of the Military Departments, the Commandant of the Coast Guard, and the Directors of the Defense Agencies and the DoD Field Activities shall:

a. Direct their respective Components to apply and uniformly implement the standards in this Instruction.

b. Ensure that:

(1) All deploying DoD personnel assigned to their respective Service, Defense Agency, or DoD Field Activity have a medical assessment in accordance with Reference (1), including a medical record review, to evaluate their medical status before contingency deployments and other deployments pursuant to paragraph 4.a. of the front matter of this Instruction.

(2) Pre-deployment processes are in place to identify individuals with deployment-limiting medical conditions.

(3) DoD personnel who occupy deployable positions maintain a high state of pre-deployment health and medical readiness.

3. CHAIRMAN OF THE JOINT CHIEFS OF STAFF. The Chairman of the Joint Chiefs of Staff shall ensure that the Combatant Commanders:

a. Establish a minimum standard when developing medical requirements for entering the theater of operations that factors in the medical conditions described in Enclosure 3 of this Instruction.

b. Implement a medical requirements waiver process that includes waiver computerization and archival storage.

*DoDI 6490.07, February 5, 2010*

4. COMBATANT COMMANDERS. For all DoD personnel deployed or deploying to a theater within their respective Combatant Commands, the Combatant Commanders shall:

a. Establish a process for reviewing recommendations from the Services regarding the granting of exceptions to medical standards (waivers) for the conditions in Enclosure 3, including a mechanism to track and archive all approved or denied waivers and the medical conditions requiring the waivers.

b. Serve as the final approval authority for exceptions to the medical standards (waivers) made pursuant to the procedures in this Instruction.

5. COMMANDER, UNITED STATES SPECIAL OPERATIONS COMMAND (CDRUSSOCOM). The CDRUSSOCOM shall perform the responsibilities in section 2 of this enclosure for SOF personnel.

# EXHIBIT I



## DoD INSTRUCTION 1332.45

### RETENTION DETERMINATIONS FOR NON-DEPLOYABLE SERVICE MEMBERS

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**Originating Component:** Office of the Under Secretary of Defense for Personnel and Readiness

**Effective:** July 30, 2018

**Releasability:** Cleared for public release. Available on the Directives Division Website at <http://www.esd.whs.mil/DD/>.

**Incorporates and Cancels:** Office of the Under Secretary of Defense for Personnel and Readiness Memorandum, "DoD Retention Policy for Non-Deployable Service Members," February 14, 2018

**Approved by:** Robert L. Wilkie, Under Secretary of Defense for Personnel and Readiness

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**Purpose:** In accordance with the authority in DoD Directive 5124.02, this issuance:

- Establishes policy, assigns responsibilities, and provides direction for retention determinations for non-deployable Service members.
- Provides guidance and instructions for reporting deployability data for the Total Force.

## TABLE OF CONTENTS

SECTION 1: GENERAL ISSUANCE INFORMATION .....	4
1.1. Applicability. ....	4
1.2. Policy. ....	4
1.3. Information Collections. ....	4
SECTION 2: RESPONSIBILITIES .....	5
2.1. Under Secretary of Defense for Personnel and Readiness (USD(P&R)). ....	5
2.2. Assistant Secretary of Defense for Manpower and Reserve Affairs (ASD(M&RA)). ....	5
2.3. Assistant Secretary of Defense for Health Affairs. ....	5
2.4. Secretaries of the Military Departments. ....	5
SECTION 3: PROCEDURES FOR TRACKING AND REPORTING SERVICE MEMBERS .....	7
3.1. Tracking. ....	7
3.2. Reporting. ....	7
3.3. Deployable with Limitations. ....	8
3.4. Training and Transient. ....	8
a. Initial Entry Training. ....	8
b. Cadets and Midshipman. ....	9
c. All Other Training. ....	9
d. Transient. ....	9
3.5. Temporary Non-Deployable Categories. ....	9
a. Medical. ....	9
b. Legal. ....	9
c. Administrative. ....	10
3.6. Permanent Non-Deployable Categories. ....	11
a. Medical. ....	11
b. Administrative. ....	11
c. Approved for Retention. ....	11
3.7. IMR Deficits. ....	12
a. Overdue PHA. ....	12
b. Dental Readiness (Dental Class 3). ....	12
c. Overdue Dental Screening (Dental Class 4). ....	12
d. Additional IMR Categories. ....	12
3.8. Prioritization of Service Members by Category. ....	12
a. Deployed. ....	12
b. Deployable with Limitations. ....	12
c. Approved for Retention. ....	12
d. Permanent Non-Deployable. ....	12
e. Training and Transient. ....	13
f. Temporary Non-Deployable. ....	13
g. IMR Deficits. ....	14
SECTION 4: RETENTION DETERMINATION .....	15
4.1. Retention Authority for Non-Deployable Service Members. ....	15
4.2. Retention Determination. ....	15
4.3. Special Categories. ....	16

*DoDI 1332.45, July 30, 2018*

SECTION 5: AUTHORITIES FOR SEPARATIONS AND RETIREMENTS ..... 17  
GLOSSARY ..... 18  
    G.1. Acronyms ..... 18  
    G.2. Definitions..... 18  
REFERENCES ..... 20

## **SECTION 1: GENERAL ISSUANCE INFORMATION**

**1.1. APPLICABILITY.** This issuance applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the “DoD Components”).

**1.2. POLICY.** It is DoD policy that:

a. To maximize the lethality and readiness of the joint force, all Service members are expected to be deployable.

b. Service members who are considered non-deployable for more than 12 consecutive months will be evaluated for:

(1) A retention determination by their respective Military Departments.

