Day 1: Monday, May 7, 2012

7:30AM TO 8:15AM  REGISTRATION (ROONE ARLEDGE AUDITORIUM RECEPTION)

7:30AM TO 8:30AM  CONTINENTAL BREAKFAST (BROADWAY LOBBY)

8:15AM TO 8:30AM  WELCOME AND INSTITUTIONAL REMARKS (ROONE ARLEDGE AUDITORIUM)
   George Gasparis, Executive Director, HRPP, Columbia University
   G. Michael Purdy, Ph.D., Executive Vice President for Research, Columbia University

8:30AM TO 9:15AM  KEYNOTE ADDRESS (ROONE ARLEDGE AUDITORIUM)
   How Relevant is the Belmont Report Now and in the Future?
   Tom Beauchamp, Ph.D., Professor of Philosophy and Senior Research Scholar,
   Kennedy Institute of Ethics, Georgetown University

9:15AM TO 10:00AM  PLENARY SESSION #1 (ROONE ARLEDGE AUDITORIUM)
   Central IRBs: More Efficient for Whom?
   P. Pearl O’Rourke, M.D., Director of Human Research Affairs at Partners HealthCare
   Systems, Associate Professor of Pediatrics, Harvard Medical School

10:00AM TO 10:45AM  PLENARY SESSION #2 (ROONE ARLEDGE AUDITORIUM)
   The ANPRM – The AAHRPP View
   Marjorie Speers, Ph.D., President and CEO, Association for the Accreditation of
   Human Research Protection Programs, Inc. (AAHRPP)

10:45AM TO 11:00AM  BREAK (COFFEE AND REFRESHMENTS PROVIDED IN THE BROADWAY LOBBY)

11:00AM TO 11:45AM  PLENARY SESSION #3 (ROONE ARLEDGE AUDITORIUM)
   The ANPRM – A Contrarian Perspective
   Greg Koski, M.D., Ph.D., Director of Clinical Research, Division of Cardiovascular
   Anesthesia, Department of Anesthesia, Critical Care and Pain Medicine,
   Massachusetts General Hospital, Senior Scientist, James Mongan Institute for
   Health Policy, Massachusetts General Hospital and Partners HealthCare System
**11:45AM TO 12:30PM**  
**PLENARY SESSION #4 (ROONE ARLEDGE AUDITORIUM)**  
**QUESTION & ANSWER SESSION:**

**Moderator:**  
Ivor Pritchard, Ph.D., Senior Advisor to the Director,  
Office for Human Research Protections (OHRP)

**Panelists:**  
Tom Beauchamp, Ph.D., Professor of Philosophy and Senior Research Scholar,  
Kennedy Institute of Ethics, Georgetown University

Greg Koski, M.D., Ph.D., Director of Clinical Research, Division of Cardiovascular  
Anesthesia, Department of Anesthesia, Critical Care and Pain Medicine,  
Massachusetts General Hospital, Senior Scientist, James Mongan Institute for  
Health Policy, Massachusetts General Hospital and Partners HealthCare System

P. Pearl O’Rourke, M.D., Director of Human Research Affairs at Partners HealthCare  
Systems, Associate Professor of Pediatrics, Harvard Medical School

Marjorie Speers, Ph.D., President and CEO, The Association for the Accreditation of  
Human Research Protection Programs, Inc. (AAHRPP)

**12:30PM TO 1:30PM**  
**LUNCH (ROONE ARLEDGE AUDITORIUM)**

**1:30PM TO 2:15PM**  
**PLENARY SESSION #5 (ROONE ARLEDGE AUDITORIUM)**  
**Protection, Over-Protection, and Pseudo-Protection**

Alan Wertheimer, Ph.D., Senior Research Scholar, Department of Bioethics,  
National Institutes of Health

**2:15PM TO 3:15PM**  
**BREAKOUT SESSION #A1 (ROONE ARLEDGE AUDITORIUM)**  
**Consent Issues Panel**

**Communicating Risk**  
Pearl O’Rourke, M.D., Director of Human Research Affairs at Partners HealthCare  
Systems, Associate Professor of Pediatrics, Harvard Medical School

**Misconceptions about Coercion and Undue Influence: Reflections on a Survey of IRB Members**

Alan Wertheimer, Ph.D., Senior Research Scholar, Department of Bioethics,  
National Institute of Health

