Fordham HIV and Drug Abuse Prevention Research Ethics Training Institute

Summer 2017 Institute Guide

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Fordham University, New York City

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I. Institute Overview

Welcome to the 2017 Fordham University HIV and Drug Abuse Prevention Research Ethics Training Institute (RETI)! In this section, you will find information about the Institute, including a broad overview of the program’s background and goals, details on the summer training program and mentored research project, contact details for fellows from previous years, instructions for accessing Institute readings and resources, details on program evaluations and accommodations, and information about the Fordham Center for Ethics Education.

About the Institute

The Fordham RETI, supported by a grant from the National Institute on Drug Abuse (#R25 DA031608: PI Celia B. Fisher) and additional funding by Santander Universities to Fordham University was initiated in 2011 to train a new generation of sexual health and substance abuse early career investigators with the skills and dedication to conduct empirical research on HIV, drug abuse and related sexual health research ethics models and practices. The Institute provides early career scientists with education, mentoring, and financial and technical support to generate ethically relevant empirical data designed to inform the decisions of investigators, IRBs, regulators, and community stakeholders, in the creation of research ethics policies and practices. Institute fellows’ biographies and projects are available at fordham.edu/info/24053/institute_fellows. The Institute also maintains an information and collaborative research web-based network fostering ongoing research, publications, and pedagogical materials to sustain advancements in national and international HIV and drug abuse research ethics practices and policies.

The RETI program involves a two-year commitment, and provides early-career investigators in HIV prevention research with the following opportunities:

• A structured summer training program for fellows in their first year.

• A two-year mentored research project generating empirical data on an ethical issue in HIV prevention and related drug use research.

• An advanced summer seminar for fellows in their second year, focusing on data analysis, publication and research dissemination.

• Continued guidance on career development in HIV research ethics prevention grants, publications and presentations.

• Continued access to social media communication networks designed to promote ongoing dialogue among Institute fellows, faculty and others in the field of HIV and drug abuse prevention research ethics, and provide a forum for disseminating knowledge, posing and answering questions, and promoting discussion on the responsible conduct of HIV prevention and related drug use research.

• Continued access to web resources including a continuously updated research ethics scales and measures webpage and HIV prevention, a newsletter and blog containing the latest funding and other news in the field, a selected bibliography of relevant articles, links to research ethics regulations and guidelines, and links to relevant governmental and organizational resources.
Summer Training Program

RETI fellows are expected to make a 2-year commitment, beginning with an intensive summer program conducted by our interdisciplinary faculty of experts in HIV and drug abuse research and research ethics. Faculty biographies are available on the RETI website (fordham.edu/ethicsinstitute).

The summer Institute offers lectures, discussions, skill-based exercises, and faculty and peer mentoring for fellows to: (a) gain knowledge in issues and empirical research on HIV and related drug use research ethics including recruitment, confidentiality, informed consent, risk-benefit analysis, social harm, standard of prevention and post-trial care and other ethical issues across diverse populations and research designs; (b) acquire skills to address and empirically examine research ethics challenges; and (c) to design, implement, interpret and disseminate data generated from their mentored research project (MRP).

All scheduled activities will take place at our Fordham University Lincoln Center Campus at 113 West 60th Street in Manhattan, NY. Fellows are expected to attend all scheduled activities on the Institute agenda.

To view the Summer Training Program curriculum and agenda, please see page 18.

Mentored Research Project (MRP)

Prior to the Institute, fellows speak with Dr. Celia Fisher and their mentors to begin refining their research plans and prepare a preliminary abstract and literature review. The MRP can be designed as a supplement to a current research investigation or as a stand-alone project, and all projects must include involvement of a community advisory board. During the first summer training program, each fellow receives individualized mentoring, and faculty and peer feedback on a proposal for an original study that empirically examines a key ethical issue related to the fellow’s area of HIV and drug abuse research. Fellows work directly with Dr. Fisher and their RETI faculty mentor (assigned based on their common research interests), to design a study that will inform and enhance the responsible conduct of HIV and drug abuse prevention research. The role of the faculty research mentor is to guide the fellow during the first year in designing and implementing his or her MRP, and during the second year assisting in the analysis and dissemination of results. Incoming fellows meet with their MRP mentor during the 8-day summer program.

Fellows will receive a small grant of up to $20,000 (plus an additional 8% indirect costs to their institution) to cover MRP costs upon Institute approval of a final budget and project proposal and IRB approval from the fellow’s home institution. The grant can cover costs of recruitment and participant compensation, travel for data collection, research assistants, recorders and other devices for data collection, transcription, statistical software, use of copyright measures, dissemination through conference presentations and publication, and other relevant expenses. **Monies may not be used for capital costs/furniture, computers, RETI Fellow salary, or course reduction. All travel must be approved in advance by the Program Director.** Additional funding is available on a competitive basis for dissemination and grant proposals related to the MRP after fellows have completed their second year.

**Timeline:** Immediately following acceptance, fellows engage in pre-institute conference calls and preparation of an abstract and literature review related to their MRP for their first summer institute. Following the Institute, during their first year Fellows are expected implement the MRP with data collection completed and initial analysis conducted in time for presentation and feedback at their second July Institute. In their second year fellows are expected to complete their analysis and begin submitting MRP manuscripts for publication and abstracts for conferences presentations. Detailed timelines for the MRP in Years 1 and 2 are available on page 29-30. Fellows should consult with their mentors bi-monthly throughout the research process.

All MRP forms and instructions are provided at the end of the Guidebook and available on the RETI “Resources for Fellows” webpage.
Incoming and Returning RETI Fellows 2017

In 2017, the RETI Multidisciplinary Advisory Council selected 8 accomplished early-career health researchers. New fellows will join the 5 fellows from last year and our faculty at the 2017 Summer Institute. Contact information for the fellows is provided on pages 13-17. Detailed biographies of all Institute fellows are available by visiting the Institute website (fordham.edu/ethicsinstitute).

Program Evaluation

The RETI is committed to annual program evaluation and continued improvement. Fellows and faculty complete annual, anonymous post-Institute surveys including evaluation and suggestions for improvement of the summer Institute and MRP experiences. All measures are administered online using firewall and other confidentiality protections in standard use by the Fordham Center for Ethics Education. Post-Institute survey links will be sent immediately following the summer program. Responses are due by August 4, 2017. Fellows’ 6, 12, 18, and 24-month MRP progress and project summary reports are used to further assess and improve the program. For a detailed timeline of when these reports are due, please see pages 29-30. The Institute is also dedicated to assisting and following the progress of our alumni and collects yearly updates of alumni achievements (see also information below about our monthly newsletter).

Program Accommodations and Logistics

RETI fellows and faculty receive support for travel, lodging, and meals for each summer institute. During the 2017 program, hotel accommodations have been arranged at the Washington Jefferson Hotel (318 West 51st Street; 212-246-7550), and is within walking distance of Fordham University’s Lincoln Center Campus (W 60th Street and Columbus Avenue) where Institute activities will be held. Individual travel arrangements are coordinated for each fellow by Lori Merone (ethicsadm@fordham.edu; 718-817-0926). Fellows will be provided with coffee and light fare in the morning and lunch most days during the Institute. There will be three group dinners held during the course of the Institute. The dates and times of these dinners are indicated on the program agenda (please see pages 18-28.) Fellows will be on their own for dinner on the remaining evenings, three mornings for breakfast and one day for lunch. Fellows will be provided with a stipend of $34 per night to spend on dinner, $17 per morning to spend on breakfast and $18 per day to spend on lunch. These funds and funds for the few mornings devoted to individual work will be distributed upon arrival. Please note that alcoholic beverages cannot be covered by these funds.
Readings and Resources

Resources on RETI Website. RETI participants have access to a comprehensive bibliography of readings and resources in research ethics generally and HIV prevention and related drug abuse research ethics specifically. These readings, as well as other resources, are available through the RETI website’s “HIV and Drug Abuse Research Ethics Resources” page found at fordham.edu/ethicsinstitute. Readings are organized by topic, and largely follow the order of the program curriculum. Readings will also be put into a shared Google Drive and fellows will find specific readings assigned to correspond to each presentation, and should review these readings prior to the relevant sessions. Please do not hesitate to contact Rimah Jaber, Program Administrator, at (718) 817-0927 or ethicsinst@fordham.edu if you have any questions or experience any difficulty accessing the shared Google Drive folder.

Newsletter. RETI current and former fellows, as well as faculty and mentors, receive a monthly newsletter from the Center for Ethics Education. This newsletter will provide fellows with RETI news, funding opportunities, calls for papers and abstracts and upcoming conferences and meetings. RETI fellows and faculty are encouraged to send any updates on their work to Rimah Jaber at ethicsinst@fordham.edu for inclusion in the newsletter.

