

BIOGRAPHICAL SKETCH

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NAME: Gay, Cynthia Leigh

eRA COMMONS USER NAME (credential, e.g., agency login): cindygay

POSITION TITLE: Clinical Associate Professor of Medicine/Infectious Diseases

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Duke University, Durham, NC	BA	05/1990	Interdisciplinary Studies
University of Maryland, College Park, MD	N/A	08/1992	Post Graduate Pre Medical Course Work
University of North Carolina, School of Public Health, Chapel Hill, NC	MPH	08/1998	Maternal and Child Health
University of North Carolina, School of Medicine, Chapel Hill, NC	MD	05/1999	Medicine
Vanderbilt University, Nashville, TN	Residency	06/2002	Internal Medicine
University of North Carolina Hospitals, School of Medicine, Chapel Hill, NC	Fellowship	06/2006	Infectious Diseases

A. Positions and Honors**Positions and Employment**

6/2002 - 8/2002 Staff physician, Department of Veterans Affairs Medical Center, Nashville, TN
6/2002 - 8/2002 Critical Care physician, Tennessee Christian and Centennial Medical Centers, Nashville, TN
8/2002 - 5/2003 Medical Director, HIV Clinic and Antiretroviral Program, Medicíns Sans Frontieres, Uganda
2004 - 2005 Physician/Researcher, Research Project, UNC Project Malawi, Lilongwe, Malawi
7/2006 - 5/2015 Clinical Assistant Professor, Department of Medicine, Division of Infectious Diseases, University of North Carolina at Chapel Hill, Chapel Hill, NC
5/2010 - 10/2012 Senior HIV/AIDS Clinical Advisor. IntraHealth International, Chapel Hill, NC
4/2011 - 10/2013 Technical Advisor on Sexually Transmitted Infections, Sexual Health and HIV Prevention, Wits Health Consortium, Johannesburg, South Africa
5/2015 - Associate Professor, Department of Medicine, Division of Infectious Diseases, University of North Carolina at Chapel Hill, Chapel Hill, NC
1/2016 - Medical Director, HIV Cure Center, University of North Carolina at Chapel Hill, Chapel Hill, NC

Other Experience and Professional Memberships

2005 - Consultant, NC DHHS Screening and Tracing Active Transmission Program (STAT)
2006 - Co-investigator, AIDS Clinical Trials Unit (ACTU), University of North Carolina, Chapel Hill 2006
- Member, International AIDS Society
2006 - Member, Infectious Diseases Society of America
2006 - Reviewer for Antiviral Therapy Journal
2008 - Reviewer for Journal of Acquired Immune Deficiency Syndromes
2009 - Editorial Board, Sexually Transmitted Diseases Journal

- 2009 - Reviewer for Clinical Infectious Diseases journal
- 2011 - Reviewer for Journal of International AIDS Society
- 2012 - Reviewer for PLoS One
- 2014 - Grant Reviewer, Special Emphasis Panel/Scientific Review Group, National Institute of Health
- 2015 - Director, UNC HIV Transplant Program
- 2015 - Grant Reviewer, NIH, National Institute of Dental and Craniofacial Research
- 2016 - Grant Reviewer, NIH, National Institute of Dental and Craniofacial Research
- 2016 - Medical Director, University of North Carolina HIV Cure Center

B. Contribution to Science

Acute HIV infection. For over a decade, I have worked on the programmatic detection and management of acute HIV infection (AHI) with the North Carolina STAT program, a statewide screening program for AHI. I have contributed to demonstrating that widespread screening for and treatment during AHI is feasible and effective. Our AHI program served as the model for the Center for HIV/AIDS Vaccine Immunology (CHAVI) 001 and 012 studies of AHI, exploring immunologic and virologic events during AHI to inform vaccine development. I have also contributed to showing the public health importance of screening for and treating AHI via studies of the sexual networks of patients with AHI.

