

## BIOGRAPHICAL SKETCH

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NAME Fiscus, Susan A.	POSITION TITLE  Professor		
eRA COMMONS USER NAME (credential, e.g., agency login) SFISCUS			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Bates College, Lewiston, ME	BS	1968	Biology
Duke University, Durham, NC	MA	1971	Botany
Colorado State University, Ft. Collins, CO	PhD	1986	Microbiology
Colorado State University, Ft. Collins, CO	Postdoctoral	1986	Microbiology

### A. Personal Statement

I am a Professor in the Department of Microbiology and Immunology at the University of North Carolina (UNC) School of Medicine, and have directed the UNC ACTG funded Clinical Retrovirology Laboratory since 1989. Under my leadership, the ACTG validated a number of important assays used to monitor study patients on treatment including the original p24 antigen assay and quantitative HIV RNA PCR. Our group also validated assays for monitoring HIV in genital secretions, CSF, and breast milk. We also validated the use of dried blood spots for viral load monitoring and early infant diagnosis used in resource constrained settings. More recently in 2006, I became the first Laboratory PI for the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network. In that role, I had primary responsibility over all laboratory functions and operations including: (1) Network Leadership as a member of the Scientific Oversight Committee, Network Executive Committee, Protocol Costing Working Group, Site PIF and Budget Committee and Network Leadership Committee; (2) Chair of the IMPAACT Laboratory Steering Committee; (3) Chair of the IMPAACT Laboratory Directors Committee; and (4) Chair of the IMPAACT Central Laboratory QA/QC Committee. We have continued to validate new assays for monitoring of infection on treatment and diagnosis of infection in HIV exposed children.

### B. Positions and Honors

Bates Key, Phi Kappa Phi - 1986  
Sigma Xi -1987

### Research and Professional Experience

1970-1976 Senior Med. Tech., Clinical Immunology, Duke University Medical Center, Durham, NC  
 1976-1982 Lab. Tech. II, Department of Pathology, Colorado State University, Ft. Collins, Colorado  
 1982-1986 Senior Res. Scientist, Syngene Prod. & Res., Ft. Collins, Colorado  
 1986-1989 Post-doctoral Fellow, Depts. of Microbiology & Pathology, Colorado State University  
 1989-1995 Assistant Professor of Microbiology & Immunology University of North Carolina at Chapel Hill (UNC)  
 1989-1995 Assistant Professor of Pathology & Laboratory Medicine, UNC  
 1989-1995 Director, Retrovirology Core Lab, UNC  
 1995-2000 Associate Professor of Microbiology & Immunology, UNC  
 1995-2000 Associate Professor of Pathology & Laboratory Medicine, UNC  
 1999-2007 Director, Center for AIDS Research (CFAR) Virology Laboratory, UNC  
 2000- Professor of Microbiology & Immunology, UNC

2000- Professor of Pathology & Laboratory Medicine, UNC  
2006- IMPAACT Central Laboratory Principal Investigator  
2008- Associate Director of CFAR Virology Laboratory, UNC