Resources and Measures Webpages. In addition to resources made available on Google Drive, the Fordham University Center for Ethics Education has also compiled a public resource in HIV and drug abuse prevention research ethics. This website, researchethicsmeasures.org, features a selected continuously-updated bibliography of relevant research articles and chapters, links to national and international guidelines and regulations, and links to government and organization resources.

Social Media/Blog. The Center for Ethics Education operates a blog called Ethics and Society (ethicsandsociety.org) and uses Twitter (twitter.com/fordhamethics). The blog has and will continue to be wonderful outlet for ethical analysis and summaries of research projects and awards by RETI faculty, fellows and alumni. Our blog posts have been reposted by the Huffington Post and the international Social Justice Solutions. Please send any updates, news or blog posts to Rimah Jaber at ethicsinst@fordham.edu.

Digital Media and Resources. The Center for Ethics Education also provides collection of digital media on our YouTube channel, Fordham Ethics, which includes videos of faculty lectures and a podcast of interviews with leaders in the field of HIV/drug abuse research ethics. The lectures cover a variety of topics from previous RETI summer institutes including (1) foundations of evidence-based research ethics; (2) community engagement and consultation; (3) informed consent and cultural competence; (4) recruitment, compensation, and implementation; (5) confidentiality and risk of partner violence; (6) ethical issues in research involving new technologies; (7) ethical issues in international research; (8) NIH funding and pilot studies; and (9) writing for publication, presentation, and grant proposals.
About the Fordham University Center for Ethics Education

The Fordham University Center for Ethics Education was established in 1999 to contribute to Fordham's commitment to cultivating lifelong habits of critical thinking, moral reflection and articulate expression. Drawing upon the Jesuit traditions of sapientia et doctrina (wisdom and learning) and homines pro aliis (men and women for others) and the rich cultural diversity of New York City, the Center sponsors activities that provide students, faculty, professionals and the public with knowledge and skills to study, inform and shape a just society that nurtures the full-flourishing of all members of the human family.

In this era of increased need for ethical discourse in academic, professional, and public spheres, Center activities draw upon theological, philosophical, scientific and other areas of inquiry to foster interdisciplinary dialogue and scholarship on moral values and ethics issues of contemporary social import. The Center embodies the University's commitment to intellectual excellence by offering educational and research opportunities and public programming enriched through moral values, religious concerns, scientific and scholarly study, and active engagement in creating a caring and just world.

Founded as an interdisciplinary, cross-university unit, the Center sponsors national conferences, professional workshops, and ethics seminars that create synergy among scholars, scientists, religious leaders, community advocates, industry leaders and policy makers for exploring rigorously and respectfully grounds of individual and collective moral thought and action. Through its funded research programs, national conferences, and academic programs the Center provides opportunities for faculty and students to engage in empirical and theoretical study of ethical issues in health care, science, and public policy.

The Center also administers the interdisciplinary Master of Arts degree in Ethics and Society (fordham.edu/ethicsandsociety), the Undergraduate Minor in Bioethics (fordham.edu/bioethics), supports international students through The Fordham/Santander Universities Ethics Scholarship (fordham.edu/info/21417/international_student_scholarship), and offers annual awards for graduate and undergraduate student scholarship in ethics.

The Center is led by its founding Director, Dr. Celia B. Fisher, Director of Academic Programs, Dr. Bryan Pilkington and Associate Director, Drs. Michael Baur and benefits from the support of the Center Administrative Assistant, Lori Merone.

To learn more about the Center for Ethics Education, please visit fordham.edu/ethics.
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<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Institution</th>
<th>Address</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>
III. Institute Curriculum and Agenda

Welcome to the 2017 Fordham University HIV and Drug Abuse Prevention Research Ethics Training Institute (RETI). The eight-day summer program is conducted by a multidisciplinary faculty of experts in HIV prevention and drug abuse research and research ethics. Ethics fellows will attend lectures, participate in facilitated discussions and skill-based exercises to: (a) gain knowledge in HIV and drug abuse research ethics issues involving diverse populations and research designs; and (b) acquire skills to address and empirically examine research ethics challenges. Fellows will also meet with their RETI mentor throughout the Institute to continue developing a presentation on the preliminary findings from their mentored research project (MRP). Individual mentoring schedules will be included in a folder containing information for fellows and faculty provided during orientation.

All scheduled activities will take place at our Fordham University Lincoln Center campus at 113 West 62nd Street in Manhattan, NY (within walking distance from the hotel). Fellows are expected to attend all scheduled activities on the Institute agenda.
Day 1: Thursday, July 13, 2017

Arrival and Orientation

INCOMING FELLOWS

8:00 a.m. – 4:00 p.m. Arrival and Registration

4:00 p.m. – 5:30 p.m. Institute Orientation
Plaza View Room, 12th Floor, Lowenstein
Overview of Institute Goals and Objectives
Introduction of Institute Faculty and RETI Fellows
Celia B. Fisher, Fordham University
Brenda Curtis, University of Pennsylvania
David Festinger, Philadelphia College of Osteopathic Medicine
Sue Fish, Boston University
Lloyd Goldsamt, New York University
David Marcotte, Fordham University
Monica Rivera-Mindt, Fordham University
Scyatta Wallace, St. John’s University
Peg Weeks, Institute for Community Research

5:30 p.m. – 8:00 p.m. Welcome Reception and Dinner
President’s Dining Room, 12th Floor, Lowenstein
Presentation: Celia B. Fisher, Fordham University “Goodness-of-Fit Ethics”
Day 2: Friday, July 14, 2017

Institute Training

INCOMING FELLOWS

9:15 a.m. – 9:45 a.m.  Coffee & Light Fare
Room 3-07, Law School

9:45 a.m. – 10:45 p.m.  Empirical Assessments of Informed Consent and Voluntariness in Research involving Drug Users
Room 3-06, Law School
David Festinger, Philadelphia College of Osteopathic Medicine

10:45 a.m. – 11:00 a.m.  Break

11:00 a.m. – 12:15 p.m.  Crafting MRP AIMS: How will your MRP advance HIV/DRUG Abuse Research (i.e. recruitment, retention, trust, validity)? What barriers to research are most relevant to crafting your aims?
Room 3-06, Law School
Celia B. Fisher, Fordham University
Brenda Curtis, University of Pennsylvania
David Festinger, Philadelphia College of Osteopathic Medicine
Sue Fish, Boston University
Lloyd Goldsamt, New York University
Peg Weeks, Institute for Community Research

12:15 p.m. – 1:30 p.m.  Lunch

1:30 p.m. – 3:00 p.m.  Developing and Working Effectively with Your MRP Community Advisory Board (CAB)
Room 3-06, Law School
Bronx Community Research Review Board (BxCRRB) - Dr. Monique Guishard, Saba Solomon, Bernice Williams, Barbara Salcedo and Nicky Smith

3:00 p.m. – 3:15 p.m.  Break

3:15 p.m. – 5:00 p.m.  Fellows meet with mentors and/or work on MRPs
Dinner on your own
**Day 3: Saturday, July 15, 2017**

**Institute Training**

**INCOMING FELLOWS**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>9:15 a.m. – 9:45 a.m.</td>
<td>Coffee &amp; Light Fare</td>
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<td>Room 3-07, Law School</td>
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<tr>
<td>9:45 a.m. – 10:45 a.m.</td>
<td>Risk Avoidance Partnership (RAP): The Story of a Peer Harm Reduction Intervention for Drug Users</td>
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<td>Room 3-06, Law School</td>
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<td>Peg Weeks, Institute for Community Research</td>
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<tr>
<td>10:45 a.m. – 11:00 a.m.</td>
<td>Break</td>
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<tr>
<td>11:00 a.m. – 12:30 p.m.</td>
<td>Operationalizing your AIMS: Selecting Dependent and Independent Variables for Your MRP</td>
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<td>Room 3-06, Law School</td>
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<tr>
<td></td>
<td>Celia B. Fisher, Fordham University</td>
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<td>Sue Fish, Boston University</td>
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<td>Lloyd Goldsamt, New York University</td>
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<tr>
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<td>Peg Weeks, Institute for Community Research</td>
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<tr>
<td>12:30 p.m. – 1:00 p.m.</td>
<td>Lunch on your own</td>
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<tr>
<td>1:00 p.m. – 4:00 p.m.</td>
<td>Fellows work on MRP</td>
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<tr>
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<td>Dinner on your own</td>
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</tbody>
</table>
Day 4: Sunday, July 16, 2017

Institute Training

INCOMING FELLOWS

Morning free to work on MRP presentations

11:15 a.m. – 12:00 p.m.  A Qualitative Study of Medical Mistrust, Perceived Discrimination, and Risk Behavior Disclosure to Clinicians by U.S. Male Sex Workers and Other Men Who Have Sex with Men: Implications for Biomedical HIV Prevention
Room 3-06, Law School
Kristen Underhill, Columbia Law School