(2) As appropriate, referral into the Disability Evaluation System (DES) in accordance with DoD Instruction (DoDI) 1332.18 or initiation of processing for administrative separation in accordance with DoDI 1332.14 or DoDI 1332.30. This policy on retention determinations for non-deployable Service members does not supersede the policies and processes concerning referral to the DES or the initiation of administrative separation proceedings found in these issuances.

c. Implementation for this policy is October 1, 2018.

**1.3. INFORMATION COLLECTIONS.** The Monthly Non-deployable Report, referred to in Paragraph 3.2. of this issuance, has been assigned report control symbol DD-P&R(M)2671 in accordance with the procedures in Volume 1 of DoD Manual 8910.01. The expiration date of this information collection is listed in the DoD Information Collections System at <https://apps.sp.pentagon.mil/sites/dodiic/Pages/default.aspx>.

## **SECTION 2: RESPONSIBILITIES**

### **2.1. UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS**

**(USD(P&R)).** The USD(P&R) establishes and oversees policy on retention determinations for non-deployable Service members.

### **2.2. ASSISTANT SECRETARY OF DEFENSE FOR MANPOWER AND RESERVE AFFAIRS (ASD(M&RA)).** Under the authority, direction, and control of the USD(P&R), the ASD(M&RA):

- a. Develops policy on the retention of non-deployable Service members.
- b. Monitors the implementation of this guidance.
- c. Tracks the number of non-deployable Service members and those non-deployable Service members retained in military service and the justification for such retention, in accordance with Section 3 of this issuance.

### **2.3. ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS.** Under the authority, direction, and control of the USD(P&R), the Assistant Secretary of Defense for Health Affairs:

- a. Develops policy recommendations to the USD(P&R) for uniform retention medical standards in coordination with the Secretaries of the Military Departments.
- b. Provides oversight of related medical policies and programs.

### **2.4. SECRETARIES OF THE MILITARY DEPARTMENTS.** The Secretaries of the Military Departments:

- a. Will:
  - (1) Determine the deployability status of Service members.
  - (2) Make retention determinations consistent with this issuance for Service members who have been non-deployable for more than 12 consecutive months.
  - (3) Submit monthly reports identifying the number of non-deployable Service members for all components within their Departments to the Office of the USD(P&R) in accordance with Paragraph 3.2. of this issuance.
  - (4) Monitor compliance with requirements established in DoDI 6025.19 to ensure required evaluations, assessments, and other medically related actions are accomplished to improve individual and overall unit readiness.

*DoDI 1332.45, July 30, 2018*

b. May:

(1) Retain in service those Service members whose period of non-deployability exceeds the 12 consecutive month limit in Paragraph 1.2. of this issuance if determined to be in the best interest of the Military Service.

(2) Delegate the authority in Paragraph 2.4.(b)(1) of this issuance to retain in service those Service members whose period of non-deployability exceeds the 12 consecutive month limit. Such a delegation must be in writing, and may only be made to Presidentially Appointed, Senate-Confirmed officials; Senior Executive Service members; or general/flag officers serving at the Military Department or Service headquarters.

(3) Initiate administrative separation processing, or referral to the DES, as appropriate, prior to a non-deployable Service member being in a non-deployable status for 12 months when the Military Service determines there is a reasonable expectation that the reason will not be resolved and the Service member will not become deployable.

*DoDI 1332.45, July 30, 2018*

## **SECTION 3: PROCEDURES FOR TRACKING AND REPORTING SERVICE MEMBERS**

### **3.1. TRACKING.**

a. The Military Departments will monitor and track the number of Service members by Military Service that are:

(1) Non-deployable in accordance with the categories established in Paragraphs 3.5. and 3.6. of this issuance.

(2) Deployable with limitations in accordance with Paragraph 3.3. of this issuance.

(3) Deployable but have individual medical readiness (IMR) deficits in accordance with Paragraph 3.7. of this issuance.

(4) In training or in a transient status in accordance with the category defined in Paragraph 3.4. of this issuance.

b. To ensure accurate and consistent accounting across the DoD, Military Services will account for Service members in only one category. If a Service member can be accounted for in more than one category, the Service member will be counted only once and in the category with the highest priority listed in accordance with Paragraph 3.8. of this issuance.

### **3.2. REPORTING.**

a. The Secretaries of the Military Departments will report to the ASD(M&RA) the number of non-deployable personnel (and other categories as provided in this section) for all Military Services, and their respective components, on a monthly basis.

(1) The format for the Monthly Non-deployable Report can be found at <https://prhome.defense.gov/M-RA/Inside-M-RA/MPP/OEPM/>.

