ETHICAL ISSUES IN GLOBAL HEALTH RESEARCH

EIGHR

SEPTEMBER 23-26, 2019

SEPTEMBER 27, 2019 (ADDITIONAL REGISTRATION REQUIRED): POST APPROVAL MONITORING AND EVALUATING YOUR HRPP: A REAL WORLD EXPERIENCE

HARVARD MEDICAL SCHOOL
BOSTON, MA

DAILY AGENDA (SUBJECT TO CHANGE)

MONDAY, SEPTEMBER 23, 2019 (COUNTWAY LIBRARY, ROOM 506, MINOT ROOM)

8:15–8:45 AM Check-in and Continental Breakfast

8:45–9:15 AM Program Introduction and Overview

Delia Y. Wolf, MD, JD, MSCI
Senior Lecturer, Health Policy & Management
Associate Dean for Regulatory Affairs & Research Compliance
Harvard T.H. Chan School of Public Health

9:15–10:30 AM Ethics of Human Subjects Research

Elisa A. Hurley, PhD
Executive Director
Public Responsibility in Medicine and Research (PRIM&R)

10:30–10:45 AM Break

10:45–12:00 PM General Data Protection Regulation: Impact on Research Conducted by U.S. Entities

David J. Peloquin, JD
Ropes & Gray LLP

12:00–1:00 PM Lunch Provided

9/23/2019
DAILY AGENDA

1:00–2:15 PM  IRB Review and Oversight of International Research: Challenges and Considerations

Leslie Howes, MPH, CIP
Director
Office of Regulatory Affairs & Research Compliance
Harvard T.H. Chan School of Public Health

2:15–2:30 PM  Break

2:30–3:45 PM  Guiding Principles for Clinical Trials Data Sharing

Barbara E. Bierer, MD
Faculty Co-Director
Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women’s Hospital and Harvard University
Program Director
Regulatory Foundations, Ethics and the Law
Harvard Catalyst
Professor of Medicine
Harvard Medical School
Senior Physician
Brigham and Women's Hospital

3:45–5:00 PM  Human Subjects Research in International Settings: Compliance, Ethics, and Logistics

Mark Barnes, Esq.
Partner
Ropes & Gray LLP
Lecturer in Law
Yale Law School
Faculty Co-Chair
Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard University

5:00 PM  Sessions End
TUESDAY, SEPTEMBER 24, 2019 (COUNTWAY LIBRARY, ROOM 506, MINOT ROOM)

8:15–8:45 AM Continental Breakfast

8:45–10:00 AM Placebo Controlled Trials in Underserved Vulnerable Populations: The "Short Course" Maternal/Fetal HIV Transmission Study
Norman Fost, MD, MPH
Professor Emeritus of Pediatrics and Bioethics
University of Wisconsin-Madison

10:00–10:15 AM Break

10:15–11:30 AM Challenges and Recommendations in Conducting Public Health Research
David C. Christiani, MD, MPH
Elkan Blout Professor of Environmental Genetics
Harvard T.H. Chan School of Public Health
Professor of Medicine
Harvard Medical School
IRB Chair
Harvard T.H. Chan School of Public Health

11:30–12:45 PM Ethical Issues in International Research Involving Vulnerable Populations
Susan Z. Kornetsky, MPH
Director of Clinical Research Compliance
Boston Children's Hospital

12:45–1:45 PM Lunch Provided

1:45–3:00 PM Informed Consent in International Health Research
David Borasky, MPH, CIP
Vice President, IRB Compliance
WIRB-Copernicus Group

3:00–3:15 PM Break

3:15–4:30 PM The Standard of Care in Research In Developing Countries
Daniel Wikler, PhD
Mary B. Saltonstall Professor of Ethics and Population Health
Harvard T.H. Chan School of Public Health
4:30 PM Sessions End

4:45-5:00 PM Group Picture (In front of Harvard Chan School’s Kresge Building)

5:00-6:15 PM Reception at Harvard T.H. Chan School of Public Health (90 Smith Street, 3rd Floor, ORARC Offices)

WEDNESDAY, SEPTEMBER 25, 2019 (COUNTWAY LIBRARY, ROOM 506, MINOT ROOM)