### C. Selected Peer-reviewed Publications (selected from 185)

#### Most relevant to the current application

1. Chasela C, Hudgens M, Jamieson D, Kayira D, Hosseinipour M, Kourtis A, Knight R, Ahmed Y, Kamwendo D, Hoffman I, Ellington S, Wiener J, **Fiscus S**, Mofolo I, Sichali D, van der Horst C. 2010.Reduced HIV-1 transmission with either maternal antiretrovirals or infant nevirapine: the Breastfeeding, Antiretrovirals, and Nutrition (BAN) Study. *NEJM* 362:2271-81. PMID: PMC 3440865.
2. PENPACT-1 (PENTA 9/PACTG 390) Study Team, Babiker A, Castro nee Green H, Compagnucci A, **Fiscus S**, Giaquinto C, Gibb DM, Harper L, Harrison L, Hughes M, McKinney R, Melvin A, Mofenson L, Saidi Y, Smith ME, Tudor-Williams G, Walker AS. First-line antiretroviral therapy with a protease inhibitor versus non-nucleoside reverse transcriptase inhibitor and switch at higher versus low viral load in HIV-infected children: an open-label, randomised phase 2/3 trial. *Lancet Infectious Dis* 11:273-283. PMID: PMC3111069.
3. Flynn PM, Mirochnick M, Shapiro DE, Bardeguez A, Rodman J, Robbins B, Huang S, **Fiscus SA**, Van Rompay KK, Rooney JF, Kearney B, Mofenson LM, Watts DH, Jean-Philippe P, Heckman B, Thorpe E Jr, Cotter A, Purswani M; PACTG 394 Study Team. Pharmacokinetics and safety of single-dose tenofovir disoproxil fumarate and emtricitabine in HIV-1-infected pregnant women and their infants. *Antimicrob Agents Chemother*. 2011 Dec;55(12):5914-22. Epub 2011 Sep 6. PMID: PMC3232794.
4. Jamieson DJ, Chasela CS, Hudgens MG, King CC, Kourtis AP, Kayira D, Hosseinipour MC, Kamwendo DD, Ellington SR, Wiener JB, **Fiscus SA**, Tegha G, Mofolo IA, Sichali DS, Adair LS, Knight RJ, Martinson F, Kacheche Z, Soko A, Hoffman I, van der Horst C; BAN study team. Maternal and infant antiretroviral regimens to prevent postnatal HIV-1 transmission: 48-week follow-up of the BAN randomized controlled trial. *Lancet*. 2012 Jun 30;379(9835):2449-58. doi: 10.1016/S0140-6736(12)60321-3. Epub 2012 Apr 26. PMID: 22541418. NIHMSID: NIHMS408835
5. Nielsen-Saines K, Komarow L, Cu-Uvin S, Jourdain G, Klingman KL, Shapiro DE, Mofenson L, Moran L, Campbell TB, Hitti J, **Fiscus S**, Currier J; ACTG 5190/PACTG 1054 Study Team. Infant outcomes after maternal antiretroviral exposure in resource-limited settings. *Pediatrics*. 2012 Jun;129(6):e1525-32. Epub 2012 May 14. PMID: PMC3362906.

#### **Additional recent publications of importance to the field**

1. Kerr RJ, Player G, **Fiscus SA**, Nelson JA. Qualitative human immunodeficiency virus RNA analysis of dried blood spots for diagnosis of infections in infants. *J Clin Microbiol*. 2009 Jan;47(1):220-2. Epub 2008 Nov 12. PMID: PMC2620881.
2. Cachafeiro A, Sherman GG, Sohn AH, Beck-Sague C, **Fiscus SA**. Diagnosis of human immunodeficiency virus type 1 infection in infants by use of dried blood spots and an ultrasensitive p24 antigen assay. *J Clin Microbiol*. 2009 Feb;47(2):459-62. Epub 2008 Dec 10. PMID: PMC2643698.
3. Nelson JA, Loftis AM, Kamwendo D, Fawzi WW, Taha TE, Goldenberg RL, **Fiscus SA**. Nevirapine resistance in human immunodeficiency virus type 1-positive infants determined using dried blood spots stored for up to six years at room temperature. *J Clin Microbiol*. 2009 Apr;47(4):1209-11. Epub 2009 Feb 18. PMID: PMC2668311.
4. Napravnik S, Cachafeiro A, Stewart P, Eron JJ Jr, **Fiscus SA**. HIV-1 viral load and phenotypic antiretroviral drug resistance assays based on reverse transcriptase activity in comparison to amplification based HIV-1 RNA and genotypic assays. *J Clin Virol*. 2010 Jan;47(1):18-22. Epub 2009 Nov 5. PMID: PMC2818273.
5. Chen YQ, Young A, Brown ER, Chasela CS, **Fiscus SA**, Hoffman IF, Valentine M, Emel L, Taha TE, Goldenberg RL, Read JS. Population attributable fractions for late postnatal mother-to-child