12:15 p.m. – 1:30 p.m.  Working Lunch: Avoiding IRB Approval Delays for Your MRP
Rooms 3-06 and 3-07, Law School
Celia B. Fisher, Fordham University
Lloyd Goldsamt, New York University
Alexis Roth, Drexel University
Kristen Underhill, Columbia Law School

1:30 p.m. – 2:30 p.m.  Persons who Inject Drugs’ Perspectives on the Risks and Benefits of Participation in a Mobile Health (mHealth) Study of Polydrug Use
Room 3-06, Law School
Alexis Roth, Drexel University

2:30 p.m. – 5:00 p.m.  Fellows meet with mentors and/or work on MRPs
Dinner on your own
Day 5: Monday, July 17, 2017

Institute Training

INCOMING FELLOWS

Morning free to work on MRPs or meet with mentors/Celia B. Fisher

11:00 a.m. – 12:00 p.m.
Neurocognitive and Cultural Factors for Research involving HIV-Positive Latino/a Participants
Room 3-06, Law School
Monica Rivera-Mindt, Fordham University

12:00 p.m. – 1:45 p.m.
Lunch
Guest Speaker: Changes to the Common Rule: Implications for Informed Consent
President’s Dining Room, 12th Floor, Lowenstein
David Strauss, Columbia University

Roundtable Discussion on IRB Challenges for HIV/Drug Abuse Research
President’s Dining Room, 12th Floor, Lowenstein
David Strauss, Columbia University

1:45 p.m. – 4:30 p.m.
Fellows work on MRPs and/or meet with mentors

4:45 p.m. – 5:30 p.m.
Peer Mentoring with Incoming and Returning Fellows

6:00 p.m.
Group Dinner
P.J. Clarke’s, 44 W. 63rd St, New York, NY 10023
Incoming and Returning Fellows

Arrival and Institute Training

RETURNING FELLOWS

Arrival and Registration
Morning free to work on MRP

12:00 p.m. – 1:45 p.m.
Lunch
Guest Speaker: Changes to the Common Rule: Implications for Informed Consent
President’s Dining Room, 12th Floor, Lowenstein
David Strauss, Columbia University

Roundtable Discussion on IRB Challenges for HIV/Drug Abuse Research
President’s Dining Room, 12th Floor, Lowenstein
David Strauss, Columbia University

1:45 p.m. – 3:00 p.m.
Overview of MRP Progress: What worked? What hasn’t? What’s next?
Room 3-06, Law School
Celia B. Fisher, Fordham University
Lloyd Goldsamt, New York University
Sarah Lord, Dartmouth College
Brian Mustanski, Northwestern University
Monica Rivera-Mindt, Fordham University
Scyatta Wallace, St. John’s University

3:15 p.m. – 4:30 p.m.
Fellows meet with mentors

4:45 p.m. – 5:30 p.m.
Peer Mentoring with Incoming and Returning Fellows

6:00 p.m.
Group Dinner
P.J. Clarke’s, 44 W. 63rd St., New York, NY 10023
Incoming and Returning Fellows
Day 6: Tuesday, July 18, 2017

Institute Training

INCOMING FELLOWS

9:15 a.m. – 9:45 a.m. Coffee & Light Fare Room 3-07, Law School

10:00 a.m. – 10:45 a.m. Ethical Challenges Using Social Media for HIV Prevention Research Involving Youth Room 3-06, Law School Brian Mustanski, Northwestern University

10:45 a.m. – 11:00 p.m. Break

11:00 a.m. – 12:30 p.m. Ethical Opportunities and Challenges Using Digital Media for HIV and Drug Abuse Prevention Research Room 3-06, Law School Brenda Curtis, University of Pennsylvania Sarah Lord, Dartmouth College

12:30 p.m. – 1:30 p.m. Lunch PL100, Plaza Level, Lowenstein

1:30 p.m. – 2:30 p.m. Ethical Issues in Providing Payment for HIV and Drug Use Research Room 3-06, Law School Brandon Brown, University of California

2:30 p.m. – 5:00 p.m. Fellows work on MRPs or meet with mentors/Celia B. Fisher
Dinner on your own

Institute Training

RETURNING FELLOWS

Morning free to work on MRP

12:30 p.m. – 1:30 p.m. Lunch PL100, Plaza Level, Lowenstein

1:30 p.m. – 3:00 p.m. Your MRP – What’s next? Publishing Your MRP Room 3-07, Law School Celia B. Fisher, Fordham University Lloyd Goldsam, New York University Richard Jenkins, National Institute on Drug Abuse Sarah Lord, Dartmouth College Brian Mustanski, Northwestern University Scyatta Wallace, St. John’s University

3:00 p.m. – 5:00 p.m. Fellows work on MRPs or meet with mentors/Celia B. Fisher
Dinner on your own
Day 7: Wednesday, July 19, 2017

Institute Training and MRP Presentations by Returning Fellows

### INCOMING FELLOWS

- **9:00 a.m. – 9:30 a.m.**
  - Coffee & Light Fare
  - President’s Dining Room, 12th Floor, Lowenstein

- **9:30 a.m. – 11:00 a.m.**
  - MRP Presentations by Returning Fellows
  - President’s Dining Room, 12th Floor, Lowenstein
  - Peer and Faculty Discussion and Feedback

- **11:00 a.m. – 11:15 a.m.**
  - Break

- **11:15 a.m. – 12:30 p.m.**
  - MRP Presentations by Returning Fellows
  - President’s Dining Room, 12th Floor, Lowenstein
  - Peer and Faculty Discussion and Feedback

- **12:30 p.m. – 1:30 p.m.**
  - Lunch
  - PL100, Plaza Level, Lowenstein

- **1:30 p.m. – 2:00 p.m.**
  - MRP Presentations by Returning Fellows
  - President’s Dining Room, 12th Floor, Lowenstein
  - Peer and Faculty Discussion and Feedback

- **2:00 p.m. – 2:15 p.m.**
  - Break

- **2:15 p.m. – 5:00 p.m.**
  - Fellows work on MRPs or meet with mentors/Celia B. Fisher
  - Dinner on your own

### RETURNING FELLOWS

- **9:00 a.m. – 9:30 a.m.**
  - Coffee & Light Fare
  - President’s Dining Room, 12th Floor, Lowenstein

- **9:30 a.m. – 11:00 a.m.**
  - MRP Presentations by Returning Fellows
  - President’s Dining Room, 12th Floor, Lowenstein
  - Peer and Faculty Discussion and Feedback

- **11:00 a.m. – 11:15 a.m.**
  - Break

- **11:15 a.m. – 12:30 p.m.**
  - MRP Presentations by Returning Fellows
  - President’s Dining Room, 12th Floor, Lowenstein
  - Peer and Faculty Discussion and Feedback

- **12:30 p.m. – 1:30 p.m.**
  - Lunch
  - PL100, Plaza Level, Lowenstein

- **1:30 p.m. – 2:00 p.m.**
  - MRP Presentations by Returning Fellows
  - President’s Dining Room, 12th Floor, Lowenstein
  - Peer and Faculty Discussion and Feedback

- **2:00 p.m. – 2:15 p.m.**
  - Break

- **2:15 p.m. – 3:30 p.m.**
  - Incorporating the MRP into Grant Applications
  - President’s Dining Room, 12th Floor, Lowenstein
  - Richard Jenkins, National Institute on Drug Abuse (NIDA)
  - Dinner on your own
Day 8: Thursday, July 20, 2017

MRP Presentations by Incoming Fellows

INCOMING AND RETURNING FELLOWS

9:00 a.m. – 9:30 a.m.  
Coffee & Light Fare  
President’s Dining Room, 12th Floor, Lowenstein

9:30 a.m. – 11:00 a.m.  
MRP Presentations by Returning Fellows  
President’s Dining Room, 12th Floor, Lowenstein  
Peer and Faculty Discussion and Feedback

11:00 a.m. – 11:15 a.m.  
Break

11:15 a.m. – 12:30 p.m.  
MRP Presentations by Returning Fellows  
President’s Dining Room, 12th Floor, Lowenstein  
Peer and Faculty Discussion and Feedback

12:30 p.m. – 1:00 p.m.  
Lunch  
PL100, Plaza Level, Lowenstein

1:30 p.m. – 3:00 p.m.  
MRP Presentations by Returning Fellows  
President’s Dining Room, 12th Floor, Lowenstein  
Peer and Faculty Discussion and Feedback

3:00 p.m. – 3:15 p.m.  
Break

3:15 p.m. – 5:00 p.m.  
MRP Presentations by Returning Fellows  
President’s Dining Room, 12th Floor, Lowenstein  
Peer and Faculty Discussion and Feedback

5:00 p.m. – 5:30 p.m.  
Closing Remarks  
Celia B. Fisher, Institute Faculty and Fellows

6:00 p.m. – 8:00 p.m.  
Closing Dinner  
Lincoln Square Steak, 208 W. 70th St., New York, NY 10023  
Institute Faculty and Fellows

Day 9: Friday, July 21, 2017

Departures Arranged for All Fellows
IV. Mentored Research Project Timelines

2017-2018 Schedule for Incoming and Returning Fellows

Below please find detailed timelines for incoming and returning fellows’ MRPs. Deadlines and suggested timing for project proposals and budgets, IRB applications, data collection and processing, progress reports, article section submission, and dissemination are provided. RETI Mentor benchmarks and responsibilities, as well as information on possible dissemination outlets in Year 2, are also provided. Fellows will receive additional information on these expectations and deadlines throughout the course of the summer training program, and as each deadline approaches. Forms for proposals, budgets and progress reports are provided beginning on page 33 and are also available for download on the RETI “Resources for Fellows” webpage: fordham.edu/info/24045/resources_for_fellows.