(2) Reports are due by the end of each month with data current as the last day of the previous month. For example, the June Non-deployable Report is due by June 30th with non-deployable data as of May 31st.

b. The number of non-deployable Service members is reported by categories, either temporary or permanent, and grouped into medical, legal, or administrative sub-categories. Each sub-category is further broken down to account for the specific reasons or conditions that make a Service member non-deployable.

c. The number of Service members who are deployable with limitations, in accordance with Paragraph 3.3. of this issuance, will be categorized separately on the monthly report. Such Service members are not to be counted in the non-deployable populations.

*DoDI 1332.45, July 30, 2018*

d. The number of Service members who require urgent or emergent dental treatment for dental readiness (Dental Class 3), are overdue for annual dental screening (Dental Class 4), or are overdue for a Periodic Health Assessment (PHA) are reported as IMR Deficits in accordance with Paragraph 3.7. of this issuance. Such Service members are not counted in the non-deployable populations.

e. The number of Service members who are in a training or transient status are reported in one of the four categories listed in Paragraph 3.4. of this issuance.

**3.3. DEPLOYABLE WITH LIMITATIONS.** Service members with a medical condition that requires additional medical screening, or Combatant Command approval prior to deployment outside the continental United States, will be categorized as Deployable with Limitations. This includes, but is not limited to, conditions referred to in DoDI 6490.07.

**3.4. TRAINING AND TRANSIENT.** The Training and Transient category provides a means to track the human resources necessary to maintain a healthy force, within current end strength constraints. This category contains Service members who are not immediately ready for deployment and fall into one of the following four categories:

**a. Initial Entry Training.** These Service members are:

(1) Enlisted Service members at recruit training, initial skill training, and other proficiency or developmental training accomplished before moving to the member's first permanent duty assignment. This includes all in-transit time commencing upon entry into active service, through completion of the final course of initial entry training that terminates enlisted trainee status.

(2) Enlisted trainees who enter officer candidate school, officer training school, and Service academy preparatory school following enlistment on active duty. These members will be considered:

(a) Enlisted trainees from initial entry on active duty until commissioning.

(b) Upon commissioning, officer accession students and will remain in the initial entry training category for any subsequent initial entry training, or until they begin travel to their first permanent duty assignment.

(3) Officers at officer basic courses, and all initial skill and proficiency training taken before travel to the Service member's first permanent duty assignment. This includes all in-transit time from entry on active duty until completion of the last initial entry course of instruction.

(4) Reserve Component (RC) Service members (enlisted and officer) who enter the Ready Reserve and are awaiting initial entry training.

*DoDI 1332.45, July 30, 2018*

**b. Cadets and Midshipman.** These are individuals currently attending the U.S. Military Academy, the U.S. Air Force Academy, or the U.S. Naval Academy. In accordance with Section 115 of Title 10, United States Code (U.S.C.), cadets and midshipman are counted in the active duty end strength for their respective Service, but by policy are non-deployable while attending school.

**c. All Other Training.** These are Service members who are attending training that is 20 weeks or more in length, and is conducted after their initial entry training. Examples include Command and Staff Colleges, Senior Service College, the United States Army Sergeants Major Academy, medical residencies, and all other post-graduate professional education opportunities.

**d. Transient.** These are Service members who are not available for duty while executing permanent change of station orders at the time of the report. This category does not include military personnel who are:

(1) On temporary duty for training between permanent duty stations, or;

(2) Moving between entry-level courses of instruction, specifically Service members who have departed from one duty station and are in transit but have not yet reported for duty at the next permanent duty station.

### **3.5. TEMPORARY NON-DEPLOYABLE CATEGORIES.**

**a. Medical.** Service members are considered temporarily non-deployable for one of three reasons:

(1) **Patient.** In accordance with DoDI 1120.11, Service members who are hospitalized and are projected to heal, recover, and return to full duty in less than 12 months are temporarily non-deployable.

(2) **Medical Condition That Limits Full Duty.** Service members who have temporary profiles or are in limited duty status are counted as temporarily non-deployable. Light duty will not be reported as non-deployable unless the duration exceeds 30 days, with discretion given to the medical officer to extend light duty status for up to 60 days, making light duty no longer than 90 days for conditions expected to recover or stabilize within that time.

(3) **Pregnancy (including post-partum).** Service members who are pregnant or in the post-partum phase are temporarily non-deployable. The post-partum phase ranges from 6 to 12 months after childbirth for female Service members and is determined by individual Service policy.

**b. Legal.** Service members are considered temporarily non-deployable for one of two reasons:

(1) **Prisoner.** Service members convicted by civilian or military authorities and sentenced to confinement of more than 30 days, but for 6 months or less, are temporarily non-

*DoDI 1332.45, July 30, 2018*

deployable. Service members confined for more than 6 months are not included in end strength numbers and will not be included in the monthly non-deployability report.

(2) **Legal Action.** Service members who are under arrest, confined 30 days or less, pending military or civil court action, under investigation, a material witness, on commander directed hold, pending non-judicial punishment action under Section 815 of Title 10, U.S.C., also known as Article 15 of the Uniformed Code of Military Justice (UCMJ), or pending discharge based on action under the UCMJ are temporarily non-deployable.

**c. Administrative.** These Service members are considered temporarily non-deployable for one of eight reasons:

(1) **Absent Without Leave or Unauthorized Absence.** Service members who are absent without leave, as defined in Section 886 of Title 10, U.S.C., also known as Article 86 of the UCMJ, will be considered as temporarily non-deployable.

