

**Office for Human Research Protections
Research Community Forum
“Protecting Human Subjects in Social, Behavioral and Educational Research”
Long Beach, CA
Friday, February 11, 2005**

8:15am

Welcome Remarks

Elizabeth Ambos - Associate Vice President for Research and External Support; CSU, Long Beach
Gary Reichard - Provost and Senior Vice President for Academic Affairs; CSU, Long Beach

8:30am

Federal Perspectives on the Human Subject Protections Enterprise: Special Emphasis on Social, Behavioral, and Educational Research

This panel will provide unique federal perspectives on the human subject protections enterprise. Representatives from the federal government will address how their respective organizations implement the Human Subject Protections regulations and ethical principles of the Belmont Report in order to maximize the protection of human subjects in federally funded protocols involving social, behavioral, and educational research. This symposium will conclude with a question-and-answer session.

Moderated by Jim Till - Director for Research Compliance; CSU, Long Beach
Paul Hammond - Director, Western Regional Office; Office of Research Oversight; U.S. Department of Veterans Affairs
Shirley Hicks - Director, Division of Education & Development; Office for Human Research Protections; HHS
Stuart Plattner - Program Director for Cultural Anthropology and National Science Foundation Human Subjects Research Office; NSF
Ivor Pritchard - Senior Fellow, Office for Human Research Protections; HHS

10:30am Break

10:45am

Keynote Address: Ten Ways to Promote Valid Science and Protection of Human Subjects

Unthinking compliance with federal regulations can lead to unethical treatment of human subjects and to invalid research. The federal regulations were deliberately designed to permit creative ethical problem solving when the "default" regulatory requirements seem inappropriate. However, researchers and IRBs often fail to take full advantage of the flexibility they might exercise. This Keynote Address will examine ten ways to foster good science, improve the operation of Institutional Review Boards, and maximize the protection of human subjects. Many useful materials, websites, and references will be provided. This Keynote address will conclude with a question-and-answer session.

Joan Sieber - Professor of Psychology, Emerita; CSU, Hayward

12:15pm Lunch

1:30pm

Human Subject Protections: Nuts & Bolts

This plenary session will: Provide information on the historical foundation of the human subject protections regulation; Discuss the flexibilities of the regulations; and Provide guidance regarding the application of the regulations to social, behavioral, and educational research. Questions are welcome at the end of this session.

Ivor Pritchard - Senior Fellow, Office for Human Research Protections; HHS

2:15pm

Listen to the Perspectives of Local Experts on: Data Safety and Monitoring Boards; Interim Analysis for Social/Behavioral Studies; Equivalent Determination of Two Social/Behavioral Interventions

A panel of local experts will provide their views and experiences on conducting social/behavioral research studies. Perspectives will be provided on: balancing the Data Safety and Monitoring Boards; the interim analysis for social/behavioral studies; and the determination of whether two social/behavioral interventions are equivalent. This panel discussion will conclude with a question-and-answer session.

Moderated by Jim Till - Director for Research Compliance; CSU Long Beach

Dennis Fisher - Professor of Psychology; Director, CSULB Center for Behavioral Research and Services: "Data Safety and Monitoring Boards for Behavioral Trials"

Scott Hershberger - Professor of Psychology; CSU, Long Beach: "Introduction to Interim Analysis for Behavioral Studies"

Brian Wiens - Senior Manager, Biostatistics; AMGEN: "How to Determine Whether Two Behavioral Interventions are Equivalent"

3:15pm **Break**

3:30pm

Advice and Guidance for Conducting Safe and Effective Social/Behavioral Research Studies

Representing academia and the federal government, this panel will offer advice and guidance on how to conduct safe and effective social/behavioral research studies. This session provides an opportunity for robust interaction between both panel members and forum participants.

Moderated by Jim Till - Director for Research Compliance; CSU, Long Beach

Dennis Fisher - Professor of Psychology; CSU, Long Beach

Paul Hammond - Director of the Western Regional Office; Office of Research Oversight; U.S. Department of Veterans Affairs

Scott Hershberger - Professor of Psychology; CSU, Long Beach

Shirley Hicks – Director; Division of Education & Development; Office for Human Research Protections, HHS

Stuart Plattner - Program Director for Cultural Anthropology and National Science Foundation Human Subjects Research Office, NSF

Ivor Pritchard - Senior Fellow; Office for Human Research Protections; HHS

Joan Sieber - Professor of Psychology, Emerita; CSU, Hayward

Brian Wiens - Senior Manager, Biostatistics; AMGEN

4:00pm

Future Horizons for Social, Behavioral, and Educational Research:

What have we learned? What's the action plan now? This session will help attendees examine the information just presented and help them develop proactive plans for change in the processes supporting social, behavioral, and educational research. The discussion will conclude with a question-and-answer session.

Moderated by Sid Kushner - Director of Research and Sponsored Programs; CSU, San Bernardino

Joseph Lovett - Professor of Health Science and Human Ecology; Chair IRB; CSU, San Bernardino

4:30pm **Adjourn**