CENTER FOR ETHICS EDUCATION
HIV & DRUG ABUSE PREVENTION
RESEARCH ETHICS TRAINING INSTITUTE
Celia B. Fisher, Ph.D., Director
fordham.edu/ethicsinstitute

HIV & Drug Abuse Prevention Research Ethics Training Institute (RETI)

Ethics Training at the Forefront of HIV and Drug Abuse Research

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Why Conduct Research on Research Ethics?

- The global HIV/AIDS and drug abuse pandemics urgently require empirically informed interventions
- Population vulnerabilities create ethical challenges and jeopardize scientific validity and participant protections
- The scientific training and moral reflections of Investigators and IRBs may not be sufficient to address these challenges.



Goodness-of-Fit Ethics (GFE)

Fisher 1999, 2002, 2004, 2014; Fisher, Brunnquel et al., 2013; Fisher & Goodman, 2009; Fisher & Ragsdale, 2006; Masty & Fisher, 2008



 Needed: Studies that provide an empirical basis for research ethics policies and practices fitted to participant values and lived experiences.



GOOD ETHICS IS NOT TANGENTIAL BUT ESSENTIAL FOR GOOD SCIENCE

Research on Research Ethics Identifies Barriers and Facilitators to Research Participation Essential to Successful Study Implementation

Recruitment
Study retention
Informed and voluntary consent
Fair and non-coercive compensation
Validity of participant responses to planned procedures
Community assistance and acceptance



Fordham Institute (RETI) Basics



Now approaching its **10th** year, the NIDA funded HIV/drug abuse research ethics training institute (RETI) has admitted **50** early-career investigators in the social, behavioral, medical and public health fields.

Trainees:

- Attend 2 Summer Training Institutes in New York City
- Receive \$30,000 to conduct a Mentored Research Project (MRP)
- Engage communities in research design, implementation, and dissemination
- Access to a web-based platform for HIV/drug abuse prevention ethics resources and collegial exchange
- Continued mentoring for professional development



Interdisciplinary Faculty and Advisory Committee

The program has outstanding, diverse multidisciplinary faculty with expertise in in the conduct and ethics evaluation of HIV and drug abuse prevention research conducted in the U.S. and in international settings.

Celia B. Fisher, Ph.D.

Leslie Alexander, Ph.D.

Julia Arnsten, M.D., M.P.H.

Brandon Brown, Ph.D., M.P.H.

Elizabeth Buchanan, Ph.D.

Silvia Cunto-Amesty, M.D.

Brenda L. Curtis, Ph.D., M.S.P.H.

Sherry Deren, Ph.D.

Don C. Des Jarlais, Ph.D.

James DuBois, Ph.D., D.Sc.

David S. Festinger, Ph.D.

Susan Fish, Pharm.D., M.P.H.

Timothy Flanigan, M.D.

Faith Fletcher, Ph.D.

Lloyd Goldsamt, Ph.D.

Robert Klitzman, M.D.
Gerald P. Koocher, Ph.D.
Sarah Lord, Ph.D.
Ruth Macklin, Ph.D.
David Marcotte, SJ, Ph.D.
Michael Marshal, Ph.D.
Patricia Marshall, Ph.D.
Lisa A. Marsch, Ph.D.
Tina Maschi, Ph.D.
E. Doyle McCarthy, Ph.D.
Jon Frederick Merz, Ph.D., J.D.
Monica Rivera Mindt, Ph.D.
Brian Mustanski, Ph.D.

Kaveh Khoshnood, Ph.D., M.P.H.

Mary Ott, M.D.
Sean Philpott-Jones, Ph.D., M.S.B.
Jonathon Rendina, Ph.D.
Alexis Roth, Ph.D., M.P.H.
Michele Shedlin, Ph.D.
Jama Shelton, Ph.D., M.S.W.
Janie Simmons, Ed.D.
David H. Strauss, M.D.
Jeremy Sugarman, M.D., M.P.H.
Kristen Underhill, Ph.D., J.D.
Scyatta Wallace, Ph.D.
Margaret Weeks, Ph.D.



Summer Institute Curriculum



AIM 1: Increase trainees' knowledge of and capacity to address ethical issues in HIV/drug abuse prevention research

Year 1: Seminars on current ethical challenges in HIV/drug abuse research, federal and international guidelines, mentored research projects design and instrumentation, and engagement with community advisory boards.

Year 2: Advanced seminars on research ethics issues, analysis, publication, professional and community dissemination and grant writing associated with mentored research project.