(2) **Family Care Plan.** In accordance with DoDI 1342.19, Service members required but failing to have a family care plan in place are temporarily non-deployable.

(3) **Adoption.** Service members who are single parents or one member of a dual military couple and are adopting a child are temporarily non-deployable. They are non-deployable for at least 6 months after the child is placed in the home, or longer dependent on the administrative stabilization period prescribed by the jurisdiction in which the adoption occurred.

(4) **Service Member Under 18.** Service members who are not yet 18 years of age are temporarily non-deployable. The Child Soldier Prevention Act of 2007 prohibits Service members under the age of 18 from taking part in hostilities as a member of governmental armed forces.

(5) **Humanitarian Assignment.** Service members assigned to a location to provide support to a family member are temporarily non-deployable. These Service members typically receive 12 to 24 months stabilization by Military Service policy.

(6) **Service Discretion.** Military Services may designate Service members temporarily non-deployable when the previous categories do not apply. Examples include:

(a) Simultaneous Membership Program or Officer Candidate School.

(b) Education stabilization; mobilization deferral for affiliation after release from Active Component.

(7) **Pending Administrative Separation.** Service members being processed for administrative separation are temporarily non-deployable.

(8) **Unsatisfactory Participants or Administrative Action Pending (RC Only).** Service members who are determined to be unsatisfactory participants, as defined in DoDI 1215.13, are temporarily non-deployable.

*DoDI 1332.45, July 30, 2018*

### **3.6. PERMANENT NON-DEPLOYABLE CATEGORIES.**

**a. Medical.** Service members are considered non-deployable for one of three reasons listed below.

(1) **Permanent Limited Duty.** Service members with a medical condition that permanently prevents deployment are non-deployable. This includes Service members processed through the DES who are not deployable and were retained in the Military Service. In accordance with Section 1214a of Title 10, U.S.C., Service members cannot be involuntarily administratively separated or denied reenlistment due to unsuitability based solely on the medical condition considered in the evaluation unless the request to separate the Service member is approved by the Secretary of Defense. The Military Service may direct the Service member to reenter the DES process to be reconsidered for retirement or separation for disability.

(2) **Enrolled in DES.** In accordance with DoDI 1332.18, Service members currently enrolled in the DES process are non-deployable. That includes those pending separation or retirement after receiving a “not fit for duty” determination through the DES.

(3) **Permanent Profile Non-duty Related Action Needed (RC).** Those RC Service members who have a permanent profile and are pending a decision on a line of duty determination are non-deployable.

**b. Administrative.** These Service members are considered non-deployable for one of three reasons:

(1) **Sole Survivor, Surviving Family Member, or Deferred from Hostile Fire Zone.** Service members who acquired the status in accordance with DoDI 1315.15 are non-deployable.

(2) **Unable to Carry a Firearm.** Service members who are subject to the provisions of Section 922 of Title 18, U.S.C. are non-deployable.

(3) **Conscientious Objector.** Service members who are granted restriction of military duties in accordance with DoDI 1300.06 are non-deployable.

**c. Approved for Retention.** This category accounts for Service members who are retained by the Military Department despite being in a non-deployable status for 12 months or longer. Service members who the Military Departments retained in Service and are considered non-deployable for one of two reasons:

(1) **Combat Wounded.** These are Service members whose injuries were the result of hostile action, meet the criteria for awarding of the Purple Heart, and whose injuries were not the result of their own misconduct.

(2) **Other.** These are Service members who are not designated as combat wounded but are non-deployable and retained in the Military Service by the Secretary of the Military Department in accordance with Paragraph 2.4. of this issuance.

*DoDI 1332.45, July 30, 2018*

**3.7. IMR DEFICITS.** These IMR categories are not considered non-deployable conditions. Components are expected to immediately correct all IMR deficits to ensure Service members are medically ready to deploy.

**a. Overdue PHA.** These Service members are not compliant with the requirement to complete a PHA in accordance with DoDI 6025.19.

**b. Dental Readiness (Dental Class 3).** Service members who require urgent or emergent dental treatment.

**c. Overdue Dental Screening (Dental Class 4).** Service members who are not compliant with the requirement to complete a dental screening in accordance with DoDI 6025.19.

**d. Additional IMR Categories.** In addition to dental categories (Dental Classes 3 and 4) and PHAs, the Military Departments track three additional areas of IMR: immunization status, medical readiness and laboratory studies, and individual medical equipment. In accordance with DoDI 6025.19, Service members who are not current in these areas are considered partially medically ready.

**3.8. PRIORITIZATION OF SERVICE MEMBERS BY CATEGORY.** This paragraph sets the prioritization for the grouping of Service members into categories to provide consistent reporting among the Military Departments, in accordance with Paragraph 3.1.(b) of this issuance. Service members will be counted only once, in a single category; Service members who may fall into more than one category will be reported in the priorities established in this paragraph. These categories are listed below in descending order of priority.

**a. Deployed.** This category includes Service members who are currently deployed. These Service members will not be counted in any other category (including deployable with limitations or approved for retention).

**b. Deployable with Limitations.**

**c. Approved for Retention.**

(1) Combat wounded – Non-deployable but retained.

