

Creating a Culture of Research Compliance: Challenges & Opportunities

March 7 and 8, 2006

Agenda*

Day 1 - Tuesday, March 7, 2006

- 7:00 - 8:00** **Registration and Breakfast Buffet (provided)**
- 8:00 - 8:05** **Acknowledgements and Conference Moderator**
Brenda Durosinmi, MPA, CIP, CIM UNLV
- 8:05 - 8:20** **Opening Remarks**
Paul Ferguson, PhD UNLV
- 8:20 - 9:15** **Keynote Address - A Walk Through the History of Research Ethics: *With Lessons Learned...or Not***
Ernest Prentice, PhD University of Nebraska Medical Center
- 9:15 - 10:15** **Panel I - Similar Challenges in Biomedical and Behavioral Research**
Moderator: Paul Jones, EdD
- Exposure to risks of biomedical research is typically faced only by the individual. In behavioral research the range of non-physical risks may have an impact on others including families, social groups, communities, ethnic populations and even entire societies. But there are similar challenges faced in biomedical and behavioral research. This session will delineate some of those challenges.
- Jeffrey Cohen, PhD, CIP* HRP Associates, Inc.
Marjorie Speers, PhD AAHRPP
George Gasparis, CIP Columbia University
John Mercer, PhD UNLV
- 10:15 - 10:30** Refreshment Break
- 10:30 - 11:30** **Breakout Session 1**
- 1A: SBER Research: Exemptions and Ethical Dilemmas**

The federal regulations for the protection of human subjects in research provide exemption categories designed to exclude many social and behavioral studies from the requirements of regulations. Being outside the scope of the regulations, however, does not mean that research studies are outside the realm of ethical review. This session will use a case study approach to review common questions about the applicability of the exemptions to social and behavioral research studies, and to illustrate ethical challenges that sometimes arise in exempt social and behavioral research activities.

Ivor Pritchard, PhD

OHRP

1B: Clinical Research Misconduct & Role of the IRB

This session will discuss what constitutes clinical research misconduct and provide examples where misconduct occurred. In addition, it will describe the role the IRB plays in the discovery and managing of those accused of misconduct.

Samuel Merrill, PhD

ORI

1C: Ethical Issues in Human Subjects Research

Many ethical issues in human subjects research has evolved out of atrocities that have occurred over the past 50 years and has focused our attention to the ethical treatment of humans in research studies. This session will describe some of the common ethical issues that investigators, IRBs and the community are presented with in reviewing studies involving human research subjects.

George Gasparis, CIP

Columbia University

1D: Human Subjects Protections: Regulations and OHRP Guidance

This session will provide a review of the Department of Health and Human Services regulations for the Protection of Human Subjects (45CFR 46) and discuss current OHRP guidance on several challenging human subject protection issues.

Lynda Lahl, RN, MS

OHRP

1E: Lessons from the Trenches: Adversities of Non-Compliance from an Institutional Perspective

Non-compliance can occur within some of the most well constructed human research protection programs. This session describes some of the lessons learned when non-compliance is found and describe how the university and the IRB dealt with finding the solutions to challenging issues.

Helen McGough, MA, CIP

University of Washington

1F: Las Vegas Confidential Series - Sensitive Populations and Topics: Navigating Through the IRB

This session will review the study: Nature and Scope of Child Sexual Abuse in the Catholic Church. The sensitive nature of this topic and the issues concerning the IRB will be the focus of this session.

Martin Wallenstein, PhD, JD

John Jay College of Criminal Justice

11:30 - 12:45 Lunch Buffet (provided)

12:45 - 2:00 **Breakout Session 2**

2A: Risk, Burdens, Opportunities, and Challenges of Clinical Research

Clinical research presents special challenges that the IRB must address. This session reveals the risks, burdens, opportunities, and challenges that occur with clinical research studies.

Pat Holobaugh

FDA

2B: Is it Human Subjects Research?

This session reviews the various types of research that involve human subjects and fall within the purview of review by the IRB. Unique cases will be presented and discussed.

Helen McGough, MA, CIP

University of Washington

Susan Rose, PhD

University of Southern California

2C: Role of the IRB Lawyer

The federal regulations applicable to human subjects research do not require an attorney to be a member of the IRB. However, an attorney can play a key role in assisting the IRB stay in compliance with applicable federal, state and local laws governing research with human participants. This session will focus on how an attorney might function with the IRB.

