Sunday, May 2, 2004

5:00 - 8:00 PM  Registration

5:00 - 7:00 PM  Wine and Cheese Reception

Monday, May 3, 2004 - Conflicts of Interest

7:00 AM  Registration Opens

7:00 - 7:45 AM  Yoga

    Harborside Walk
    Self-guided walk along Boston Harbor

7:00 - 8:30 AM  Continental Breakfast

8:30 - 8:45 AM  Welcome and Conference Overview
    Ruth Fischbach

8:45 - 9:45 AM  Plenary Addresses
    Conflicts of Interest and the Research Enterprise:
    Are Protection of Human Subjects and Research Integrity on the Line?
    Susan Eringhause

9:45 - 11:00 AM  Conflicts Panel I
    Financial Conflicts of Interest and “Interesting” Financial Conflicts
    Moderator: Richard Bianco
    Panelist: Theodore Cicero
    Panelist: Peter Lurie
    Panelist: Barbara Mishkin

11:00 - 11:15 AM  Break

11:15 - 11:45 AM  Keynote Address
    Thinking Critically about Conflicts of Interest in Biomedical Research - Thomas Murray
11:45 - 1:00 PM  Conflicts Panel II

Conflicts of Interest are Here to Stay: Investigator/Individual Conflicts and Their Impact on Research
Moderator: Ronald Newbower
Panelist: Paul Citron
Panelist: Susan Ellenberg
Panelist: Mark Horn
Panelist: Thomas Moore

1:00 - 2:00 PM  Luncheon and Speaker - Marcia Angell

2:15 - 3:30 PM  Conflicts Workshop Series


A2 Everything Researchers Need to Know About the Regulations, and Relevant Guidance Documents, Regarding Conflicts of Interest (Financial and Non-Financial Conflicts) (Regulatory I) Claudia Adkison, Susan Ellenberg

A3 Industry Considerations: Three Views - Pharmaceutical, Medical Devices, and the Public Perspective (Industry) Paul Citron, Peter Lurie, Roger Porter

A4 Individual and Institutional Conflicts of Interest Involving IRB Members (IRB Members) Mark Barnes, Airlie Cameron, Richard Bianco

A5 Creating a “Culture of Conscience” Not Just a “Culture of Compliance” in a Research-Intensive Institution (Institutional Officials) Mary Faith Marshall, Daniel Vasgird

A6 The Inventor as Principal Investigator: Conflicts, Conflicts, Conflicts! (Investigator Issues) Theodore Cicero, Barbara Mishkin

A7 Conflicts of Interest from the Research Participant’s Perspective: What Do Participants Want to Know? (Research Subjects/Advocacy) Ruth Fischbach, Judy Perotti
A8 IRB Policies on Financial Incentives, Finder’s Fees, Bonus Payments, Participant Payments, and Protocol Review Fees (Hot Spots) Susan Fish, Susan Kornetsky

3:30 – 3:45 PM Break

3:45 – 5:00 PM Conflicts Panel III
Managing Conflicts of Interest at the IRB and Institutional Levels
Moderator: Susan Kornetsky
Panelist: Claudia Adkison
Panelist: Mark Barnes
Panelist: Roger Porter

5:00 – 5:15 PM Closing Remarks and Next Steps
Barbara Mishkin

5:15 – 6:15 PM Wine and Cheese Reception
Tuesday, May 4, 2004 - Privacy and Confidentiality

7:00 AM Registration Opens

7:00 - 7:45 AM Yoga

Harborside Walk
Self-guided walk along Boston Harbor

7:00 - 8:30 AM Continental Breakfast

8:30 - 8:50 AM Welcome and Conference Overview
Privacy and Confidentiality - Where Do We Stand? Where Are We Heading?
Pearl O'Rourke

8:50 - 9:15 AM Keynote Address
A Privacy and Confidentiality Primer
Mary McCabe

9:15 - 10:30 AM Privacy Panel I
Fusing/Confusing Ethics and Privacy/Confidentiality - Principles and Regulations
Moderator: Susan Fish
Panelist: Jeffrey Cohen
Panelist: Moira Keane
Panelist: Mary Faith Marshall

10:30 - 10:45 AM Break

10:45 - 11:30 AM Plenary Talk
Privacy Problems Involving Genetic Information
Philip Reilly

11:45 AM - 1:00 PM Privacy/Confidentiality Workshop Series A


A2 Security of Electronic Data - Computer and “PDA” Issues (Hot Spots) Jeffrey Cohen
A3  Reviewing Research with Special Populations (Including Prisoners, Substance Abusers, Persons with HIV/AIDS, Pregnant Women, etc.) (Special Populations)  
*Judy Brookshire, Moira Keane*

A4  HIPAA and Repositories: A Case Study (HIPAA I)  
*Marianna Bledsoe, Mary McCabe*