Year 1

July 6, 2017 Prior to the RETI, all fellows should complete and submit a brief literature review of empirical research relevant to the rationale for and design of their mentored research project, as well as a preliminary project abstract organized using the following headings: (1) Nature of the problem; (2) HIV research ethics question; (3) background/rationale for the study; (4) specific aims; (5) study population; and (6) research design and proposed measures. Fellows are expected to submit a draft of their MRP Proposal and literature review prior to this due date.

July 20, 2017 Fellows’ MRP PowerPoint Presentations to RETI faculty and fellows.

August 4, 2017 Completion of Institute anonymous evaluations due. The website and password will be emailed to you following the July Institute.

August – September First monthly contact with mentor to help shape MRP Proposal, budget and IRB protocol.

September 15, 2017 Fellows submit MRP proposal, budget and human subjects sections to the RETI Program Administrator (ethicsinst@fordham.edu) and their mentors for review and feedback from them and Dr. Celia Fisher. Template forms for proposals and budgets will be provided. Fellows may use their institutions IRB submission form as a template for their human subjects section. A monthly mentor call should be scheduled following Dr. Fisher’s written review.

October 16, 2017 Fellows submit final MRP proposal, budget and human subjects section to the RETI Program Administrator (ethicsinst@fordham.edu) for RETI final approval. Upon approval, fellows should submit the protocol to their IRB. Fellows should email documentation of IRB approval to ethicsinst@fordham.edu, following which contracts with home institution will be finalized through the Fordham Office of Research.

November 2017 Fellows begin the process of convening a community advisory board, contacting appropriate recruitment sites, preparing materials for data collection and hiring research assistants if applicable. Fellows should be communicating with their mentors during this process.

January – May 2018  MRP data collection. Monthly calls with mentors to report on progress and strategize challenges that may occur. Dr. Fisher and Institute staff are always available for consultation. Fellows should be communicating with their mentors bimonthly.

March 16, 2018  First Year 6-Month MRP Progress Report submitted to mentors and ethicsinst@fordham.edu. Instructions for this progress report will be provided, and are available on the RETI “Resources for Fellows” webpage.

Year 2

May 2018  Conference call with Dr. Fisher

June 2018  Fellows consult with mentor in preparing MRP Introduction (literature review, rationale and hypotheses), method section, and preliminary results section sent to ethicsinst@fordham.edu no later than July 1st, 2018. Fellows prepare preliminary version of MRP PowerPoint Presentations to be presented at the July meeting.

July 2018  RETI Institute

Aug 2018/May 2019  MRP funding is based on the expectation that fellows will give a conference presentation and submit a manuscript for publication during Year 2. Fellows should be submitting abstracts of their MRP for conference presentations and writing manuscripts for publication. See budget instructions for funding requirements.

October 2, 2018  12-Month MRP Progress Report submitted to mentors and ethicsinst@fordham.edu. Instructions for this progress report will be provided, and are available on the RETI “Resources for Fellows” webpage.

March 4, 2019  18-Month MRP Progress Report submitted to mentors and ethicsinst@fordham.edu. Instructions for this progress report will be provided, and are available on the RETI “Resources for Fellows” webpage.

August 16, 2019  Final MRP Progress Report submitted to mentors and ethicsinst@fordham.edu. Instructions for this progress report will be provided and are available on the RETI “Resources for Fellows” webpage.
Mentor Benchmarks and Responsibilities

MENTORING IN BRIEF

Mentors Benchmarks in Year 1:
- One pre-institute mentoring conference call in May/early June to help guide pre-institute MRP abstract and literature review
- Two meetings during the July Institute (scheduled with the help of the RETI staff) and participation in the final day presentation
- Contact in late summer/early fall to assist the mentee in finalizing their MRP proposal;
- Bi-monthly calls or email contacts through the first year to help ensure mentee is on track to conduct the CAB, complete data collection and begin preliminary analysis by the end of June.

Mentor Benchmarks in Year 2:
- One meeting during the July Institute and attendance at the Institute MRP Presentations;
- Bimonthly meetings to guide analysis, encourage meeting abstract submissions and collaborate or advise on completing a manuscript for publication.

DETAILED BENCHMARKS & RESPONSIBILITIES

Pre-Institute Call. The RETI Director, Dr. Celia Fisher, has an initial phone call with each fellow following their acceptance to begin crafting theoretically valid and methodologically feasible projects and recommending relevant readings. After this, mentors should arrange a Pre-Institute Call in May or early June, 2017 to help their mentee further craft the required Pre-Institute Mentored Research Project (MRP) Abstract and recommend addition readings and framework for the literature review. The abstract should include (1) Nature of the problem; (2) HIV research ethics question; (3) background/rationale for the study; (4) specific aims; (5) study population; and (6) research design and proposed measures.

Mentees are expected to submit a draft of their MRP proposal and literature review to mentors prior to its due date on July 6, 2017.

Institute Meeting July 13 – 20, 2017. Mentors will have two meetings (at least 1 in-person) with their mentees during the July Institute of their mentee’s first year and attend the Final Presentations sessions and dinner on July 20, 2017. The meetings should be scheduled at the beginning of the Institute and toward the end of the Institute. Meetings should focus on continued refinement of the mentored research project, the PowerPoint presentation the mentee will give on July 20th, 2017 and suggestions for budget planning (e.g. research assistants, participation compensation, etc.) before they finalize a budget with Dr. Fisher.

MRP Proposal Guidance (August – October 2017). After the July Institute, mentors should arrange a follow-up call with their mentee in August or early September 2017 to help mentees draft their full Mentored Research Project (MRP) Proposal, which includes the research proposal, budget and IRB protocol (the IRB proposal will be submitted to the mentee’s institution and therefore should be based on the institution’s protocol template). The mentee will send the draft to the RETI Program Administrator (ethicsinst@fordham.edu) by September 15, 2017 for review and feedback by the mentor (written or by phone) and Dr. Fisher. The mentee is required to submit the final version to RETI by October 16, 2017. We have found that many MRPs are delayed by the mentee’s IRB schedule and reviews. Mentors should assist mentees in flagging and anticipating issues that may occur during the Institutional Review Board (IRB) approval process.

Bimonthly contact (November 2017 – June 2018). The goal of mentoring will be to guide mentees in meeting the following benchmarks.
- No later than November 2017, mentees should begin the process of convening a Community Advisory Board (CAB), contacting recruitment sites, preparing materials for data collection and hiring research assistants if applicable.
- Mentees should begin MRP data collection no later than January/February, 2018.
- Their first progress report is due on March 15, 2018.
• They should aim to complete data collection in early June 2018 and begin initial data analysis in time for presentation and discussion at the July 2018 Summer Institute.

**Institute Meeting July, 2018 (specific dates TBA).** The goal of year 2 is to guide the mentee in completing the MRP, submitting abstracts to conferences, and finalizing a manuscript for publication. In June, mentees will consult with mentors in preparing MRP Introduction (literature review, rationale and hypotheses), method section and preliminary results section sent to the RETI administrator no later than July 1, 2018. During the July 2018 Institute mentors should arrange 1 in-person meeting with their mentee and attend the MRP presentation day.

**Bimonthly Contact in Year 2 (August 2018 – August 2019).** Mentors should have contact with mentees to ensure they are on the right track by ensuring they conduct their final CAB meeting and assisting with MRP manuscripts in preparation for submission and identifying publications and abstracts for presentations. Mentees are required to send the RETI an 18-Month Progress Report due October, 2018. Mentors are encouraged to collaborate with mentees on publication and presentations (and grant proposals if mentor and fellow wish to do so). The Institute supports travel and registration for conferences (at which an MRP related paper is accepted). Support for conference attendance is contingent upon mentees submitting a draft of manuscript for publication to the RETI. The Institute also supports publication costs (where appropriate). The subcontract with the mentee’s university ends on **August 31, 2019** so it is important that mentors keep mentees aware of this deadline.
Possible MRP Dissemination Outlets

**Relevant Journals:** Below are journals specifically geared toward law, theory and research on human subjects protections, as well as journals in related disciplines (e.g. AIDS, HIV, Addiction) that have published articles on research ethics. When considering submitting to a specific journal it is important to consider the extent to which your project is similar to the mission of the journal and other published articles with respect to sample size, methodology (qualitative, quantitative), population, and application.