- transmission of HIV-1 in Sub-Saharan Africa. *J Acquir Immune Defic Syndr*. 2010 Jul;54(3):311-6. PMID: PMC3086731.
6. Farr SL, Nelson JA, Ng'ombe TJ, Kourtis AP, Chasela C, Johnson JA, Kashuba AD, Tegha GL, Wiener J, Eron JJ, Banda HN, Mpasu M, Lipscomb J, Matiki C, **Fiscus SA**, Jamieson DJ, van der Horst C; BAN Study Team. Addition of 7 days of zidovudine plus lamivudine to peripartum single-dose nevirapine effectively reduces nevirapine resistance postpartum in HIV-infected mothers in Malawi. *J Acquir Immune Defic Syndr*. 2010 Aug;54(5):515-23. Erratum in: *J Acquir Immune Defic Syndr*. 2011 Oct 1;58(2):e53. PMID: PMC2913302.
  7. Gay CL, Mwapasa V, Murdoch DM, Kwiek JJ, **Fiscus SA**, Meshnick SR, Cohen MS. Acute HIV infection among pregnant women in Malawi. *Diagn Microbiol Infect Dis*. 2010 Apr;66(4):356-60. PMID: PMC2864613.
  8. Stewart P, Cachafeiro A, Napravnik S, Eron JJ, Frank I, van der Horst C, Bosch RJ, Bettendorf D, Bohlin P, **Fiscus SA**. Performance characteristics of the Cavidix ExaVir viral load assay and the ultra-sensitive P24 assay relative to the Roche Monitor HIV-1 RNA assay. *J Clin Virol*. 2010 Nov;49(3):198-204. Epub 2010 Sep 15. PMID: PMC3025774.
  9. Mwapasa V, Cachafeiro A, Makuta Y, Beckstead DJ, Pennell ML, Chilima B, Mwangomba B, **Fiscus SA**, Kwiek JJ. Using a simplified human immunodeficiency virus type 1 p24 antigen assay to diagnose pediatric HIV-infection in Malawi. *J Clin Virol*. 2010 Dec;49(4):299-302. Epub 2010 Sep 19. PMID: PMC2981665.
  10. Jennings C, Harty B, Granger S, Wager C, Crump JA, **Fiscus SA**, Bremer JW. Cross-platform analysis of HIV-1 RNA data generated by a multicenter assay validation study with wide geographic representation. *J Clin Microbiol*. 2012 Aug;50(8):2737-47. Epub 2012 Jun 12. PubMed Central PMID: PMC3421531.

## D. Research Support

### Ongoing Research Support

- |  |                    |                   |
|--|--------------------|-------------------|
| 5 R37 DK049381-17<br>HIV in Semen-Effects of STDs and Antiviral Therapy<br>To understand the biology of HIV in the male genital tract and semen to improve both HIV treatment and prevention. The specific aims of this renewal are: 1) to detect patients with acute HIV infection (AHI) and 2) compare HIV in blood and semen.<br>Role: Co-investigator  | Cohen (PI)         | 5/1/96- 4/30/15   |
| 5 P30 AI50410-15<br>National Inst. of Health<br>UNC Center for AIDS Research (Core D-Virology/Cancer Core)<br>This lab develops new assays and provides state of the art existing virologic assays to members of CFAR.<br>Role: Associate Virology Core Director   | Nelson (PI Core D) | 8/20/01- 7/31/16  |
| 5 UM1 AI100645-01<br>Center for HIV/AIDS Vaccine Immunology (CHAVI) ID (Subcontract)<br>UNC will participate in a multi-center effort to develop a new HIV vaccine strategy. The overall goals are 1) elucidate early viral and immunological events and host genetic factors associated with HIV-1 transmission, establishment of productive infection, and (partial) containment of virus replication, 2) determine correlates of SIV immune protection in primates, 3) design, develop, and test novel immunogens and adjuvants that elicit persistent mucosal and/or systemic immune responses in human and primates, and 4) evaluate HIV-1 vaccine candidates in early phase trials.<br>Role: UNC Repository Director | Haynes (PI)        | 7/15/12 - 6/30/13 |

BRS-IMPCT-Q-06-00102

Fiscus (PI)

7/01/06 - 5/31/13

Social & Scientific Systems, Inc.

IMPAACT Central Laboratory

Serve as the IMPAACT CENTRAL LABORATORY that will be responsible for overall laboratory operations providing scientific leadership, setting laboratory priorities, establishing SOPs for specimen management, training, helping to transfer technology, overseeing quality assurance and quality control (QA/QC) and performance in the network laboratories, delegating responsibilities to other network laboratory directors, and collaborating with other networks.

Role: Central Laboratory PI

5 R01 AI083059-04

Miller (PI)

8/01/09 - 7/31/13

Acute HIV Infection-A Key Link for Transmission Prevention

To 1) develop a novel program to prevent HIV transmission by identifying and informing persons with acute HIV infection (AHI) in Lilongwe, Malawi, 2) intervene using motivational interviewing and short term antiretroviral therapy in person with AHI, and 3) determine the potential individual and combined impact of each component of the intervention using mathematical modeling.

Role: Co-Investigator

### **Completed Research Support**

R56 AI091547

Fiscus (PI)

9/15/10 - 8/31/12

National Inst. of Health

Breastmilk Transmission of HIV: Virology, Pharmacokinetics, and Adherence in BAN (No Cost Ext)

We propose to develop strategies that will prevent future transmission, such as improving adherence, or using combination maternal HAART and infant prophylaxis.

Role: PI