- a. Wu H, Hightow-Weidman LB, **Gay CL**, Zhang X, Beagle S, Hall L, Jackson T, Marmorino J, Do AN, Peters PJ. Unreported male sex partners among men with newly diagnosed HIV infection - North Carolina, 2011-2013. *MMWR Morb Mortal Wkly Rep.* 2015 Sep 25;64(37):1037-1041. PMID: 26401589.
- b. Cope AB, Crooks AM, Chin T, Kuruc JD, McGee KS, Eron JJ, Hicks CB, Hightow-Weidman LB, **Gay CL**. Incident sexually transmitted infection as a biomarker for high risk sexual behavior after diagnosis of acute HIV. *Sex Transm Dis.* 2014 Jul;41(7):447-66. PMID: PMC4191902.
- c. **Gay C**, Dibben O, Anderson JA, Stacey A, Mayo AJ, Norris PJ, Kuruc JD, Salazar-Gonzalez JF, Li H, Keele BF, Hicks C, Margolis D, Ferrari G, Haynes B, Swanstrom R, Shaw GM, Hahn BH, Eron JJ, Borrow P, Cohen MS. Cross-sectional detection of acute HIV infection: timing of transmission, inflammation and antiretroviral therapy. *PLoS One.* 2011 May 10;6(5):e19617. PMID: PMC3091862.
- d. Ferrari G, Korber B, Goonetilleke N, Liu MK, Turnbull EL, Salazar-Gonzalez JF, Hawkins N, Self S, Watson S, Betts MR, **Gay C**, McGhee K, Pellegrino P, Williams I, Tomaras GD, Haynes BF, Gray CM, Borrow P, Roederer M, McMichael AJ, Weinhold KJ. Relationship between functional profile of HIV-1 specific CD8 T cells and epitope variability with the selection of escape mutants in acute HIV-1 infection. *PLoS Pathog.* 2011 Feb 10;7(2):e1001273. PMID: PMC3037354.

Treatment during Acute HIV Infection. I have been the PI for five acute HIV treatment studies at UNC and remain PI of an ongoing AHI longitudinal cohort study.

- a. Vinikoor MJ, Cope A, **Gay CL**, Ferrari G, McGee KS, Kuruc JD, Lennox JL, Margolis DM, Hicks CB, Eron JJ. (2013) Antiretroviral therapy initiated during acute HIV infection fails to prevent persistent T cell activation. *J Acquir Immune Defic Syndr.* 2013 Apr;15(62):505-8. PMID: PMC3683110.
- b. **Gay CL**, Mayo AJ, Mfalila CK, Chu H, Barry AC, Kuruc JD, McGee KS, Kerkau M, Sebastian J, Fiscus SA, Margolis DM, Hicks CB, Ferrari G, Eron JJ; Duke-UNC Acute HIV Infection Consortium. Efficacy of NNRTI-based antiretroviral therapy initiated during acute HIV infection. *AIDS.* 2011 Apr 24;25(7):941-9. PMID: PMC3569481
- c. [McKellar MS](#), [Cope AB](#), **Gay CL**, [McGee KS](#), [Kuruc JD](#), [Kerkau MG](#), [Hurt CB](#), Fiscus S, [Ferrari G](#), [Margolis DM](#), [Eron JJ](#), [Hicks CB](#). Acute HIV infection in the Southeastern United States: A Cohort Study. (2012) *AIDS Res Hum Retroviruses.* 2013 Jan;29(1):121-8. PMID: 22839749. PMID: PMC3537297.

Novel HIV Testing: I have led studies of the use of fourth-generation, combined antigen/antibody testing for the diagnosis of HIV and acute HIV in real world settings.