- Accountability in Research: Policies and Quality
- Assurance
- Addiction Research and Theory
- AIDS
- AIDS Care
- The American Journal of Bioethics
- American Journal of Public Health
- Archives of General Psychiatry
- Archives of General Psychiatry
- Behavioral Sciences & Law
- Bioethics
- BMC Medical Ethics
- Developing World Bioethics
- Drug and Alcohol Dependence
- Ethics & Behavior
- Global Advances in Health and Medicine
- International Journal of Drug Policy
- International Journal of Humanities & Social Sciences
- International Journal of Law & Psychiatry
- IRB: Ethics and Human Research
- Journal of Acquired Immune Deficiency Syndromes
- Journal of Law, Medicine, & Ethics
- Journal of Medical Ethics
- Journal of Pediatric Psychology
- Kennedy Institute of Ethics Journal
- Law and Human Behavior
- Law Medicine Ethics
- Narrative Inquiry in Bioethics
- New England Journal of Medicine
- Prevention Science
- Public Health Ethics
- Public Health Reports
- Public Health Reviews
- Sexually Transmitted Infections
- Social Science & Medicine
- Substance Use and Misuse

**Relevant Conferences:**

Dr. Fisher is pleased to help organize symposia for upcoming conferences. Please alert Rimah Jaber to any such conference announcements that you think would be of interest to RETI fellows.
Relevant Funding Opportunities:

The Institute encourages and provides support for fellows’ grant proposals. Lectures and round table discussions regarding MRP publication and grant applications a specific focus of Year 2. The MRP can be utilized as initial research for a grant proposal focused exclusively on a research ethics issue, as feasibility data for an application on sexual health or drug abuse that highlights the compatibility of the proposed research with participant and community values, or as empirical support for your Human Subjects procedures proposed in the application for funders and the IRB. Below we list current ethics relevant funding opportunities. However, the MRP-related funding proposals need not be limited to announcements specifically focused on ethics. As we will discuss at the Institute, MRPs focused on enhancing understanding of participant attitudes toward research risks and benefits, research and medical mistrust, as well as other aspects of human subjects protections can enhance the responsible conduct of HIV and drug abuse prevention research recruitment, retention, external validity, data analysis and interpretation.

- The Fogarty International Center Offer various funding opportunities: [fic.nih.gov/Funding/Pages/Fogarty-Funding-Opps.aspx](fic.nih.gov/Funding/Pages/Fogarty-Funding-Opps.aspx)
  - Short-Term Courses in Research Ethics (T15)
  - The Ethical, Legal and Social Implications (ELSI) Research Program Funding Opportunities
  - Office of Research Integrity, Research on Research Integrity Program
  - International Bioethics Research Training Program (D43)
  - Advancing Exceptional Research on HIV/AIDS and Substance Abuse (R01)
  - HIV/AIDS High Priority Drug Abuse Research (R01)

Specific NIH Funding Opportunity Announcements (FOAs) will be provided to fellows through the RETI monthly newsletter and on the Ethics & Society blog (ethicsandsociety.org) as they are announced.

NIH submissions focusing on topics in research ethics may be reviewed by the Societal and Ethical Issues in Research (SEIR) Study Section. The SEIR Study Section reviews applications focusing on ethical issues in human subjects research, clinical issues, clinical trials, and recruitment. For more information on SEIR visit: [https://public.csr.nih.gov/StudySections/IntegratedReviewGroups/PSEIRG/SEIR/Pages/default.aspx](https://public.csr.nih.gov/StudySections/IntegratedReviewGroups/PSEIRG/SEIR/Pages/default.aspx)

Topics that fall under SEIR purview include:
- Evaluating informed consent processes, including consent capacity of populations, and strategies to improve the process of informed consent in clinical care and research studies.
- Evaluating questions about the ethics in the architecture of clinical trial study designs and its relationship to clinical care decisions and outcomes.
- Evaluating ethical, legal, and social issues (ELSI) in decision making by either the health care provider or the patient and family in areas such as testing for genetic diseases, end of life, transplant and organ allocation, reproductive technology, intensive care units, and emergency medicine.
- Evaluating ethical issues in research participation (including ethical issues associated with recruitment and retention of human subjects).
- Evaluating how the environmental context alters ethical issues in clinical care and research studies (i.e., intensive care units, neurology, pediatrics, emergency medicine, and of allocation limited resources).
- Psychosocial, ethical, and legal issues for consumers and professionals in use of new testing, diagnostic and treatment modalities (i.e., genomics, stem cell, and nanotechnology).
- Sociological/anthropological studies related to societal and ethical issues
V. Mentored Research Project Proposal

Incoming fellows are expected to submit a final proposal, budget and human subjects section for their MRP no later than October 16, 2017. Prior to this date, proposals should be submitted to project mentors for feedback with a cc to the RETI Program Administrator (ethicsinst@fordham.edu) by September 15, 2017. Instructions for the project proposal and a template budget form follow. These forms are also available for download on the RETI website (fordham.edu/ethicsinstitute). Fellows may use their institution’s IRB submission form as a template for their human subjects section.

MRP Proposal Instructions

1. Title Page (limited to 1 page)
   a. Title of Project
   b. Name and contact information of RETI Fellow
   c. Name and contact information of Mentor
   d. Date Submitted
   e. Description: A 150-word summary of your project goals, population, and procedures and a clear statement describing the project's potential to improve HIV prevention research ethics practices. *Project Descriptions of approved projects will be posted on the RETI website.*

2. Specific Aims (limited to 1 page)
   a. State concisely the goals of the proposed research
   b. Summarize short-term and long-term outcome(s), including the impact that the results of the proposed research will exert on the responsible conduct of HIV/Drug Abuse prevention research.
   c. List specific objectives of the research proposed, e.g., to test a stated hypothesis, solve a specific ethics relevant problem, challenge the population appropriateness of a current research or ethical practice, address a critical ethically relevant research barrier, address a problem with IRB review, or develop and validate new ethical approaches.

3. Background and Significance (limited to 1 page):
   a. Summarize the relevant theoretical and empirical literature
   b. Identify the knowledge gaps relevant to you’re the goals of your research
   c. Explain the significance of your project to the responsible conduct of HIV/Drug Abuse prevention research ethics: That is how will your MRP address the gaps in knowledge.

4. Research Strategy (limited to 5 pages)
   a. Participants (sample size, relevant participant characteristics, inclusion/exclusion criteria)
   b. Design Plan (methods and measures)
   c. Data Collection Procedures (e.g. recruitment, informed consent)
   d. Data Analysis Plan
   e. Community Consultation/Dissemination Plan
   f. Timetable

5. References

6. Attachments:
   a. Budget
   b. Budget Justification
   c. IRB Application/Human Subjects Section
   d. Mentor’s approval
Mentored Research Project Detailed Budget Request Form

INSTRUCTIONS FOR FELLOWS: This form asks you to provide specific budget information for direct costs requests (up to $20,000 USD) related to your two-year mentored research project. This funding can be used to cover costs of recruitment and participant compensation, travel for data collection, research assistants, recorders, and other devices for data collection, transcription, statistical software, use of copyrighted measures and other relevant expenses. Monies will not be given to pay for capital costs/furniture, computers, RETI Fellow salary, release time or course reductions. This award allows indirect costs (at 8%) to be added to the total requested.

Final MRP materials and budget requests must be submitted to ethicsinst@fordham.edu no later than October 15, 2017 and reviewed and approved by Dr. Celia Fisher prior to submission of a human subjects application to the fellow’s IRB/ERB. A copy of the budget will be sent to the Institutional Official(s) identified on the form below. Funds will be available following documentation of IRB approval and appropriate documentation from the fellow’s Institutional Official(s). To qualify for reimbursement, all invoices from your institution must be itemized and accompanied by original receipts and documentation of payments made to research staff.

Data Collection and Analysis. The July 2018 meeting will focus on MRP data analysis, publication, and grant writing. The Year 1 budget for participant payments, research assistance, the 1st community advisory board meeting and other related costs should reflect the expectation that data collection will be completed by June 15, 2018. The Year 2 budget for research assistance and the 2nd community advisory board meeting should reflect the expectation that data analysis will be completed in Year 2 by December 15, 2018, a manuscript submitted for publication, and abstracts submitted to conferences by March 15, 2019.

