

*Conflicts of Interest, Privacy/Confidentiality,
and Tissue Repositories:
Protections, Policies, and Practical Strategies*
May 3 - 5, 2004

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 Eringhouse
- 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

- A1 Reviewing, Responding to, and Managing Conflicts of Interest:
Who, What, Where, and When? (Nuts and Bolts)
Ronald Newbower
- 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
- A1 Federal Guidelines Governing Privacy and Confidentiality:
An IRB Reviewer's Checklist for Biomedical Protocols
(Regulatory) *George Gasparis*
- 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

B1 Federal Guidelines Governing Privacy and Confidentiality: An IRB Reviewer's Checklist for Behavioral Protocols (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

Wednesday, May 5, 2004 -Tissue Repositories/Tissue Banking

- 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.

Case Studies Groups	Room
Group One	<i>Britanic</i>
Group Two	<i>Aquitania</i>
Group Three	<i>Michelangelo</i>
Group Four	<i>Olympia</i>
Group Five	<i>Constitution</i>
Group Six	<i>Constellation</i>
Group Seven	<i>Congress</i>

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!