(2) Other – Non-deployable but retained.

**d. Permanent Non-Deployable.**

(1) Medical permanent limited duty.

(2) Administrative.

(a) Sole survivor, surviving family member, or deferred from hostile fire zone.

(b) Unable to carry a firearm (e.g., Lautenberg Amendment).

*DoDI 1332.45, July 30, 2018*

- (c) Conscientious objector.
- (d) Ex-prisoner of war.
- (3) Medical Enrolled in DES.
- (4) Permanent profile non-duty related action needed (RC).

**e. Training and Transient.**

- (1) Initial entry training.
- (2) Cadets or Midshipmen.
- (3) All other training.
- (4) Transient (permanent change of station).

**f. Temporary Non-Deployable.**

- (1) Medical.
  - (a) Patient (assigned to “Individuals Account”).
  - (b) Medical condition that limits full duty.
  - (c) Pregnancy (including post-partum).
- (2) Legal.
  - (a) Prisoner.
  - (b) Legal Action.
- (3) Administrative.
  - (a) Absence without leave.
  - (b) Family Care Plan.
  - (c) Adoption.
  - (d) Service member under 18.
  - (e) Humanitarian assignment.
  - (f) Service Discretion.
  - (g) Pending Administrative Separation.

(h) Unsatisfactory participants or admin action pending (RC).

**g. IMR Deficits.**

- (1) Overdue PHA.
- (2) Dental readiness (Dental Class 3).
- (3) Overdue dental screening (Dental Class 4).

*DoDI 1332.45, July 30, 2018*

## **SECTION 4: RETENTION DETERMINATION**

**4.1. RETENTION AUTHORITY FOR NON-DEPLOYABLE SERVICE MEMBERS.** In accordance with Paragraph 2.4. of this issuance, the Secretaries of the Military Departments have retention authority.

### **4.2. RETENTION DETERMINATION.**

a. The Secretaries of the Military Departments may retain Service members who are non-deployable in excess of 12 consecutive months, on a case-by-case basis, if determined to be in the best interest of the Service, based on:

(1) The Service member's ability to perform appropriate military duties commensurate with his or her office, grade, rank, or skill.

(2) The likelihood that the Service member will resolve the condition or reason that is the underlying cause of his or her non-deployable status.

b. The Secretaries of the Military Departments may approve retention for Service members who are non-deployable in excess of 12 consecutive months for up to:

(1) The length of time remaining on a Service member's enlistment contract; or

(2) Three years for officers, including warrant officers, and those enlisted members serving on indefinite contracts.

(3) Upon expiration of the retention period, the Secretary of the Military Department concerned may renew retention for a Service member on a case-by-case basis for periods stated in this paragraph.

c. The Secretaries of the Military Departments may establish procedures for Service members who are or will be non-deployable for 12 months or longer due to an administrative reason to request retention consideration.

d. Approval of the retention for Service members who are non-deployable for 12 months or longer will only be made for individual Service members, not an entire cohort or skill set of Service members.

e. Except as required by DoDI 1332.18, the Secretaries of the Military Departments may request from the Secretary of Defense the authority to automatically exempt Service members serving in specified positions from the requirement for a retention determinations pursuant to Paragraph 2.4.b.

f. When appropriate, Service members not recommended for further retention will be considered for processing for administrative separation in accordance with DoDI 1332.14 or DoDI 1332.30, or referral for disability separation in accordance with DoDI 1332.18.

*DoDI 1332.45, July 30, 2018*

#### **4.3. SPECIAL CATEGORIES.**

a. Pregnant and post-partum Service members, as a group, are exempt from Paragraph 2.4.a., for pregnancy-related health conditions during pregnancy through the post-partum period.

b. The Secretaries of the Military Departments have the authority to retain combat wounded Service members who have been evaluated through the DES and whose reason for non-deployability is a direct result of their combat wounds, if requested by the Service member.

(1) Disapproval of retention for non-deployable combat wounded Service members, who wish to be retained and whose reason for non-deployability is a direct result of their combat wounds, may not be delegated.

(2) Retention will be authorized in accordance with Paragraph 4.2.b.

c. Unless found unfit for duty through the DES, Service members serving in specified positions approved by the Secretary of Defense pursuant to Paragraph 4.2.e. are exempt from requiring a retention determination based solely on being in a non-deployable status for 12 months or longer. Upon reassignment, these Service members will again require a retention determination in accordance with Paragraph 4.2.a.

d. Unless sooner discharged or retired under another provision of law, or discharged due to misconduct or sub-standard performance, the Secretaries of the Military Departments may retain those Service members who are, or will be, non-deployable for 12 months or longer due to administrative reasons and who have attained such years of creditable service so as to be within 3 years of qualifying for:

(1) Regular retirement (or in the case of enlisted members of the Navy or Marine Corps, transfer to the Fleet Reserve or Fleet Marine Corps Reserve, as the case may be) pursuant to Sections 3911, 3914, 6323, 6330, 8911, or 8914 of Title 10, U.S.C.; or

(2) Non-regular retirement (but for age) pursuant to Sections 12731 and 12735 of Title 10, U.S.C., if, in the case of RC members other than RC members within 3 years of qualifying for regular retirement, they have attained at least 17 years of qualifying creditable service as computed in accordance with Section 12732 of Title 10, U.S.C., and continue to attain qualifying creditable service as computed under attains Section 12732 of Title 10, U.S.C. to become eligible for non-regular retirement within the 3-year period.