Post-Institute: Continued guidance for publication, teaching, grant applications, and professional development; Institute participation as faculty lecturers, advisory committee members, and peer-mentors



Mentored Research Project (MRP)

AIM 2: Increase fellows' capacity to design and implement research om research ethics exploring HIV/drug abuse current challenges encountered by trainees and their colleagues:

- Pre-Institute Mentoring: Literature review and project abstract
- A faculty mentor with expertise in trainees' MRP area providing regular in-person and remote guidance over 2 years
- \$30,000 funding for data collection and conference presentations
- Support for publication and grant writing





Community Advisory Boards (CABs)

AIM 3: Increase capacity to engage communities in the construction, interpretation and dissemination of HIV/drug abuse research

 CABS contribute to population sensitive procedures and measures, successful recruitment, interpretation, and dissemination of MRP results

 2 CAB meetings are required at the design and interpretation stages of the MRP



Bronx Community Research Review Board



MRPs Around the World

- Brandon Brown: Ethics of HPV vaccine trials in Peru
- Lianne Urada: Female sex workers consent in the Philippines
- Roberto Abadie: Trust among PWID in Puerto Rico
- Charmaine Thokoane: Sexual health programs for youth in South Africa
- Thespina Yamanis: HIV prevention and finance training of young men in Tanzania
- Arunansu Talukdar: Informed consent or partner consent of women patients LWH India
- Shira Goldenberg: FSW/Migrant sex workers risks and benefits of research participation in Guatemala
- Anthony Estreet: Research trust among BMSM substance users PLWH in Baltimore

- Randy Hubach, use of ecological momentary assessment in US rural MSM
- Thomas Guadamuz: Consent for YMSM in HIV prevention research in Thailand
- Sean Young: Social media for HIV Prevention studies in Peru
- Rebecca Fielding-Miller: Emotional distress amount frontline research staff in **Swaziland**
- Courtney Peasant Bonner: HIV testing and prevention to reach vulnerable women in Cape Town, South Africa
 - Argentina Servin: Adolescent perspectives on HIV and GBV research participation in **Mexico**
- Stacy Ryan: Drug court interventions for justice involved youth,

 Texas



MRP Publications

Since completing training, Institute fellows have published over 300 articles related to HIV/drug abuse prevention and/or research ethics: 44 articles directly based on their MRP

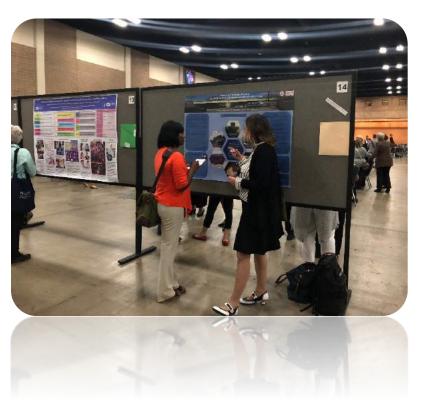
- Ethics & Behavior
- Journal of Empirical Research on Research Ethics (JEHRE)
- PLOS One
- Addictive Behaviors
- Prevention Science: Official Journal of the Society for Prevention Research
- AIDS Care
- Substance Use & Misuse
- Journal of the International AIDS Society
- Journal of Psychoactive Drugs
- BMC: International Health and Human Rights

- The Hastings Center Report
- Sexually Transmitted Diseases
- Journal of Immigrant and Minority Health
- Journal of the Association of Nurses
- International Journal of Public Health
- International Journal of Gynecology and Obstetrics: Official Journal of the International Federation of Gynecology and Obstetrics
- Culture, Health & Sexuality



MRP Professional Presentations

To-date, RETI Fellows and Alumni have given over 230 MRP-related presentations.



- APHA Annual Meeting
- APA Annual Meeting
- PRIM&R Annual Meeting
- GEOMED Annual Meeting
- International AIDS Conference
- NIH
- Society for Behavioral Medicine Annual Meeting
- Society for Applied Anthropology Annual Meeting
- British Sociological Association Annual Meeting
- National Bioethics Conference
- National HIV Prevention Conference
- EDUCAVIDA



Institute Fellows at PRIM&R

Award Winners for Public Responsibility in Medicine & Research: Suzanne Carlberg-Rachich, Alexis Roth, Abby Rudolph, Kristen Underhill





Suzanne Carlberg-Racich, 2017

Morgan Philbin, 2018

Shira Goldenberg, 2018



Institute Fellows and NIH Programs

NIH program officers attend the Summer Institute to speak with fellows about NIH funding for their MRPs

Each year a visit to NIH is organized by RETI for fellows to present their MRP projects to program officers.



From left to right: Randy Hubach (RETI Fellow), Nancy Jones (NIMHD Program Officer), Eliseo Perez-Stable (NIMHD Director), Celia B. Fisher (RETI Director), Aaliyah Gray (Fordham University PhD Candidate), Anthony Estreet (RETI Fellow), and Stacy Ryan-Pettes (RETI Fellow)



Continued Professional Development

AIM 4: RETI Alumni serve as institute faculty, mentors, and members of our advisory board and receive continued professional development guidance from RETI faculty



Faith Fletcher, PhD Assistant Professor University of Alabama

"Stigma, Vulnerability, and Distrust among Black Women Living with HIV," July 2019



Jonathon Rendina, Ph.D., M.P.H. Assistant Professor Hunter College, City University of New York

"Stigma and Sexual Minority Stress," July 2019

Jonathon Rendina is also a member of the MAC.