Support for Conferences, Publication, Grant Submissions. MRP funding is based on the expectation that fellows will give a conference presentation and submit a manuscript for publication during Year 2. The Year 2 budget must include monies for travel or publication for a minimum of $1,500 and no more than $4,000. The budget justification must include the name(s) of the conferences and journals to which you plan to submit your MRP; these are not binding, but must reflect consideration of appropriate dissemination venues. Use of funds for travel and publication are contingent upon the approval of the RETI director and must meet the following criteria:

Support for Conference Travel, Per Diem and Registration. You may submit a conference presentation abstract to an organization based on your MRP at any time. The following is required to qualify for reimbursement of conference related travel, per diem, or registration costs:

1. Documentation that the MRP related paper/poster was accepted at the conference
2. Completion of data collection and analysis
3. A first draft manuscript, including the journal considered for publication, submitted to your mentor and the RETI preceding or accompanying any invoice for conference related expenses.

Publication or Grant Submission Costs. Budget requests for publication or grant submissions associated with the cost of graphics, images, or other similar costs can be reimbursed with appropriate justification and contingent upon submission of a full manuscript to your mentor and the RETI.

Budget requests for funds to support publication in open access journals like PLOS or BMC Public Health will not be approved unless there is a legitimate justification for why such journals are a more appropriate vehicle for publication than high quality journals that do not charge publication costs.

Budget Period and Extensions. The budget period for your project is scheduled to end August 31, 2019. All MRP-related expenses must be incurred on or before that date, unless an extension has been approved by RETI and your university’s grants office through an executed agreement to facilitate MRP-related publication, conference, or grant preparation satisfying the requirements above.

The budget justification should be included in the fillable spaces starting on page 3. This form should be submitted at the same time as your abstract and detailed two-year project proposal to the RETI (ethicsinst@fordham.edu).
### Personnel

<table>
<thead>
<tr>
<th>Name</th>
<th>Role on project (Research Assistant, Project Coordinator, Other)</th>
<th>Hours/Week</th>
<th>No. of Weeks</th>
<th>Total Salary Requested YR 1 9/1/16-8/31/17</th>
<th>Total Salary Requested YR 2 9/1/17-8/31/18</th>
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**SUBTOTALS**

*Data Collection should be completed in Yr 1.*

**TOTAL SALARY REQUESTED (YEARS 1 -2)** (Sum of 1a and 1b)

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**BUDGET PERIOD**

**FROM (ESTIMATED START DATE)**

August 31, 2019

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**DATE**

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**RETI FELLOW NAME, INSTITUTIONAL ADDRESS, AND EMAIL**

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**RETI MENTOR NAME, INSTITUTIONAL ADDRESS, AND EMAIL**

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**INSTITUTIONAL OFFICIAL(S) RESPONSIBLE FOR RESEARCH AWARDS: NAME AND CONTACT INFORMATION** (there may be more than one official eg: administrative contact, financial contact, authorized individual)

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<tr>
<th>BUDGET CATEGORY</th>
<th>Total Requested Year 1</th>
<th>Total Requested Year 2</th>
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<tr>
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<td>9/1/16-8/31/17</td>
<td>9/1/17-8/31/18</td>
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<tr>
<td>EQUIPMENT COSTS (itemize)</td>
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<td>SUPPLIES/SOFTWARE</td>
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<tr>
<td>TRAVEL (Yr. 1 travel should be limited to project administration; Yr. 2 travel can include costs of dissemination at professional meetings and community groups)**</td>
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<tr>
<td>COMMUNITY ADVISORY BOARD MEMBERS OR OTHER COMMUNITY ADVISORS</td>
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<tr>
<td>PARTICIPANT COMPENSATION (itemize and specify compensation for peer-driven sampling if relevant)</td>
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<tr>
<td>OTHER EXPENSES (itemize by category)</td>
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<tr>
<td>SUBTOTALS</td>
<td>2a</td>
<td>2b</td>
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<tr>
<td>TOTAL NON-PERSONNEL MONIES REQUESTED (YEARS 1 -2)</td>
<td>(Sum of 2a and 2b)</td>
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**TOTALS**

| PERSONELL SUBTOTAL (1c)            |                        |
| TOTAL-PERSONNEL SUBTOTAL (2c)      |                        |
| TOTAL DIRECT COSTS FOR ALL BUDGET PERIODS | (Sum of 1c and 2c)     |
| 8% Indirect Costs                  |                        |
| TOTAL DIRECT AND INDIRECT COSTS FOR ALL BUDGET PERIODS |                        |

NOTE: IN COMPLIANCE WITH THE NIH BUDGET YEARS FOR THIS TRAINING GRANT, SUB-CONTRACTS WITH YOUR BUDGET OFFICE WILL INCLUDE 2 NO-COST EXTENSIONS.

1. The first subcontract will begin on the date of your approval through March 31, 2018
2. The first no-cost extension will begin April 1, 2018 – March 31, 2019
3. The final no-cost extension will begin April 1, 2019 – August 31, 2019.

THIS SHOULD NOT AFFECT THE YEAR 1 AND 2 PROPOSED BUDGET ABOVE.

The budget justification should be included in the fillable space on page 4.

An abstract for your MRP must be included in the fillable space on page 5.
BUDGET JUSTIFICATION
Please provide justification below with a brief explanation for each category of expenses requested, including time frame, where relevant.
VI. Progress Reports

Fellows are expected to complete progress reports at the end of their first and second years in the RETI program. Progress reports should be submitted via email to ethicsinst@fordham.edu. Instructions for these progress reports are included below and are available for download on the RETI webpage: fordham.edu/ethicsinstitutedownloads. Incoming and returning fellows will also be sent brief progress reports periodically throughout the research process, and will be provided with specific instructions and deadlines at that time.

First-Year 6-Month Mentored Research Project Progress Report

Please complete the questionnaire below and email to ethicsinst@fordham.edu no later than March 16, 2017

The purpose of this progress report is to provide a record of activities that can help the Institute identify additional support needs during the first year of a fellow’s mentored research project. It also serves as a basis for Institute program evaluation and improvement and our yearly progress report to NIDA. We recommend that you touch base with your mentor during the month of March and use the questions on this form as a way of brainstorming any new ideas or challenges that may have arisen.

Instructions

A. Project Title, Abstract and Contact Information

1. Name and contact information of RETI Fellow  
2. Title of Project  
3. Name and contact information of Mentor  
4. Brief 1 paragraph description of your proposed project/abstract (this description can be identical to the one in your approved project proposal if appropriate)  
5. Date submitted

B. IRB Approval

1. Has your study been approved by your Institutional IRB? Yes ☐ No ☐  
   If you answered “no” please provide:  
   a. An anticipated date for IRB approval  
   b. An explanation for the delay and if relevant suggestions for how the Institute can help facilitate approval

2. Has your study been approved by an additional (e.g. foreign) IRB if required?  
   Yes ☐ No ☐ Not Applicable ☐  
   If you answered “no” please provide:  
   a. An anticipated date for IRB approval  
   b. An explanation for the delay and if relevant suggestions for how the Institute can help facilitate approval

C. Personnel and CAB

3. Have you been hired/engaged needed personnel to assist in project implementation?  
   Yes ☐ No ☐ Not Applicable ☐
a. If yes, please list the names of the individuals and their project roles
b. If you answered provide an explanation for the delay and if relevant suggestions for how the Institute can help you facilitate hiring.

4. Have you identified and obtained agreements from individuals invited to be Community Advisory Board (CAB) members? Yes ☐ No ☐
Remember the CAB should review and/or contribute to development of your recruitment, informed consent and research procedures and materials.

a. If yes, please list the members and their institutional, community, or group affiliations
b. If no please provide an explanation for the delay and if relevant suggestions for how the Institute can help

c. Please list the date(s) you have met and/or plan to meet with your CAB

D. Finalization of Research Materials, Recruitment, Data Collection

5. Have you completed the development of your research materials? Yes ☐ No ☐

a. If you answered “No” please provide a description of what still needs to be completed and if relevant how the Institute might help.

6. Have you begun participant recruitment? Yes ☐ No ☐

a. If yes, please provide the date recruitment was initiated, and the percentage of your population comprised of drug users.

b. If no please provide the date for which recruitment is planned

7. Have you encountered any unexpected challenges to recruitment? Yes ☐ No ☐

a. If you answered yes, please provide a brief description and if relevant suggest how the Institute might help.

8. Have you begun data collection? Yes ☐ No ☐

a. If yes, please provide the date data collection was initiated

b. If no please provide the date for which the beginning of data collection is planned

Do you have any other comments or suggestions for how the Institute can be of help to you during this period? Please remember to feel free to contact Dr. Fisher anytime.
12-Month Mentored Research Project Year 1 Progress Report

Please email to ethicsinst@fordham.edu no later than October 2, 2017 (Incoming)

The purpose of this progress report is to provide a record of accomplishment that can help the Institute identify additional support needs during the second year of a fellow’s mentored research project. It also serves as a basis for Institute program evaluation and improvement and helps the Institute prepare its annual report to the funding agency.