## **SECTION 5: AUTHORITIES FOR SEPARATIONS AND RETIREMENTS**

5.1. In accordance with Paragraph 1.2. of this issuance, a Service member who has been non-deployable for an administrative reason (not medical or legal) for more than 12 consecutive months, will be processed for administrative separation in accordance with DoDI 1332.14 or DoDI 1332.30. Military Services should ensure expeditious administrative separation proceedings in accordance with Military Department and Military Service policies.

5.2. A Service member who has been non-deployable due to a physical disability that makes him or her potentially unfit for the duties of his or her office, grade, rank, or rating for more than 12 consecutive months will be referred into the DES in accordance with DoDI 1332.18.

## GLOSSARY

### G.1. ACRONYMS.

ASD(M&RA)	Assistant Secretary of Defense for Manpower and Reserve Affairs
DES	Disability Evaluation System
DoDI	DoD instruction
IMR	individual medical readiness
PHA	periodic health assessment
RC	Reserve Component
UCMJ	Uniformed Code of Military Justice
U.S.C.	United States Code
USD(P&R)	Under Secretary of Defense for Personnel and Readiness.

**G.2. DEFINITIONS.** Unless otherwise noted, these terms and their definitions are for the purpose of this issuance.

**active duty.** Defined in the DoD Dictionary of Military and Associated Terms.

**active service.** Defined in Section 101(d)(3) of Title 10, U.S.C.

**active status.** Defined in Section 101(d)(4) of Title 10, U.S.C.

**combat wounded.** Service members whose injuries were the result of hostile action, who meet the criteria for awarding of the Purple Heart, and whose injuries were not the result of their own misconduct.

**deployable.** A Service member who does not have a Service-determined reason that precludes him or her from deployment.

**deployment.** The movement of personnel into and out of an operational area or in support of operations. Deployment encompasses all activities from origin or home station through destination, specifically including inter-theater, and intra-theater movement legs, staging, and holding areas.

**Military Departments.** The Departments of the Army, Navy, and Air Force.

**Military Service Headquarters.** Headquarters, United States Army; Headquarters, United States Navy; Headquarters, United States Air Force; and Headquarters, United States Marine

Corps.

**Military Services.** The United States Army, the United States Navy, the United States Air Force, and the United States Marine Corps.

**military specialty.** A military occupational specialty in the Army and the Marine Corps; an Air Force specialty code in the Air Force; or a rating or Navy enlisted classification in the Navy.

**non-deployable.** A Service member who has a Service-determined reason that precludes him or her from deployment.

**permanently non-deployable.** A Service member who has a reason that precludes them from deployment, and there is a Service expectation that the reason will not be resolved and the Service member will never be deployable.

**profile.** A document used to communicate to commanders the individual medical restrictions for Soldiers and Airmen.

**Ready Reserve.** Defined in the DoD Dictionary of Military and Associated Terms.

**reason code.** The term used to define non-deployable categories.

**separation.** A general term that includes discharge, release from active duty, release from custody and control of the Military Services, transfer to the Individual Ready Reserve, and similar changes in Active and Reserve status.

**temporarily non-deployable.** A Service member who has a reason or reasons that precludes him or her from deployment, and there is a Service expectation that the reason or reasons will be resolved and the Service member will be deployable.

*DoDI 1332.45, July 30, 2018*

## REFERENCES

- DoD Directive 5124.02, “Under Secretary of Defense for Personnel and Readiness (USD(P&R)),” June 23, 2008
- DoD Instruction 1120.11, “Programming and Accounting for Active Component (AC) Military Manpower,” March 17, 2015
- DoD Instruction 1215.13, “Ready Reserve Member Participation Policy” May 5, 2015
- DoD Instruction 1300.06, “Conscientious Objectors,” July 12, 2017
- DoD Instruction 1315.15, “Special Separation Policies for Survivorship,” May 19, 2017
- DoD Instruction 1332.14, “Enlisted Administrative Separations,” January 27, 2014, as amended
- DoD Instruction 1332.18, “Disability Evaluation System (DES),” August 5, 2014, as amended
- DoD Instruction 1332.30, “Commissioned Officer Administrative Separations,” May 11, 2018
- DoD Instruction 1342.19, “Family Care Plans,” May 7, 2010, as amended
- DoD Instruction 6025.19, “Individual Medical Readiness (IMR),” June 9, 2014
- DoD Instruction 6490.07. “Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees” February 5, 2010
- DoD Manual 8910.01, Volume 1, “DoD Information Collections Manual: Procedures for DoD Internal Information Collections,” June 30, 2014, as amended
- Office of the Chairman of the Joint Chiefs of Staff, “DoD Dictionary of Military and Associated Terms,” current edition
- The Child Soldier Prevention Act of 2007, 110<sup>th</sup> Congress, S.1175
- United States Code, Title 10
- United States Code, Title 18

# EXHIBIT J



## Department of Defense **INSTRUCTION**

**NUMBER 6485.01**  
June 7, 2013

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USD(P&R)