**BREAKOUT SESSION #A2 (JED D. SATOW ROOM 567)**  
**Conflicts of Interest**

Naomi Schrag, J.D., Associate Vice President, Research Compliance, Columbia University

**BREAKOUT SESSION #A3 (ROOM 555)**  
**Globalization of Research: Enhancing Excellence and Safety**

Greg Koski, M.D., Ph.D., Director of Clinical Research, Division of Cardiovascular  
Anesthesia, Department of Anesthesia, Critical Care and Pain Medicine,  
Massachusetts General Hospital, Senior Scientist, James Mongan Institute for  
Health Policy, Massachusetts General Hospital and Partners HealthCare System

**BREAKOUT SESSION #A4 (ROONE ARLEDGE CINEMA)**  
**Research Coordinator Workshop with Association of Clinical Research Professionals (ACRP)**  
**Part I: Tips and Tricks for Document Management Compliance**

**Moderator:**

Esther Daemen, BSN, CPP, CPM, PG, Director of Professional Development,  
Association for Clinical Research Professionals (ACRP)

**Presenters:**

Janet Ellen Holwell, CCRC, CCRA, Clinical Quality Lead (CQL), US Clinical Operations,  
Pfizer, President, New York Metropolitan Chapter of ACRP

Sherif Ibrahim, M.D., Principal Clinical Research Specialist, Medtronic, Inc.
3:15PM TO 3:30PM  BREAK (COFFEE AND REFRESHMENTS PROVIDED IN THE BROADWAY LOBBY)

3:30PM TO 4:30PM  BREAKOUT SESSION #B1 (JED D. SATOW ROOM 567)
Contract Issues
Jean Gabeau, J.D., Manager of Contracts, Clinical Trials Office, Columbia University

BREAKOUT SESSION #B2 (ROOM 555)
Community-Based Participatory Research
Rafael Lantigua, M.D., Associate Director of the Division of General Medicine, Director for Medical Research at Columbia’s Stroud Center for Geriatric Research, and Medical Director of the Associates of Internal Medicine (AIM) Practice, NewYork-Presbyterian Hospital

Joyce Moon Howard, Dr.P.H., Assistant Professor of Clinical Sociomedical Sciences, Mailman School of Public Health

BREAKOUT SESSION #B3 (ROONE ARLEDGE AUDITORIUM)
Internet Research with Social Media – Perspectives from Researchers
User Studies on the Internet
Steven Bellovin, Ph.D., Professor of Computer Science, Columbia University

Youth and New Media: New and Old Challenges for Human Subjects Protection
John Santelli, M.D., M.P.H., Professor of Clinical Population and Family Health, Mailman School of Public Health; Professor of Clinical Pediatrics, Columbia University College of Physicians and Surgeons

BREAKOUT SESSION #B4 (ROONE ARLEDGE CINEMA)
Research Coordinator Workshop with Association of Clinical Research Professionals (ACRP) – Part II: Tips and Tricks for Document Management Compliance
Moderator:
Esther Daemen, BSN, CPP, CPM, PG, Director of Professional Development, Association for Clinical Research Professionals (ACRP)

Presenters:
Janet Ellen Holwell, CCRC, CCRA, Clinical Quality Lead (CQL), US Clinical Operations, Pfizer, President, New York Metropolitan Chapter of ACRP
Sherif Ibrahim, M.D., Principal Clinical Research Specialist, Medtronic, Inc.

4:30PM TO 5:30PM  WINE AND CHEESE RECEPTION (BROADWAY LOBBY)
Institutional Review Board Educational Conference
May 7 – May 8, 2012
Current IRB Challenges and Practical Solutions

Day 2: Tuesday, May 8, 2012

7:30AM TO 8:15AM  REGISTRATION (ROONE ARLEDGE AUDITORIUM RECEPTION)

7:30AM TO 8:30AM  CONTINENTAL BREAKFAST (BROADWAY LOBBY)

8:15AM TO 8:30AM  WELCOME (ROONE ARLEDGE AUDITORIUM)
  George Gasparis, Executive Director, HRPP, Columbia University
  Steven Shea, M.D., Senior Vice Dean, Columbia University Medical Center

8:30AM TO 9:15AM  KEYNOTE ADDRESS (ROONE ARLEDGE AUDITORIUM)
  Microbe Hunting
  Ian Lipkin, M.D., Director, Center for Infection & Immunity, John Snow Professor of Epidemiology, Mailman School of Public Health, Professor of Neurology and Pathology, Columbia University