HIV and Drug Abuse Prevention

Research Ethics

Training Institute

Brandon Brown, PhD, MPHAssistant Professor, University of California, Riverside

"Ethical Issues in the Use of Research Incentives," July 2019

Brandon Brown also served as a peermentor.



Alexis Roth, JD, Ph.D., M.P.H. Assistant Professor, Drexel University

"Assessing Participant Perspectives on the Risks and Benefits of Substance Use Research" & "Putting It Together: Developing an Interview Guide," July 2019

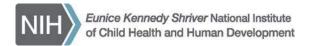
Alexis Roth is also a member of the MAC.

NIH Awards/Grants Post-Institute

Since entering the Institute, trainees received 132 grants and awards

Michelle Broaddus, Peter Davidson, Jennifer Hettema, Cynthia Pearson, Elizabeth Reed, Purnima Madhivanan, Lianne Urada, Brandon Brown, Brenda Curtis, Shira Goldenberg, Thomas Guadamuz, Kristen Underhill, Alexis Roth, Sean Young, Erin Bonar, Faith Fletcher, Julia Lechuga, Abby Rudolph, Nina Yamanis, Kimberly Nelson, Jonathon Rendina, and John Sauceda.



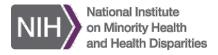


















NIH...Turning Discovery Into Health®







Online Research Ethics Resources

- Podcasts, YouTube Videos and Downloadable Faculty Lectures
- Research Ethics Scales and Measures and HIV/Drug Abuse Research Ethics Bibliography (over 500 articles)
- Monthly Newsletter including NIH Funding Opportunities

In 2018, the *Ethics & Society* blog and Institute Website had over **70,000** views and **21,000** visitors from **181** countries!



Fordham Ethics Channel





Applying to Become a RETI Fellow Application requirements, questions, and more.



Applying to Become a RETI Fellow

- 1. Curriculum Vita
- 2. Official transcript from highest completed degree
- 3. Two letters of recommendation from:
 - A senior member of your current institution (e.g. postdoctoral supervisor or department chair) describing how your RETI training and research will be encouraged and supported at your institution
 - A senior colleague who can describe your work and contributions to HIV prevention research
- 4. Lead-authored or other peer-reviewed empirical article that best reflects ability to independently design and implement the proposed for project.





1. Statement of Interest

Your specific interest in HIV or drug use prevention research ethics. What ethical challenges have you experienced in your work?

Statement should demonstrate familiarity with contemporary issues in research ethics (300 words)



2. Research Experience:

Description of you HIV/drug abuse research, relevant training, scholarship (i.e. publications), funding and awards, and immediate and long-term research and career goals.

Description of the research methods and data analytic techniques you have mastered specifically relevant to the proposed project. (500 words)



3. MRP Proposal: Description of the HIV prevention research ethics topic you would like to examine for your (MRP) (700 words):

Relationship to current/parent research Specific aims of the project Sample and sample size Research Design



4. Feasibility:

Document your access to the sample and extent to which the research environment at your home institution will support your work on the MRP. (300 words)



Becoming a RETI Fellow

Remember to Propose Research Ethics Topics!!!

- Informed Consent
- Fair vs. Undue Incentives
- Research Risks and Benefits
- Equipoise in Treatment and Control Conditions
- Confidentiality and Privacy Risks and Protections
- IRB, Investigator, Research Staff Perceptions of Research Ethics Practices & Policies

Examples of MRP Topics & Populations

- IRB attitudes toward HIV/drug abuse research
- Secondary trauma among HIV research staff
- Research capacity building for AIAN community
- Recruitment barriers & mistrust among BMSM
- Informational risks in mHealth research
- Informed consent preparedness among YMSM,
- Due and undue influence of monetary incentives for HIV/drug abuse research
- Risks and benefits of peer-delivered HIV interventions with PWID





Becoming a RETI Fellow: MRP Budget

\$30,000 (plus 8% indirect costs)

The **Year 1** budget includes participant payments, research assistants, the first community advisory board meeting, travel for data collection, and other related costs, e.g. statistical software, audio recorders, copyrighted measures

The **Year 2** budget for research assistants, data analysis, and the second community advisory board. Support for conference travel and registration fees based on the expectation that the MRP manuscript has been submitted for publication.



Becoming a RETI Fellow

2020 Program: July 13 – 21, 2020 New York City

Application Deadline: Wednesday, February 20th,

2020

Homepage:

fordham.edu/ethicsinstitute

Application:

fordham.edu/info/24031/applying_to_the_institute/629 5/application_requirements