**SUBJECT:** Human Immunodeficiency Virus (HIV) in Military Service Members

**References:** See Enclosure 1

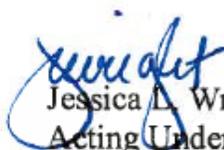
1. **PURPOSE.** In accordance with the authority in DoD Directive (DoDD) 5124.02 (Reference (a)), this instruction reissues DoD Instruction (DoDI) 6485.01 (Reference (b)) to establish policy, assign responsibilities, and prescribe procedures for the identification, surveillance, and management of members of the Military Services infected with HIV and for prevention activities to control transmission of HIV.
2. **APPLICABILITY.** This instruction applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD.
3. **POLICY.** It is DoD policy to:
  - a. Deny eligibility for military service to persons with laboratory evidence of HIV infection for appointment, enlistment, pre-appointment, or initial entry training for military service pursuant to DoDI 6130.03 (Reference (c)).
  - b. Periodically screen Service members for HIV infection.
4. **RESPONSIBILITIES.** See Enclosure 2.
5. **PROCEDURES.** See Enclosure 3.
6. **RELEASABILITY.** **Unlimited.** This instruction is approved for public release and is available on the Internet from the DoD Issuances Website at <http://www.dtic.mil/whs/directives>.

*DoDI 6485.01, June 7, 2013*

7. EFFECTIVE DATE. This instruction:

a. Is effective June 7, 2013.

b. Must be reissued, cancelled, or certified current within 5 years of its publication in accordance with DoDI 5025.01 (Reference (d)). If not, it will expire effective June 7, 2023 and be removed from the DoD Issuances Website.

  
Jessica D. Wright  
Acting Under Secretary of Defense for  
Personnel and Readiness

Enclosures

1. References
2. Responsibilities
3. Procedures

Glossary

TABLE OF CONTENTS

ENCLOSURE 1: REFERENCES.....4

ENCLOSURE 2: RESPONSIBILITIES.....5

    UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS  
        (USD(P&R)).....5

    ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS (ASD(HA)).....5

    UNDER SECRETARY OF DEFENSE FOR POLICY (USD(P)).....5

    SECRETARIES OF THE MILITARY DEPARTMENTS.....5

ENCLOSURE 3: PROCEDURES.....6

    TESTING AND SCREENING.....6

    MANAGEMENT.....6

    TRANSMISSION CONTROL.....7

    ADVERSE PERSONNEL ACTION.....7

    PRIVACY.....7

GLOSSARY .....8

    PART I: ABBREVIATIONS AND ACRONYMS .....8

    PART II: DEFINITIONS.....8

*DoDI 6485.01, June 7, 2013*

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
- (b) DoD Instruction 6485.01, "Human Immunodeficiency Virus," October 17, 2006 (hereby cancelled)
- (c) DoD Instruction 6130.03, "Medical Standards for Appointment, Enlistment, or Induction in the Military Services," April 28, 2010, as amended
- (d) DoD Instruction 5025.01, "DoD Directives Program," September 26, 2012
- (e) DoD Directive 6490.02E, "Comprehensive Health Surveillance," February 8, 2012
- (f) DoD Instruction 6025.19, "Individual Medical Readiness (IMR)," January 3, 2006
- (g) DoD Instruction 6490.03, "Deployment Health," August 11, 2006
- (h) DoD Instruction 6025.13, "Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)," February 17, 2011
- (i) DoD 6025.13-R, "Military Health System (MHS) Clinical Quality Assurance Program (CQA) Regulation," June 11, 2004
- (j) DoD Instruction 6490.07, "Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees," February 5, 2010
- (k) DoD Instruction 1332.38, "Physical Disability Evaluation," November 14, 1996, as amended
- (l) Section 705(c) of Public Law 99-661, "National Defense Authorization Act for Fiscal Year 1987," November 14, 1986
- (m) DoD 5400.11-R, "Department of Defense Privacy Program," May 14, 2007
- (n) DoD 6025.18-R, "DoD Health Information Privacy Regulation," January 24, 2003

*DoDI 6485.01, June 7, 2013*

ENCLOSURE 2

RESPONSIBILITIES

1. UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS (USD(P&R)). The USD(P&R) provides overall policy implementation guidance for:

a. The personnel management of Service members with laboratory evidence of HIV infection.

b. Compliance with host-nation requirements for screening and related matters for Service members.

2. ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS (ASD(HA)). Under the authority, direction, and control of the USD(P&R), the ASD(HA) provides overall policy implementation guidance for the medical management of Service members with laboratory evidence of HIV infection and for health education programs to prevent the transmission of HIV.

3. UNDER SECRETARY OF DEFENSE FOR POLICY (USD(P)). The USD(P):

a. Identifies or confirms host-nation HIV screening and other related requirements and transmits this information to the USD(P&R).

b. Coordinates matters involving host-nation screening and other related requirements with the Department of State.

4. SECRETARIES OF THE MILITARY DEPARTMENTS. The Secretaries of the Military Departments:

a. Implement this instruction and any guidance issued under the authority of this instruction.

b. Report HIV test results to the Defense Medical Surveillance System pursuant to DoDD 6490.02E (Reference (e)).

c. Direct health care personnel providing medical care to follow the recommendations of the Centers for Disease Control and Prevention for preventing HIV transmission in health-care settings.