9:15AM TO 10:00AM  PLENARY SESSION #6 (ROONE ARLEDGE AUDITORIUM)
  Public Health Research and Public Health Practice: A CDC Perspective
  Ron Otten, Ph.D., Director of the Office of Scientific Integrity (OSI), Centers for Disease Control and Prevention (CDC)

10:00AM TO 10:45PM  PLENARY SESSION #7 (ROONE ARLEDGE AUDITORIUM)
  Disaster/Rapid Review Research
  David Abramson, Ph.D., M.P.H., Deputy Director, National Center for Disaster Preparedness, Assistant Professor of Clinical Sociomedical Sciences, Mailman School of Public Health

10:45AM TO 11:00AM  BREAK (COFFEE AND REFRESHMENTS PROVIDED IN PRESIDENTIAL BALLROOM & SEMINAR ROOM)

11:00AM TO 12:15PM  PLENARY SESSION #8 (ROONE ARLEDGE AUDITORIUM)
  Exploring the Boundaries Between Practice and Research in Public Health
  Moderator:
  Hugh Tilson, M.D., M.P.H., Dr.P.H., Adjunct Professor and Senior Advisor, University of North Carolina at Chapel Hill, School of Public Health
  Presenters:
  Ron Otten, Ph.D., Director of the Office of Scientific Integrity (OSI), Centers for Disease Control and Prevention (CDC)
  Ivor Pritchard, Ph.D., Senior Advisor to the Director, Office for Human Research Protections (OHRP)
  Marjorie Speers, Ph.D., President and CEO, Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)

12:15PM TO 1:15PM  LUNCH (ROONE ARLEDGE AUDITORIUM)
1:15PM TO 2:00PM  **PLENARY SESSION #9** (ROONE ARLEDGE AUDITORIUM)
**Social Media – Facebook Privacy**
Latanya Sweeney, Ph.D., Visiting Professor and Scholar, Director of the Data Privacy Lab, Harvard University

2:00PM TO 2:15PM  **COMMUTING TIME**

2:15PM TO 3:15PM  **BREAKOUT SESSION #C1** (ROONE ARLEDGE AUDITORIUM)
**Data Security: Considerations for Research**

*Moderator:*  
Latanya Sweeney, Ph.D., Visiting Professor and Scholar, Director of the Data Privacy Lab, Harvard University

*Presenters:*  
Erik Decker, M.S., CCISSP, Assistant Director of Information Security, Columbia University Medical Center  
Karen Pagliaro-Meyer, Privacy Officer, Columbia University

**BREAKOUT SESSION #C2** (JED D. SATOW ROOM 567)
**New York City Department of Education (DOE) IRB FAQs**
Mary Mattis, Ph.D., Chair, Institutional Review Board, Research & Policy Support Group, New York City Department of Education

**BREAKOUT SESSION #C3** (ROOM 555)
**Responsibilities of the Sponsor Investigator**
Helen Kim, Pharm.D., Director of Regulatory Affairs & Clinical Development, Columbia University Clinical Trials Office

**BREAKOUT SESSION #C4** (ROONE ARLEDGE CINEMA)
**IRB Review and Responsibilities for Atypical Submissions: Infrastructure Grants, Data Coordinator Centers, 46.118 Determinations, etc.**
George Gasparis, Executive Director, Human Research Protection Program, Columbia University

3:15PM TO 3:30PM  **BREAK** (COFFEE AND REFRESHMENTS PROVIDED IN THE BROADWAY LOBBY)

3:30PM TO 5:00PM  **PLENARY SESSION #10** (ROONE ARLEDGE AUDITORIUM)
**NYC IRB Consortium Panel – Open Discussion of Human Subject Issues:**  
**BRING YOUR QUESTIONS!**

*Panelists:*  
Elan Czeisler, IRB Director, NYU Langone Medical Center  
Alison Dewhurst, Human Research Compliance Director, NYU  
George Gasparis, Executive Director, Columbia University HRPP  
Raffaella Hart, IRB Director, BRANY  
Rosemary Kraemer, Ph.D., Director, Human Subjects Protections, Weill-Cornell Medical College  
David Strauss, M.D., Deputy Director for Research, New York State Psychiatric Institute  
David Wallach, IRB Director, Albert Einstein College of Medicine  
Ilene Wilets, Ph.D., Assistant Director, IRB Chair, Mount Sinai School of Medicine  
Program for the Protection of Human Subjects