ETHICAL ISSUES IN GLOBAL HEALTH RESEARCH

EIGHR

JULY 24–27, 2017

DAILY AGENDA (SUBJECT TO CHANGE)

MONDAY, JULY 24, 2017

8:00–8:30 AM Check-in and Continental Breakfast

8:30–8:45 AM Classroom Technology Orientation

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

Delia Y. Wolf, MD, JD, MSCI
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)

10:30–11:00 AM Refreshment Break

11:00–12:15 PM Human Subjects Research in International Settings: Compliance, Ethics, and Logistics

Mark Barnes, JD, LLM
Partner
Ropes & Gray, LLP
Lecturer in Law
Harvard Law School
Co-Chair, Multi-Regional Clinical Trials (MRCT) Center
Harvard Global Health Institute

12:15–1:15 PM Lunch

1:15–2:30 PM Informed Consent in International Health Research

David Forster, JD, MA, CIP
Chief Compliance Officer
Office of Compliance
WIRB-Copernicus Group IRB
2:30–2:45 PM Refreshment Break

2:45–4:00 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

4:00–5:15 PM IRB Review and Oversight of International Research: Challenges and Considerations

Leslie Howes, MPH, CIP
Managing Director
Office of Human Research Administration
Harvard T.H. Chan School of Public Health

5:15 PM Sessions End

TUESDAY, JULY 25, 2017

8:00–8:30 AM Continental Breakfast

8:30–8:45 AM Program Updates and Logistics

Delia Y. Wolf, MD, JD, MSCI

8:45–10:00 AM Guiding Principles for Clinical Trials Data Sharing

Barbara E. Bierer, MD
Faculty Co-Director
Multi-Regional Clinical Trials (MRCT) Center
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

10:00–10:15 AM Refreshment Break

10:15–11:30 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
DAILY AGENDA

11:30–12:45 PM Ethical Issues in International Research Involving Children

Susan Z. Kornetsky, MPH
Director of Clinical Research Compliance
Boston Children's Hospital

12:45–1:30 PM Lunch

1:30–3:30 PM Mock IRB Review

Leslie Howes, MPH, CIP

Delia Y. Wolf, MD, JD, MSCI

3:30 PM Sessions End

4:00–5:30 PM Reception at Harvard Medical School

WEDNESDAY, JULY 26, 2017

8:00–8:30 AM Continental Breakfast

8:30–8:45 AM Program Updates and Logistics

Delia Y. Wolf, MD, JD, MSCI

8:45–10:00 AM Providing Equivalent Protections When Reviewing International Research: Points to Consider

Delia Y. Wolf, MD, JD, MSCI

10:00–10:30 AM Refreshment Break

10:30–11:45 AM Tissue Banking

P. Pearl O'Rourke, MD
Associate Professor of Pediatrics
Harvard Medical School
Director of Human Research Affairs
Partners HealthCare

11:45–12:45 PM Lunch

12:45–2:00 PM Challenges and Recommendations in Conducting Public Health Research

David C. Christiani, MD, MPH
DAILY AGENDA

Elkan Blout Professor of Environmental Genetics
Harvard T.H. Chan School of Public Health
Professor of Medicine
Harvard Medical School

2:00–2:30 PM Refreshment Break

2:30–3:45 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)

3:45–5:00 PM Case Studies

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

Scott Meyers, CIP
QA/QI Specialist
Office of Human Research Administration (OHRA)
Harvard T.H. Chan School of Public Health

5:00 PM Sessions End

THURSDAY, JULY 27, 2017

8:00–8:30 AM Continental Breakfast

8:30–8:45 AM Program Updates and Logistics

Delia Y. Wolf, MD, JD, MSCI

8:45–10:00 AM Video Discussion Session

10:00–10:30 AM Refreshment Break

10:30–11:45 AM Tips for Increasing Review Efficiency

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

11:45–12:45 PM Lunch
DAILY AGENDA

12:45–1:15 PM  How to Audit

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

1:15–3:15 PM  Mock Audit of Research Site (with refreshments)

  Lisa Gabel, CIP
  Senior QA/QI Specialist
  Office of Human Research Administration (OHRA)
  Harvard T.H. Chan School of Public Health

  Scott Meyers, CIP
  QA/QI Specialist
  Office of Human Research Administration (OHRA)
  Harvard T.H. Chan School of Public Health

3:15–4:15 PM  Wrap up and Evaluation

4:15 PM  Program Adjournment