Laura Odwazny, JD, MA

DHHS Office of General Counsel

Martin Wallenstein, PhD, JD

John Jay College of Criminal Justice

2D: The IRB Administrative Office: How to Effectively Educate the IRB Committee and Research Community

An important component of any human research protection program is an educated IRB committee and research community. Many IRB administrative offices are aware of this need to educate, but lack the resources and the time to supply the education. This session presents an effective way to educate the IRB committee and research committee.

Roberto Rivera, MD

Family Health International

2E: Unanticipated Problems/Adverse Events Involving Risks to Subjects

This session will provide guidance regarding the HHS Regulations for the Protection of Human Subjects (45 CFR Part 46) related to the review and reporting of (a) adverse events, and (b) unanticipated problems involving risks to subjects or others. Among the questions reviewed will be: What are unanticipated problems, and how do they relate to adverse events? How do you determine which adverse events are unanticipated problems that need to be reported under 45 CFR Part 46?

Shirley Hicks, RN

OHRP

2F: Las Vegas Confidential Series - Sensitive Populations and Topics: Public Health Data Mining

Privacy concerns are a major stumbling block to public health surveillance, including bioterrorism surveillance and epidemiological research. The Health Insurance Portability and Accountability Act (HIPAA) of 2002 imposes very strict standards for rendering health information. This session will discuss the challenges and opportunities of data mining.

Elizabeth Bankert, MA

Dartmouth College

Jeffrey Cohen, PhD, CIP

HRP Associates Inc.

2:00 - 2:15

Refreshment Break

2:15 - 3:45

Panel II- Federal Update

Moderator: Paul Jones, EdD

Office for Human Research Protections (OHRP)

Shirley Hicks, RN

National Institutes of Health (NIH)

Kelly Fennington

Office of Research Integrity (ORI)

Samuel Merrill, PhD

Veterans Affairs (VA)

Marisue Cody, PhD, RN and Joan Porter, DPA, MPH

3:45 - 4:00 Closing Remarks

Day 2 - Wednesday, March 8, 2006

7:00 - 8:00 Breakfast Buffet (provided)

8:00 - 8:15 **Opening Remarks**

Mark Rudin, PhD

UNLV

8:15 - 8:30 **Guest Speaker**

Lacy Thomas

University Medical Center

8:30 - 9:00 **Guest Speaker - Social & Psychological Risks in Biomedical Research**

Jeffrey Cohen, PhD, CIP

HRP Associates, Inc.

9:00 - 9:15 Transition Time

9:15 - 10:15 **Breakout Session 3**

3A: International Research: Challenges and Opportunities

While we cannot impose our standards for written documentation on other cultures, we do not relax our standards for ethical conduct of research for a meaningful consent process. This session will focus on the special attention that should be given to local customs and to local cultural and religious norms in drafting written consent documents or proposing alternative consent procedures.

Roberto Rivera, MD

Family Health International

3B: Research Involving Vulnerable Populations

The federal regulations require that IRBs give special consideration to protecting the welfare of vulnerable subjects. Who should be categorized as vulnerable and factors to assist in the protection of these volunteers will be discussed.

Marjorie Speers, PhD

AAHRPP

3C: IRB and IBC Oversight of Recombinant DNA Research

Reciprocal communication on a regular basis between the IRB and the IBC for Human participant research projects involving recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins is essential in order for the IRB to fulfill its functions relative to human participant research. The why and how will be discussed from a federal regulatory perspective.

Kathryn Harris, PhD

ORI

3D: Common Findings of Non-Compliance

OHRP Educational Division will discuss common findings of noncompliance with 45 CFR Part 46 based on compliance determination letters.

Lynda Lahl, RN, MS

OHRP

3E: Preparing for Clinical Inspections

The Food and Drug Administration representative will discuss how to successfully prepare for clinical inspections.

Pat Holobaugh

FDA

3F: Las Vegas Confidential Series - Sensitive Populations and Topics: Alcohol and Other Legal Substance Research

Research on alcohol and other legal substances can present special challenges. This session describes some of these unique challenges and discusses innovative guidelines that IRBs have instituted to aid the researcher in the protection of human subjects and in its IRB review of this research.