- a. Peters PJ, Westheimer E, Cohen S, Hightow-Weidman LB, Moss N, Tsoi B, Hall L, Fann C, Daskalakis DC, Beagle S, Patel P, Radix A, Foust E, Kohn RP, Marmorino J, Pandori M, Fu J, Samandari T, **Gay**

- CL.** Screening yield of HIV antigen/antibody combination and pooled HIV RNA testing for acute HIV infection in a high-prevalence population. JAMA. 2016 Feb 16;315(7):682-90. PMID: 26881371.
- b. Wu H, Hightow-Weidman LB, **Gay CL**, Zhang X, Beagle S, Hall L, Jackson T, Marmorino J, Do AN, Peters PJ. Unreported male sex partners among men with newly diagnosed HIV infection - North Carolina, 2011-2013. MMWR Morb Mortal Wkly Rep. 2015 Sep 25;64(37):1037-1041. PMID: 26401589.
 - c. Peters PJ, **Gay C**, Beagle S, Shankar A, Switzer WM, Hightow-Weidman LB; Centers for Disease Control and Prevention (CDC). HIV Infection among partners of HIV-infected black men who have sex with men - North Carolina, 2011-2013. MMWR Morb Mortal Wkly Rep. 2014 Feb 7;63(5):90-4. PMID: 24500287.
 - d. Pandori MW, Westheimer E, **Gay C**, Moss N, Fu J, Hightow-Weidman LB, Craw J, Hall L, Giancotti FR, Mak ML, Madayag C, Tsoi B, Louie B, Patel P, Owen SM, Peters PJ. The Multispot rapid HIV-1/HIV-2 differentiation assay is comparable with the Western blot and an immunofluorescence assay at confirming HIV infection in a prospective study in three regions of the United States. J Clin Virol. 2013 Dec;58 Suppl 1:e92-6. PMID: 24342485.

Expanded HIV Testing. During my early career, I expanded HIV testing, early HIV diagnosis and operations research. I have contributed to demonstrating feasibility and acceptability of expanding HIV testing in real world settings, including the emergency department, an infectious disease clinic and sexually transmitted infection clinics.

- a. Hightow-Weidman L, Beagle S, Pike E, Kuruc J, Leone P, Mobley V, Foust E, **Gay C**. "No one's at home and they won't pick up the phone": using the internet and text messaging to enhance partner services in North Carolina. Sex Transm Dis. 2014 Feb;41(2):143-8. PMID: 24413497.
- b. Hoots B, Klein P, Martin IB, Leone P, Quinlivan E, Larson J, Young J, Miller M, **Gay C**. Implementation of a collaborative HIV testing model between an Emergency Department and Infectious Diseases Clinic. J Acquir Immune Defic Syndr. 2014 Jul 1;66(3):e67-70. PMID: 24675588.
- c. Bischof JJ, Bell LL, Pierce JK, Cooper KL, Heine AD, Quinlivan EB, **Gay CL**. Detecting HIV among persons accompanying patients to an infectious diseases clinic. Sex Transm Dis. 2014 Jan;42(1):54-6. PMID: 25504303.
- d. Bishoff JJ, Kuruc JD, Embry JA, Hatch JE, Ashton FA, Schmitz JL, Miller WC, Leone PA, **Gay CL**. Prospective study of the ARCHITECT HIV Ag/Ab Combo fourth generation assay to detect HIV infection in sexually transmitted infection clinics. AIDS. 2011 Sep;25(15):1925-1929. PMID: 21811138.

Complete List of Published Work in MyBibliography:

<http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PgT7IEFIAJBtGMRDdWFmiWAO/?sort=date&direction=ascending>

C. Research Support

Ongoing Research Support

HIV Vaccine Trials Network/ HIV Prevention Trials Network (HVTN/HPTN) 03/2016-
HVTN 704/HPTN 085 - A phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection among men and transgender persons who have sex with men.

