

Protecting Research Participants: Ethical Challenges Within a Regulatory Framework
An OHRP Research Community Forum
Preliminary Agenda
February 4, 2010
Bell Harbor Conference Center
Seattle, Washington

Time	Presentation
7:00 am – 7:45 am	Breakfast and Registration
7:45 am – 8:00 am	<p style="text-align: center;">Welcome and Introductions</p> <p style="text-align: center;">Susan Adler Executive Director Northwest Association for Biomedical Research</p>
8:00 am – 9:00 am	<p style="text-align: center;">Morning Plenary Session</p> <p style="text-align: center;">Informed Consent: Challenges and Opportunity</p> <p style="text-align: center;">Jerry Menikoff, MD, JD Director, Office for Human Research Protections</p>
9:00 am – 10:00 am	<p style="text-align: center;">Keynote Address</p> <p style="text-align: center;">Tissue Banking and Genetic Information</p> <p style="text-align: center;">Pearl O'Rourke, MD; Director, Human Research Affairs, Partners Healthcare System</p>

10:00 am – 10:15 am	Coffee Break			
10:15 am – 11:15 am	Research Team Track* (investigators, research coordinators, etc)	Basic IRB Nuts and Bolts*	Advanced Biomedical Topics	Advanced Social, Behavioral and Educational Research (SBER) Topics
	<p>Learning objectives:</p> <ol style="list-style-type: none"> 1. Speeding up the Review Process 2. Determining Risks to Subjects 3. Writing Protocols and Consent Forms <p>Speakers: Patricia Seymour, CCRC, MA, CIP; Director, Business Development/Institutions, Western Institutional Review Board</p> <p>Charlotte Shupert, PhD, CIP; Associate Director, Research Integrity Office, Oregon Health & Science University</p>	<p>Learning objectives:</p> <ol style="list-style-type: none"> 1. Introduction to Regulatory Oversight 2. Responsibilities of the IRB 3. Vulnerable Populations <p>Speaker: Elyse Summers, JD; Director, Division of Education and Development, Office for Human Research Protections</p>	<p>Learning objectives:</p> <ol style="list-style-type: none"> 1. Coercion 2. Multiple Study Participation Requirements 3. Separation of Physician Turned Investigator Priorities 4. Other Recruitment Issues <p>Speaker: Benjamin S Wilfond, MD; Treuman Katz Center for Pediatric Bioethics, Seattle Children’s Hospital, Division of Bioethics, Department of Pediatrics, University of Washington School of Medicine</p>	<p>Understanding Historical Trauma: Examining Latino Participation in Research</p> <p>Speaker: Beti Thompson, PhD; Member, Fred Hutchinson Cancer Research Center</p>

11:15 am – 11:25 am	Break			
11:25 am – 12:25 pm	Research Team Track* (investigators, research coordinators, etc)	Basic IRB Nuts and Bolts* (cont)	Advanced Biomedical Topics (cont)	Advanced Social, Behavioral and Educational Research (SBER) Topics (cont)
	<ol style="list-style-type: none"> 1. Monitoring Research Staff 2. Communicating with Patients – Research vs. Treatment: A Case Study 3. Good Clinical Practice 4. NIH’s request to reject patient initials for clinical trials/consent forms <p>Speakers: Patricia Seymour, CCRC, MA, CIP; Director, Business Development/Institutions, Western Institutional Review Board</p> <p>Chris Witwer, CIP; Compliance Manager,</p>	<ol style="list-style-type: none"> 1. Writing Consent Forms 2. Determining Risk 3. How to review an application 4. Continuing Review and Post Approval Monitoring <p>Speakers: Cami Gearhart, JD; CEO, Quorum Review IRB</p> <p>Charlotte Shupert, PhD, CIP; Associate Director, Research Integrity Office, Oregon Health & Science University</p>	<p>Reporting Unanticipated Problems to the IRB – Making the Process Meaningful</p> <p>Speaker: Bradley E Waite, DO, CIP; International Fellowship Coordinator, Western Institutional Review Board</p>	<p>Learning objectives:</p> <ol style="list-style-type: none"> 1. Foundation of current regulatory structure 2. Examining Flexibility in the Regulations 3. Institutional perspective <p>Speakers: Patricia A MacCubbin, MS; Executive Director of Research Conduct, Special Advisor to the Vice Chancellor for Research, City University of New York</p> <p>Elyse Summers, JD; Director, Division of Education and Development, Office for</p>

	Institute for Systems Biology			Human Research Protections
12:25 pm – 1:30 pm	Networking Lunch			
1:30 pm – 2:30 pm Breakout Sessions	<p>Research Ethics 2.0? Exploring Internet Research Ethics and IRBs</p> <p>Speaker: Elizabeth A. Buchanan, PhD; Director, Center for Information Policy Research, School of Information Studies, University of Wisconsin - Milwaukee</p>	<p>Improving Communications between the Investigator and Compliance Office</p> <p>Facilitators: Paul J. Martin, MD; Clinical Research Division, Fred Hutchinson Cancer Research Center</p> <p>James Riddle, MCSE, CNE, CIP; Assistant Director, Institutional Review Office, Fred Hutchinson Cancer Research Center</p> <p>Charlotte Shupert, PhD, CIP, Associate Director, Research Integrity Office, Oregon Health & Science University</p>	<p>Exception from Consent in Emergency Medicine: The Regulations and the Reality</p> <p>Speaker: Casey Bush, Research Regulatory Specialist, Legacy Health System</p>	<p>Conducting Research in Canada</p> <p>Speakers: Laurel Evans, BA, LLB; Associate Director, Research Ethics, University of British Columbia</p> <p>Susan Zimmerman, Executive Director, Interagency Secretariat on Research Ethics</p>
2:30 pm – 2:45 pm	Coffee Break			

<p>2:45 pm – 3:45 pm Breakout Sessions</p>	<p>Writing Readable Consent Forms</p> <p>Speaker: Jessica Ridpath, Research Communications Coordinator, Group Health Research Institute</p>	<p>Identifying and managing institutional and investigator conflicts of interest</p> <p>Speakers: Linda Coleman, JD; Director of Regulatory Affairs, Quorum Review IRB</p> <p>Lynette Schenkel, Assistant Vice President, Office for Responsible Conduct of Research, University of Oregon</p>	<p>Recruiting and Training New Board Members</p> <p>Speakers: Julie Wall, PhD; IRB Manager, St. Luke’s Health System</p> <p>Mia Gussie, CCRP; IRB Assistant, St. Luke’s Health System</p>	<p>Stem Cells</p> <p>Speaker: Pearl O’Rourke, MD; Director, Human Research Affairs, Partners Healthcare System</p>
<p>3:45 pm – 3:55 pm</p>	<p style="text-align: center;">Break</p>			
<p>3:55 pm – 4:45 pm</p>	<p style="text-align: center;">Afternoon Plenary Session</p> <p style="text-align: center;">From Washington to Washington: An Update from OHRP</p> <p style="text-align: center;">Elyse Summers, JD Director, Division of Education and Development Office for Human Research Protections</p>			
<p>4:45 pm – 5:00 pm</p>	<p style="text-align: center;">Closing and Evaluation</p>			

5:00 pm	Adjourn
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* Session does not qualify as 'advanced' for CIP continuing education credits.