8:15–8:45 AM Continental Breakfast

8:45–10:00 AM Conflict of Interest

Richard Cash, MD, MPH
Senior Lecturer on Global Health
Department of Global Health and Population
Harvard T.H. Chan School of Public Health

10:00–10:15 AM Break

10:15–11:30 AM The International Compilation of Human Research Standards: Fifteen Year Retrospective

Edward Bartlett, PhD
International Human Research Liaison
Office for Human Research Protections
U.S. Department of Health and Human Services

11:30–12:30 PM Lunch Provided

12:30–1:45 PM Top 10 Findings from AAHRPP’s International Applications and Site Visits

Elyse I. Summers, JD
President and CEO
Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)

1:45–2:15 PM Break

2:15–4:15 PM Mock IRB Review

Panel #1 (Gordon Hall, Room 311, Alumni Conference Room)
David C. Christiani, MD, MPH

Alyssa A.K. Speier, MS, CIP
Associate Director for Regulatory Affairs & Research Compliance
Harvard T.H. Chan School of Public Health

Panel #2 (TMEC, Room 443, Conference Room)

Kimberly Serpico, MEd, CIP
Assistant Director, IRB Operations
Harvard T.H. Chan School of Public Health

Leslie Howes, MPH, CIP

Panel #3 (TMEC, Room 448, Conference Room)

Delia Y. Wolf, MD, JD, MSCI
Alma Castro, MA, CIP
IRB Review Specialist
Harvard T.H. Chan School of Public Health

4:15 PM  Sessions End

THURSDAY, SEPTEMBER 26, 2019 (COUNTWAY LIBRARY, 5TH FLOOR, LAHEY ROOM)

8:15–8:45 AM  Continental Breakfast

8:45–10:00 AM  Tips for Increasing Review Efficiency

Jeffrey A. Cooper, MD, MMM
Vice President Global Consulting
WIRB-Copernicus Group

10:00–10:15 AM  Break
DAILY AGENDA

10:15–11:30 AM Ethical Issues in Research Design: the Use of Deception in Research, and the Limits of Conflicts of Interest Disclosure

Ichiro Kawachi, MD, PHD
Professor of Social Epidemiology
Department Chair, Social and Behavioral Sciences
Harvard T.H. Chan School of Public Health
IRB Chair
Harvard T.H. Chan School of Public Health

11:30–12:30 PM Lunch Provided

12:30-1:45 PM Case Study Break-Out Sessions

Group #1 (Gordon Hall, Room 212, Bibring Conference Room)
Kimberly Serpico, MEd, CIP

Group #2 (Countway Library, 5th Floor Lahey Room)
Alyssa A.K. Speier, MS, CIP

Group #3 (Gordon Hall, Room 311, Alumni Conference Room)
Alma Castro, MA, CIP

1:45–2:15 PM Case Study Summary Discussion (Countway Library, 5th Floor Lahey Room)

2:15 PM Wrap up and Evaluation

3:00 PM Program Adjournment
FRIDAY, SEPTEMBER 27, 2019 (ADDITIONAL REGISTRATION REQUIRED) (ORARC OFFICES AT 90 SMITH STREET, 3RD FLOOR)

8:30–9:00 AM  Continental Breakfast

9:00–9:30 AM  How to Audit

   Alyssa A.K. Speier, MS, CIP

9:30–12:30 PM  Mock Not for Cause Site Audit

   Lisa Gabel, CIP
   Senior QA/QI Specialist
   Harvard T.H. Chan School of Public Health

   Alyssa A.K. Speier, MS, CIP

   This exercise will cover:
   • Preparing for a study site audit
   • Site orientation/introduction
   • Participant file review
   • Exit interview
   • Report writing and audit wrap up

12:30–1:30 PM  Lunch Provided

1:30-4:30 PM  Evaluation of the HRPP

   Delia Y. Wolf, MD, JD, MSCI

   Alyssa A.K. Speier, MS, CIP

   Kimberly Serpico, MEd, CIP

   This session will cover:
   • Overview
   • Hands on Auditing of IRB minutes
   • HRPP metrics
   • AAHRPP Accreditation, Compliance, and Efficiency of the HRPP

4:30 PM  Program Adjournment