Role: Site PI

AIDS Clinical Trials Group (ACTG) (Gay, Protocol Vice-Chair, Site PI 01/01/14-11/30/16
A5326- Safety, Pharmacokinetics and Immunotherapeutic Activity of an Anti-PD-L1 Antibody (BMS-936559) in HIV-1 Infected Participants on Suppressive cART: A Phase I, Double-Blind, Placebo-Controlled, Ascending Single Dose Study

U01AI117844-01 NIH/NIAID (Gay, Site PI) 03/01/15-02/28/20
A Pilot Trial of the Effect of Vorinostat and AGS-004 on Persistent HIV-1 Infection

CARE Collaboratory, U19-A1096113-02, Supplement (Gay Study PI) 07/08/11-06/30/16
A Phase I/II Study to Evaluate the Kinetics of the Immunologic Response and Virologic Impact of AGS-004 in HIV-Infected Individuals Suppressed on Antiretroviral Therapy Initiated During Acute and Chronic HIV Infection

HIV Prevention Trials Network (HPTN) (Gay, Site PI) Ongoing
HPTN 069 - A Phase II Randomized, Double-Blind, Study of the Safety and Tolerability of Maraviroc (MVC), Maraviroc + Emtricitabine (MVC+FTC), Maraviroc + Tenofovir disoproxil fumarate (MVC+TDF), or Tenofovir disoproxil fumarate + Emtricitabine (TDF+FTC) for Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission in At-Risk Men Who Have Sex with Men and in At-Risk Women

Argos Therapeutics, Inc., N01AI60019-11-0-1 (Gay, Co-PI) 05/25/11-07/31/16
AGS-004-003- A Randomized, Double Blind, Phase 2B Study Testing the Efficacy and Safety of AGS-004 on Host Control of HIV Replication during Analytical Treatment Interruption

U01 AI069423-04 NIH/NIAID (Gay, Co-Investigator) 12/01/13-11/30/19
UNC AIDS Clinical Trials Unit
The major goal is to provide an effective and efficient system to evaluate the safety and efficacy of the therapeutic interventions against HIV infection and associated conditions.

North Carolina Department of Health and Human Services 01516-09 (Gay, PI) 04/01/12-08/31/16
The ONE CALL Program. The goal of the program is to implement and evaluate a statewide HIV call center facilitating linkage and re-entry to care for HIV-infected patients and non-HIV providers.

Investigator initiated study supported by Gilead Sciences, Inc. (Gay, PI) 12/04/12-12/31/16
CID-12-1274 Treatment of Acute HIV Infection with Elvitegravir, Cobicistat, Emtricitabine, and Tenofovir Disoproxil Fumarate [Quad FDC Tablet], a Study of Response to Therapy and HIV Pathogenesis

Investigator initiated study supported by VIIV Healthcare (Gay, PI) 03/31/15-03/31/20
IGHID 11417 - PHI 05 - The Safety and Efficacy of Fixed Dose Combination
Dolutegravir/Abacavir/Lamivudine FDC Initiated During Acute HIV Infection: Impact on the Latent HIV Reservoir and Long-Term Immunologic Effect

Completed Research Support

amFAR Research Grant, 108839-55-RGRL (Gay, PI) 01/01/14-12/31/15
Safety and Immunologic and Virologic Response to HIV-CTL Therapy in HIV Infection

Centers for Disease Control and Prevention 1U01PS001559-01 (Gay, PI) 06/01/10-06/01/15
Screening Targeted Populations to Interrupt Ongoing Chains of Transmission with Enhanced Partner Notification - The STOP Study

Center for HIV/AIDS Vaccine Immunology, 5U19AI067854-07 06/14/10-06/15/13
CHAVI 001 Acute HIV-1 Infection Prospective Cohort Study
Role: Co-Investigator

Investigator initiated study supported by Janssen Pharmaceuticals (Gay, PI) 10/19/09-12/31/15
CID 0821 - Pilot Study to Evaluate HIV Viremia and Persistence in Acutely HIV-Infected Antiretroviral Naive Patients Treated With Darunavir/Ritonavir and Etravirine