A5  Waivers of HIPAA Authorization (e.g., When you waive the requirement for documentation of consent - how does that “wash” with HIPAA? Also include “Waiver of Documentation of Consent: What To Do With HIPAA?”) (HIPAA II)  
*Bartley Barefoot, Lora Kutkat, Patricia Roche*

A6  Privacy and Confidentiality in Social Science Research: Ethical Issues in Ethnographic Research  
(Social/Behavioral Science)  
*Mary Faith Marshall*

A7  Nooks and Crannies of Privacy in Industry Research  
*Oliver Johnson*

A8  Privacy Issues in Focus Groups (Potpourri)  
(Industry Track)  
*Lawrence Muhlbaier, Susan Waisbren*

1:00 – 2:00 PM  
Luncheon

2:15 – 3:30 PM  
Privacy Panel II  
*Privacy/Confidentiality Challenges in the HIPAA Era: Identified Areas of Difficulty and Proposed Strategies for Their Resolution*  
Moderator:  
*Pearl O’Rourke*  
Panelist:  
*Bartley Barefoot*  
Panelist:  
*Oliver Johnson*  
Panelist:  
*Lora Kutkat*

3:30 – 3:45 PM  
Break

3:45 – 5:00 PM  
Privacy/Confidentiality Workshop Series B

(Regulatory)  
*Lora Kutkat, Irene Stith Coleman*
B2 “Hands Off” My Research Data: Certificates of Confidentiality - When are They Appropriate? (Facilitators will include a federal agency representative [NIAAA] who is involved with granting the certificates) (Hot Spots) Miriam Kelty, Susan Stayn

B3 Privacy and Confidentiality Issues When Conducting Research in Different Cultural Contexts (Special Populations)
Mary Faith Marshall

B4 “Preparatory to Research” and Recruitment: What is Allowed, and What is Required? (HIPAA I)
Steve Bernstein, Airlie Cameron

B5 Multi-Center Research in the HIPAA Era: ACES, Hybrids, Covered Entities, etc. (HIPAA II)
Heather Fields, Pearl O'Rourke

B6 Assessing Risks of Inadvertent Disclosure in Social Science and Behavioral Research (Social/Behavioral Science)
Jeffrey Cohen, Moira Keane

B7 IRBs and Genetic Research: Privacy and Confidentiality Considerations, including Pedigree and Epidemiological Studies (Industry)
Barbara Handelin, Mira Irons

B8 Survey and Public Health Research: How is Privacy Assured in Surveillance and Public Use Databases? (Potpourri)
Lawrence Muhlbaier

5:00 - 5:15 PM Closing Remarks and Next Steps
Pearl O'Rourke

5:15 - 6:15 PM Wine and Cheese Reception
7:00 AM  Registration Opens

7:00 - 7:45 AM  Yoga
Harborside Walk
*Self-guided walk along Boston Harbor*

7:00 - 8:00 AM  Continental Breakfast

8:00 - 8:15 AM  Welcome and Conference Overview
*Tissue Banking: Defining the Landscape*
*Pearl O’Rourke*

8:15 - 8:45 AM  Keynote Address
*The Importance of Tissue Banking and Tissue Research*
*Mark Sobel*

8:45 - 10:00 AM  Tissue Panel I
*Perspectives From Those Who Regulate Tissue Banks*
Moderator:  *Steve Bernstein*
Panelist:  *Julie Kaneshiro*
Panelist:  *Elizabeth Hohmann*
Panelist:  *Sally Hojvat*

10:00 - 10:15 AM  Break

10:15 - 11:30 AM  Tissue Panel II
*Perspectives From Those Who Want/Need Tissue Banks*
Moderator:  *Mark Sobel*
Panelist:  *Elizabeth Hammond*
Panelist:  *Barbara Handelin*
Panelist:  *Judy Perotti*

11:45 AM - 1:00 PM  Tissue Panel III
*Current Challenges*
Moderator:  *Dale Hammerschmidt*
Panelist:  *Sara Hull*
Panelist:  *Joyce Mull*
Panelist:  *Ada Sue Selwitz*

1:00 - 2:00 PM  Luncheon
2:00 - 3:30 PM  Case Studies Workshops

Each workshop will be given a series of cases that focus on specific problem areas. Each case will be designed to solicit viewpoints and thoughts, and the groups will be encouraged to develop suggested approaches to the problems presented by the cases.

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3:30 - 3:45 PM  Break

3:45 - 5:00 PM  Tissue Panel IV

*Strategies and Protections that Have Worked!*

Moderator:  Kristin Ardlie
Panelist:  Roger Aamodt
Panelist:  Lawrence Muhlbaier
Panelist:  Shawn Murphy

5:00 - 5:15 PM  Closing Remarks and Next Steps

*Marianna Bledsoe*

5:15 - 6:00 PM  Wine, Cheese, and Fond Farewells!