*DoDI 6485.01, June 7, 2013*

ENCLOSURE 3

PROCEDURES

1. TESTING AND SCREENING

a. Applicants for appointment, enlistment, or individuals being inducted into the Military Services will be screened for laboratory evidence of HIV infection in accordance with Reference (c).

b. Applicants to the U.S. Service Academies, the Uniformed Services University of the Health Sciences, and other officer candidate programs will be tested for laboratory evidence of HIV within 72 hours of arrival to the program and denied entry to the program if such test is positive. Reserve Officer Training Corps program cadets and midshipmen must be tested for laboratory evidence of HIV not later than during their commissioning physical examination, and denied a commission if they test positive.

c. All Service members will be screened periodically for laboratory evidence of HIV infection.

(1) Active duty (AD) and Reserve Component (RC) Selected Reserve (SELRES) personnel will be routinely screened every 2 years unless more frequent screenings are clinically indicated.

(2) Members of the SELRES will be screened at least once every 2 years. RC personnel will be screened when called to a period of AD greater than 30 days if they have not received an HIV test within the last 2 years.

(3) Testing for laboratory evidence of HIV for pre- and post-deployment must be conducted in accordance with DoDI 6025.19 (Reference (f)) and DoDI 6490.03 (Reference (g)).

d. A serum sample from all HIV force screenings will be forwarded to the DoD Serum Repository as directed by Reference (e).

2. MANAGEMENT

a. Clinical management of an AD Service member and an RC Service member on AD for a period of more than 30 days with laboratory evidence of HIV infection will be conducted consistent with standard of care, evidence-based HIV clinical practice standards, and medical management guidelines, as described in DoDI 6025.13 and DoD 6025.13-R (References (h) and (i)).

*DoDI 6485.01, June 7, 2013*

b. In accordance with DoDI 6490.07 (Reference (j)), the cognizant Combatant Command surgeon will be consulted in all instances of HIV seropositivity before medical clearance for deployment.

c. An AD Service member with laboratory evidence of HIV infection will be referred for appropriate treatment and a medical evaluation of fitness for continued service in the same manner as a Service member with other chronic or progressive illnesses in accordance with DoDI 1332.38 (Reference (k)). An AD Service member with laboratory evidence of HIV infection determined to be fit for duty will be allowed to serve in a manner that ensures access to appropriate medical care.

d. An RC Service member with laboratory evidence of HIV infection will be referred for a medical evaluation of fitness for continued service in accordance with Service regulations, and in the same manner as an RC Service member with other chronic or progressive illnesses. Eligibility for active duty for a period of more than 30 days will be denied to those RC Service members with laboratory evidence of HIV infection (except under conditions of mobilization and on the decision of the Secretary of the Military Department concerned). RC Service members who are not on active duty for a period of more than 30 days or who are not on full-time National Guard duty, and who show laboratory evidence of HIV infection, will be transferred involuntarily to the Standby Reserve only if they cannot be used in the SELRES.

e. AD and RC Service members with laboratory evidence of HIV infection who are determined to be unfit for further duty will be separated or retired pursuant to Reference (k).

3. TRANSMISSION CONTROL. Transmission of HIV will be controlled through aggressive disease surveillance and health education programs for Service members. A Service member with laboratory evidence of HIV infection will receive training on the prevention of further transmission of HIV infection to others and the legal consequences of exposing others to HIV infection.

4. ADVERSE PERSONNEL ACTION. Information obtained during or primarily as a result of an epidemiologic assessment interview will not be used to support any adverse personnel action against the Service member in accordance with section 705(c) of Public Law 99-661 (Reference (l)). This prohibition does not apply to the use of such information for otherwise authorized rebuttal or impeachment purposes.

5. PRIVACY. The privacy of a Service member with laboratory evidence of HIV infection will be protected consistent with DoD 5400.11-R and DoD 6025.18-R (References (m) and (n)).

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

AD	active duty
ASD(HA)	Assistant Secretary of Defense for Health Affairs
DoDD	DoD Directive
DoDI	DoD Instruction
HIV	human immunodeficiency virus
RC	Reserve Component
SELRES	Selected Reserves
USD(P&R)	Under Secretary of Defense for Personnel and Readiness
USD(P)	Under Secretary of Defense for Policy

PART II. DEFINITIONS

These terms and their definitions are for the purposes of this instruction.

adverse personnel action. A court-martial, non-judicial punishment, involuntary separation for other than medical reasons, administrative or punitive reduction in grade, denial of promotion, an unfavorable entry in a personnel record (other than an accurate entry concerning an action that is not an adverse personnel action), or a bar to reenlistment other than for medical reasons.

epidemiologic assessment interview. Questioning of a Service member who has been confirmed by DoD to have laboratory evidence of HIV infection for purposes of medical treatment or counseling or for epidemiologic or statistical purposes.

HIV. The virus(es) associated with the acquired immune deficiency syndrome (commonly referred to as “AIDS”).

laboratory evidence of HIV infection. A reactive and confirmed serologic result, and/or, reactive or quantitative nucleic acid result for HIV infection according to a Food and Drug Administration-approved test.