Sections A – D of the Progress Report should be a brief presentation of the accomplishments of the mentored research project during the first year and in total should not exceed 2 pages. The 2-page limit does not include Sections E – G documenting IRB continuing approval, a listing of project personnel and their certifications in research ethics training, and enrollment of women and minorities.

Title Page (limited to 1 page)

a. Title of Project
b. Name and contact information of RETI Fellow
c. Name and contact information of Mentor
d. Date Submitted
e. Abstract

A. Specific Aims: If the aims of the study have changed in scope from those submitted for RETI approval, give the revised aims and the reason for the modification. If they aims have not been modified, state this.

B. Study Implementation: Describe those aspects of the study that have been completed (recruitment, data collection, data analysis, data interpretation, community consultation). If applicable, describe significant events, institutional, or contextual factors that facilitated or impeded implementation and any significant modifications in research design, measures, or population sampling stemming from these factors. Please include the percentage of your population comprised of drug users.

C. Plans: Summarize plans to address the specific aims during the next year of support including: completion of data collection and data analysis, community consultation and dissemination, submission of manuscripts for publication, abstracts for professional meetings, and use of the study results as pilot data or previous work to strengthen a grant application.

D. Budget: State whether there were or are expected to be significant changes in the budget allocations approved for this project. Provide a description and rationale. If no significant changes are expected, state this.

E. Institutional Review Board Continuing Review: Submit any addendums to and approved by your IRB. Provide a statement for your plans to submit a continuing review protocol to your IRB. If you are continuing to collect data and are applying continued approval state the date the application will be reviewed and remember to send a copy of the IRB continuing approval to ethicsinst@fordham.edu. If you have completed data collection and your institution does not require further continued review, state that.

F. Project Personnel: List all personnel hired to work on the project for at least one month and their role on the project. Provide certification for any personnel involved in data collection for your study that they have completed an educational program in the protection of human subjects.

G. Women and Minority Inclusion*: Include a detailed numeric accounting in narrative or table form of the gender and race/ethnicity of participants in your study, and when applicable residence outside the U.S. State whether changes in the targeted enrollment plan were made or are expected.

* The U.S. Office of Management and Budget recommends the following ethnic/racial categories.

Ethnic Categories:
Hispanic or Latino: A person of Cuba, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, “Spanish origin,” can be used in addition to “Hispanic or Latino.”

Not Hispanic or Latino

Racial Categories:
American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America and maintains tribal affiliation or community.

Asian: A person having origins in any of the original peoples of the Far East, Southern Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.”

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

Ethnic/racial subpopulations. In addition to the OMB ethnic and racial categories, NIH uses the following definition for ethnic/racial subpopulations:

Subpopulations. Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self-identify with more than one ethnicity or race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study. (http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

Foreign Populations. When completing the Inclusion Enrollment report, you should add an asterisk and footnote the report to indicate that data is from foreign participants.
18-Month Mentored Research Project Progress Report

Please email to ethicsinst@fordham.edu no later than March 4, 2019

The purpose of the 18-month progress report is to provide an update on your mentored research project status and related professional activities and to provide the RETI with information on how it may continue to assist you in the completion of your MRP and your post-Institute professional advancement. The report also serves as a basis for the Institute program evaluation and improvement and helps the Institute prepare its annual report to the funding agency.

Title Page (limited to 1 page)
   a. Title of Project
   b. Name and contact information of RETI Fellow
   c. Name and contact information of Mentor
   d. Date Submitted

Abstract: A 250-500 word summary of specific aims, population, methods and procedures, results and a clear statement describing the project’s potential to improve HIV prevention research ethics practices. If relevant, indicate data collection or analysis that is in progress.

A. Expanded Summary:
   This section should be a brief presentation of the accomplishments of the mentored research project thus far. It should include:*
   a. Specific Aims
   b. Background/Rationale
   c. Participants (If relevant, indicate how many more participants will be recruited and anticipated data of data collection completion. Please include the percentage of your participants comprised of drug users.)
   d. Methods
   e. Results (If relevant, indicate additional analyses that will be conducted and anticipated date of data analysis completion)
   f. Conclusion stating the significance of the results to HIV prevention research ethics /research ethics practices and/or policies.

• If you have written an article describing your completed MRP, you can simply attach a copy of the article. If you have not yet completed all aspects of your MRP but have written papers or presentations reporting on some completed parts, please attach these and then provide an updated description of your data collection, analysis and conclusions to date.

B. Women and Minority Inclusion*: Use the attached NIH table to provide I a detailed numeric accounting of the gender and race/ethnicity of participants in your study. Foreign Populations. Add an asterisk to each number and a footnote to indicate that data is from foreign participants and when applicable residence outside the U.S.

C. Dissemination:
   We would like to know all of the professional activities that you have been involved in during the past 18 months whether they are directly related to the MRP or to related work in ethics, HIV, drug use, or related infectious diseases. Provide a list or narrative where appropriate for the following:
a. **Manuscripts**: In preparation or submitted for publication review (title and journal), accepted for or published (appropriate reference). Attach copies of all submitted, accepted or published works.

b. **Professional Presentations**: In preparation, submitted, accepted, or presented (title, name and location of conference/presentation site, date). Attach a copy of presentation abstract, paper or PowerPoint.

c. **Research Ethics Lectures, Workshops, or Consultations**: Any teaching, lecturing or consulting experiences related to expertise you developed as an Institute Fellow.

d. **Ethics Review Activities**: IRB or Ethics Review Board membership or consultation activities.

D. **Community Consultation and Dissemination**:

   a. Provide a summary of community advisory board meetings (with dates) and/or description of other community consultations (with local leaders, advocacy groups etc).

   b. Provide a summary and attach relevant documents if applicable for how results of the study were or will be disseminated to communities and participants.

E. **Grant Applications**:

   Describe planned or submitted grant applications incorporating or based on the mentored research project. Include the funding agency and RFP or PA number and date of previous or planned submission.

F. **Suggestions for Continued Involvement**:

   We look forward to your continued involvement with the RETI. Remember you will all be invited to attend a conference in the summer of 2017 (with travel and lodging provided). In the meantime, please let us know of ways the RETI can assist you in your continued HIV prevention research ethics professional development (e.g. Webinars, group publications, multi-site grants, symposia, peer mentoring, workshop/certificate on teaching research ethics, other).
# Inclusion Enrollment Report

**Study Title:**

**Total Enrollment:**

**Protocol Number:**

**PART A. TOTAL ENROLLMENT REPORT:** Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

<table>
<thead>
<tr>
<th>Ethnic Category</th>
<th>Females</th>
<th>Males</th>
<th>Sex/Gender Unknown or Not Reported</th>
<th>Total</th>
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<tbody>
<tr>
<td>Hispanic or Latino</td>
<td></td>
<td></td>
<td></td>
<td>**</td>
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<tr>
<td>Not Hispanic or Latino</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown (individuals not reporting ethnicity)</td>
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<tr>
<td><strong>Ethnic Category: Total of All Subjects</strong></td>
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</table>

**Racial Categories**

- American Indian/Alaska Native
- Asian
- Native Hawaiian or Other Pacific Islander
- Black or African American
- White
- More Than One Race
- Unknown or Not Reported

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Females</th>
<th>Males</th>
<th>Sex/Gender Unknown or Not Reported</th>
<th>Total</th>
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<tr>
<td><strong>Racial Categories: Total of All Subjects</strong></td>
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**PART B. HISPANIC ENROLLMENT REPORT:** Number of Hispanics or Latinos Enrolled to Date (Cumulative)

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Females</th>
<th>Males</th>
<th>Sex/Gender Unknown or Not Reported</th>
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<tbody>
<tr>
<td>American Indian or Alaska Native</td>
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<td>**</td>
</tr>
<tr>
<td>Asian</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Black or African American</td>
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<td></td>
</tr>
<tr>
<td>White</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More Than One Race</td>
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<td></td>
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<td></td>
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<tr>
<td>Unknown or Not Reported</td>
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<td></td>
</tr>
<tr>
<td><strong>Racial Categories: Total of Hispanics or Latinos</strong></td>
<td></td>
<td></td>
<td></td>
<td>**</td>
</tr>
</tbody>
</table>

* These totals must agree.  ** These totals must agree
Final Mentored Research Project Progress Report

Please email to ethicsinst@fordham.edu no later than August 16, 2019

The purpose of the final progress report is to provide a record of accomplishment and to provide the RETI with information on how it may continue to assist in your post-Institute professional advancement. The report also serves as a basis for Institute program evaluation and improvement and helps the Institute prepare its annual report to the funding agency. The final report will build upon items listed in the 18-month progress report, in addition to providing a detailed budget summary, a write-up of your Mentored Research Project (MRP) and copies of any manuscripts and presentations.