Mary Becker

Penn State

Charles Rasmussen, PhD

UNLV

10:15 - 10:30 Refreshment Break

10:30 - 11:45 Breakout Session 4

4A: Informed Consent - Consistencies and Differences in Biomedical and Behavioral Research

Informed Consent is one of the most important components of a research study involving human subjects. This session will describe some of the unique challenges that can occur with both biomedical and behavioral research and provide a summary of the similarities and differences that each type of research presents.

Helen McGough, MA, CIP

University of Washington

Susan Rose, PhD

University of Southern California

4B: Human Subject Protection Issues in Device Research

Investigational device research presents its own challenges for IRBs. This presentation will discuss the sponsor's interrelationship with the IRB, the IRB's attention to device issues when performing initial and continuing review of device research, and the importance of the informed consent process for device research.

Marian Serge, RN

FDA

4C: Evidence-based Ethical Problem Solving

Finding ways within the flexibility of the federal regulations to use those procedures that have proven empirically to be the most ethically and scientifically satisfactory instead of one-size-fits all application of simple precedents will be the focus of this session

Joan Sieber, PhD

Cal State East Bay

4D: HIPAA, Research, and the IRB

The *Standards for Privacy of Individually Identifiable Health Information* ("Privacy Rule") and its applicability to research and standards for the protection of certain health information will be discussed at this session.

Lori Coleman

HCA

Linda Mullins, RN, BSN

Sunrise Hospital

4E: Mission Creep

This session will discuss the looming issues surrounding mission creep and its impact on the campus community.

Ernest Prentice, PhD

UNMC

Jeffrey Cohen, PhD, CIP

HRP Associates, Inc.

**4F: Las Vegas Confidential Series - Sensitive Populations and Topics:
Informed Consent: How do you know if participants “understand”?**

How can we tell if the Informed Consent has really informed? Practical tools will be discussed to help insure participants are well informed.

Elizabeth Bankert, MA

Dartmouth College

11:45 - 1:00

Lunch Buffet (provided)

1:00 - 2:15

Breakout Session 5

5A: Medical Device 101: Who, What, Where, When, and How?

Basic medical device information will be discussed in this session.

Marian Serge, RN

FDA

5B: Key Lawsuits in Human Subject Research

Human research participants have become savvier in knowing their rights and their expectation of ethical treatment when enrolled in a research study. They are holding researchers and their institutions accountable. This session will discuss some of the current lawsuits sustained by researchers and their institutions.

Mark Cardinali, JD

UNLV

Laura Odwazny, JD, MA

DHHS Office of General Counsel

5C: Privacy and Confidentiality: Liability and Limits

Unveiling the distinct differences in privacy and confidentiality with techniques to ensure participant protection will be the focus of this session.

Joan Sieber, PhD

Cal State East Bay

5D: The IRB Office: Administration and Records

Records management is one of the most important aspects of any institutions human protection program. This session will focus on the aspects of IRB records management.

Mary Becker

Penn State

Susan Rose, PhD

University of Southern California

5E: Research in Educational Settings

Three sets of federal laws and regulations sometimes come into play in school-based research: The regulations of the federal policy for the protection of human subjects - also known as the Common Rule, the Family Educational Rights and Privacy Act (FERPA) regulations governing access to student's education records, and the Protection of Pupil Rights Amendment (PPRA) law governing the administration of surveys, analyses or evaluations involving sensitive personal information. This session will provide an overview of how the three sets of federal requirements apply, and tips for researchers and IRBs considering research involving these requirements.

Ivor Pritchard, PhD

OHRP

5F: Las Vegas Confidential Series - Sensitive Populations and Topics: Conducting Field Research - Challenges and Opportunities

A case study will provide information to overcome the challenges researchers and IRBs can face during the review process and the implementation of qualitative research projects.

Lori Olafson, PhD

UNLV

Michael Stitt, PhD

UNLV

2:15 - 2:30

Refreshment Break

2:30 - 3:45

Panel III - Surreptitious Monitoring of Electronic Traffic (Internet, cell phones, chat rooms, land line taps)

Moderator: Paul Jones, EdD

The electronic age has opened a completely new arena of accessing research participants. What protections can and should be offered to these participants will be discussed.

Jeffrey Cohen, PhD, CIP

HRP Associates, Inc.

Ernest Prentice, PhD

UNMC

Michael Stitt, PhD

UNLV

3:45 - 4:00

Closing Remarks

*Agenda is subject to change without notification.