



COLUMBIA UNIVERSITY

IN THE CITY OF NEW YORK

Institutional Review Board Educational Conference
April 20, 2010

Current IRB Challenges and Practical Solutions

8:00 TO 8:30AM	REGISTRATION (Lobby)
8:30 TO 8:45AM	WELCOME AND INSTITUTIONAL REMARKS (AUDITORIUM) George Gasparis, Executive Director HRPP, Columbia University
8:45 TO 9:15AM	KEYNOTE ADDRESS International Research – What Directions are Likely in the Next Decade and What Have We Learned From the Past One? Jeffrey D. Sachs, M.A., Ph.D., Director of The Earth Institute, Quetelet Professor of Sustainable Development, and Professor of Health Policy and Management at Columbia University
9:15 TO 10:30AM	PLENARY SESSION #1 International Research – Are the Resources Available to Implement IRB Requirements? Pragmatic and Idealistic Discussions Regarding Capacity Building and the Protection of Human Subjects <i>Moderator:</i> Jeffrey D. Sachs M.A., Ph.D., Director of The Earth Institute Wafaa El-Sadr, M.D., M.P.H., Chief of the Infectious Disease Division, Harlem Hospital and the Director of the Center for Infectious Diseases Epidemiologic Research at the Mailman School of Public Health at Columbia University. James Lavery, MSc., Ph.D., Assistant Professor, Dalla Lana School of Public Health, University of Toronto
10:30 TO 10:45AM	BREAK
10:45 TO 12:00PM	PLENARY SESSION #2 Improving Governance and Oversight of Genomic Biobanks: Dynamic Science? Stale Ethics? Barbara A. Koenig, Ph.D., Professor of Medicine, Mayo Clinic College of Medicine and Faculty Associate at the Center for Bioethics, University of Minnesota
12:00 TO 1:15PM	NETWORKING LUNCH
1:15PM TO 1:30PM	TRAVEL TIME
1:30 – 2:45PM	SPLIT SESSION/BREAKOUT #1 (ALFRED J. LERNER HALL) A. FDA Regulated Research – Current Challenges with Investigational Devices Lynn Henley, M.S., M.B.A., Investigational Device Exemption and Humanitarian Device Exemption Staff, Center for Devices and Radiological Health (CDRH), FDA B. Collecting and Protecting Sensitive Data in Research: a presentation and discussion of “High-Use Alcohol Venues: Tourism, Sex work and HIV in the Dominican Republic.” Vincent Guilamo-Ramos, Ph.D., Associate Professor of Social Work, Columbia University Joyce Plaza, M.S., M.B.E., CIP, Asst. Manager, MS IRB, Columbia University

1:30 – 2:45PM

SPLIT SESSION/BREAKOUT #1 (CONT'D)

C. Alzheimer's Disease, Dementia, and Other Neurological Disorders: How and How Often is Capacity Determined and How Are Subjects Protected Once Capacity is Lost?

Moderator:

David Strauss, M.D., Associate Clinical Professor of Psychiatry, Columbia University
Chair, New York State Psychiatric Institute IRB

Karen Bell, M.D., Clinical Professor of Neurology, Taub Institute for Research
on Alzheimer's Disease and the Aging Brain and the Gertrude H. Sergievsky
Center in Columbia University's College of Physicians and Surgeons

Jason H. T. Karlawish, M.D., Director, Education and Information Transfer Core
(Core E, Alzheimer's Disease Center), University of Pennsylvania

2:45 TO 3:00PM

TRAVEL TIME

3:00 – 4:15PM

SPLIT SESSION/BREAKOUT #2

A. Race for a Cure: What if There are No Alternative Therapies? Subject Advocacy vs. Therapeutic Misconception

Gigi McMillan, B.A., Director, We Can, Pediatric Brain Tumor Network

Paul Appelbaum, M.D., Elizabeth K. Dollard Professor of Psychiatry, Medicine and Law,
Columbia University

B. Implementing Protections of Human Subjects on the Front Lines of Community Research – Real Challenges and Solutions

Robert Fullilove, Ed.D., Associate Dean of Community and Minority Affairs, Professor of
Clinical Sociomedical Sciences, and Co-Director of the Community Research
Group

C. A Gathering for those Interested in Exploring the Certified IRB Professional (CIP) Credential: Your Chance to Ask Us About the Certification and Recertification Process

Susan J. Delano, CIP, Chair, CIP, Deputy Managing Director,
Research Foundation for Mental Hygiene Inc., Chair, Council for Certification of
IRB Professionals (CCIP)

Corine Rogers, M.S., CIP, Administrator, Institutional Review Board,
New York State Psychiatric Institute IRB

4:15 – 5:00PM

WINE AND CHEESE RECEPTION