A. Title Page (limited to 1 page)
   a. Title of Project
   b. Name and contact information of RETI Fellow
   c. Name and contact information of Mentor
   d. Date Submitted
   e. Abstract: A 250-word summary of project goals, population, methods and procedures, results and a clear statement describing the project’s potential to improve HIV prevention research ethics practices.

B. Expanded Summary:
   This section should be a brief presentation of the accomplishments of the mentored research project across the 2-year budget period and should not exceed 3 single-spaced pages (not counting tables). It should include:
   a. Specific Aims
   b. Background/Rationale
   c. Participants (including the percentage that are drug users)
   d. Methods
   e. Results
   f. Conclusion stating the significance of the results to HIV prevention research ethics practices and/or policies.

B. Dissemination:
   Provide a list or narrative where appropriate for the following:
   a. Manuscripts: In preparation or submitted for publication review (title and journal), accepted for or published (appropriate reference). Attach copies of all submitted, accepted or published works.
   b. Professional Presentations: In preparation, submitted, accepted, or presented (title, name and location of conference/presentation site, date). Attach a copy of presentation abstract, paper or PowerPoint.

C. Community Consultation and Dissemination:
   a. Provide a summary of community advisory board meetings (with dates) and/or description of other community consultations (with local leaders, advocacy groups etc).
   b. Provide a summary and attach relevant documents if applicable for how results of the study were or will be disseminated to communities and participants.

D. Grant Applications:
   Describe planned or submitted grant applications incorporating or based on the mentored research project. Include the funding agency and RFP or PA number and date of previous or planned submission.
E. Suggestions for Follow-Up:
   We look forward to your continued involvement with the RETI. Please let us know of ways the RETI can assist you in your continued HIV prevention research ethics professional development.

F. Resulting Opportunities
   Please provide us with a narrative evaluation explaining the career opportunities, contributions to your research, and personal growth that has resulted from your participation in the RETI.

G. Budget:
   Provide a detailed summary of all funded expenditures.

H. Women and Minority Inclusion*: Include a detailed numeric accounting in narrative or table form of the gender and race/ethnicity of participants in your study, and when applicable residence outside the U.S.*

   * The U.S. Office of Management and Budget recommends the following ethnic/racial categories.

   **Ethnic Categories:**
   **Hispanic or Latino:** A person of Cuba, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, “Spanish origin,” can be used in addition to “Hispanic or Latino.”
   **Not Hispanic or Latino**

   **Racial Categories:**
   **American Indian or Alaska Native:** A person having origins in any of the original peoples of North, Central, or South America and maintains tribal affiliation or community.
   **Asian:** A person having origins in any if the original peoples of the Far East, Southern Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
   **Black or African American:** A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.”
   **Native Hawaiian or Other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
   **White:** A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

   **Ethnic/racial subpopulations.** In addition to the OMB ethnic and racial categories, NIH uses the following definition for ethnic/racial subpopulations:

   **Subpopulations.** Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one ethnicity or race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study. (http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

   **Foreign Populations.** When completing the Inclusion Enrollment report, you should add an asterisk and footnote the report to indicate that data is from foreign participants.
## Appendix 1: Fordham University HIV and Drug Abuse Prevention Research Ethics Training Institute MRP and MRP-Related Publications

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Title</th>
<th>Journal</th>
<th>Volume</th>
<th>Issue</th>
<th>Pages</th>
<th>DOI</th>
<th>PMID</th>
<th>PMCID</th>
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Appendix 2: Fordham University HIV and Drug Abuse Prevention Research Ethics Training Institute
MRP-Related Professional Presentations

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Title</th>
<th>Event</th>
<th>Year</th>
<th>Bibliographic Details</th>
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<tbody>
<tr>
<td>Broaddus, M. (2015)</td>
<td>“She makes me feel that I'm not alone”: Linkage to Care Specialists provide social support to people living with HIV.</td>
<td>Paper presented at the 143rd American Public Health Association meeting, Chicago, IL.</td>
<td>2015</td>
<td>PMCID: PMC40441031.</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Conference/Meeting</td>
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<tr>
<td>Curtis, B. (2014)</td>
<td>Recruitment and Consent Challenges and Opportunities in Internet Research. PRIM&amp;R’s Advancing Ethical Research Conference, Baltimore, MD.</td>
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<tr>
<td>Curtis, B. (2013)</td>
<td>Conducting a workshop using data obtained from this research project. Poster presented at PRIM&amp;R’s Advancing Ethical Research conference, Boston, MA.</td>
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<td>Davidson, P. J. (2012)</td>
<td>Differences between the ways researchers and people who inject drugs think about research participation, and the ethical consequences of these differences. Paper presented at the National Harm Reduction conference, Portland, OR.</td>
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<tr>
<td>Name</td>
<td>Title</td>
<td>Conference/Meeting Details</td>
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<tr>
<td>Reed, E.</td>
<td>Female Sex Workers Participating in HIV Prevention Research in Andhra Pradesh, India.</td>
<td>American Public Health Association annual meeting, Boston, MA.</td>
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<tr>
<td>Reed, E.</td>
<td>Confidentiality, Privacy, &amp; Respect: Perspectives of Female Sex Workers Participating in HIV</td>
<td>141st American Public Health Association annual meeting, Boston, MA.</td>
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<tr>
<td>Goldenberg, S.</td>
<td>La perspectiva de las trabajadoras sexuales sobre la participación en estudios de investigación sobre VIH: Evidencia empírica para informar futuros estudios de investigación.</td>
<td>Universidad del Valle de Guatemala, Guatemal City, Guatemala.</td>
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<tr>
<td>Pearson, C.R.</td>
<td>Protections in Community Based Participatory Research? A Case Example from Indian Country.</td>
<td>PRIM&amp;R's Advancing Ethical Research conference, Boston, MA.</td>
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<tr>
<td>Hettema, J. E., Russo, J. M., &amp; Fisher, C. B.</td>
<td>Disparities in prescribing behavior towards injection drug users living with HIV. Oral presentation as part of the symposium titled Enhancing the Responsible Conduct of HIV Treatment and Prevention in Community Contexts.</td>
<td>141st American Public Health Association annual meeting, Boston, MA.</td>
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<tr>
<td>Kostick, K.</td>
<td>Participant and Staff Experiences in a Peer-Delivered HIV Intervention with Injection Drug Users.</td>
<td>Society for Applied Anthropology annual meeting, Denver, CO.</td>
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<tr>
<td>Madhivanan, P.</td>
<td>Effect of Highly Active Antiretroviral Therapy on Risky Sexual Behaviors Among HIV Positive</td>
<td>Fordham University, New York, NY.</td>
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<td>Madhivanan, P., Krupp, K., Philpott, S. &amp; Fisher, C. B.</td>
<td>Ethical Implications of Policy Change for HIV testing among pregnant women in Public Hospitals in India.</td>
<td>141st American Public Health Association annual meeting, Boston, MA.</td>
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<tr>
<td>Pearson, C.</td>
<td>It Takes a Village: Community Members as Research Partners in Community Based Participatory</td>
<td>Fordham University, New York, NY.</td>
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<tr>
<td>Pearson, C.</td>
<td>Psychological wellbeing in the face of adversity among American Indians: Preliminary Evidence of</td>
<td>143rd American Public Health Association meeting, Chicago, IL.</td>
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<tr>
<td>Pearson, C.</td>
<td>Virtual worlds: Reducing HIV transmission and acquisition for Young American Indian and Alaska</td>
<td>143rd American Public Health Association meeting, Chicago, IL.</td>
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<tr>
<td>Pearson, C. R.</td>
<td>Enhancing the Responsible Conduct of HIV Prevention Research across Culturally and Globally</td>
<td>141st American Public Health Association annual meeting, Boston, MA.</td>
<td></td>
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<tr>
<td>Pearson, C. R. &amp; Parker, M.</td>
<td>Are the CITI Certification Modules Adequate to Ensure Human Subjects Protections in Community Based Participatory Research? A Case Example from Indian Country.</td>
<td>PRIM&amp;R’s Advancing Ethical Research conference, Boston, MA.</td>
<td></td>
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<tr>
<td>Reed, E., Khoshnood, K., Blankenship, K., &amp; Fisher, C.B.</td>
<td>Confidentiality, Privacy, &amp; Respect: Perspectives of Female Sex Workers Participating in HIV Prevention Research in Andhra Pradesh, India.</td>
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<tr>
<td>Reed, E.</td>
<td>Confidentiality, Privacy, &amp; Respect: Perspectives of Female Sex Workers Participating in HIV</td>
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</table>
Prevention Research in Andhra Pradesh, India. Paper presented at the 141st American Public Health Association annual meeting, Boston, MA.


