

**HUMAN SUBJECTS WORKING GROUP
FALL WORKSHOP AGENDA
November 16, 2008
Orlando, Florida: Swan and Dolphin Hotel
Room: Peacock**

Sunday, November 16, 2008

Time	Presentation	Speakers
7:30 – 8:00 a.m.	Registration and Continental Breakfast	
8:00 – 8:30 a.m.	<ul style="list-style-type: none"> • Welcome and Introductions • Headquarters Expectations for Workshop 	Libby White, DOE/HQ/SC Peter Kirchner, DOE/HQ/SC John Ordaz, NNSA
8:30 – 9:30 a.m. <i>NOTE: The session, 8:30 – 11:00 a.m., is closed to the general audience. Only DOE and DOE site representatives are invited.</i> <i>Sessions from 11:00 a.m. – 4:45 p.m. are open to ALL Human Subjects Program Representatives.</i>	IRB Determinations - Why & How Such Determinations Were Made Moderator: Libby White, DOE/HQ/SC Case examples <ul style="list-style-type: none"> • Unanticipated Incidental Findings • Worker Programs – Use of Worker Data • Sampling Scenarios – When is it human subjects research? • Whole Body Counting and Urinalysis (Bioassay) Radiological Protection Monitoring in the Marshall islands 	Speakers: Harold Blackman, INL Karen Brown, WSRC Chris Byrne, LBNL Ann-Marie Dake & John Knezovich, LLNL
9:30 – 10:00 a.m.	Break	
10:00 – 11:00 a.m.	IRB Determinations - Why & How Such Determinations Were Made (continued) Moderator: Peter Kirchner, DOE/HQ/SC Case examples <ul style="list-style-type: none"> • Changes in Diffraction-limited Spatial Vision Associated with Aging and Retinal Disease • An Image-Based Method for Screening and Diagnosis of Blinding Eye Disease • The Hidden Person • Evaluation of Pyramid LT and XL2 Sensors • Conflict of Interest – Drug Efficacy Study 	Speakers: Ann-Marie Dake & John Knezovich, LLNL Becky Hawkins, ORISE James Morris & Kathy Ertell, PNNL Terry Reser, Sandia Angela Baumann, BNL
11:00 – 11:15 a.m.	Short Break	

11: 15 – 12:00 noon	<p>Ethical Issues in Nanotechnology</p> <p>Moderator: James Morris, PNNL</p> <p>Abstract: Nanoscience and nanotechnology is the study and application of materials smaller than 100 nm. Many materials present unique properties compared with the material at larger size. Over 300 nano-enabled products are in commercial use now with 3-4 introduced each week. Several nanomaterials are in clinical trials for diagnostic imaging and drug delivery. The diverse use of nanomaterials will soon present complex challenges to the experimental design and oversight of Human Subjects Research.</p>	<p>Speaker:</p> <p>Joel Pounds, PNNL</p>
12:00 – 1:15 p.m.	<p>Working Lunch provided</p>	
1:15 – 2:00 p.m.	<p>HIPAA and Human Subjects Research</p> <p>Moderator: Kathy Ertell, PNNL</p> <p>Abstract: The Health Insurance Portability and Accountability Act (HIPAA) was not written to change human subjects research, but has had that effect by: changing how hospitals control access to medical records, creating a public perception of greater control over medical information, and has redefined the traditional exceptions allowing release of medical information without consent. Another result has been the creation of a new category of biological information – research data. This presentation will clarify some of these distinctions, and provide some advice on how to take HIPAA into account when reviewing human subjects protocols.</p>	<p>Speaker:</p> <p>Peter Lichty, LBNL</p>
2:00 – 2:45 p.m.	<p>Social and Behavioral Research – Updated Guidelines</p> <p>Introduction: Peter Kirchner, DOE/SC</p> <p>Moderator: Bill Nebo, LLNL IRB</p>	<p>Speaker:</p> <p>Ivor Pritchard, OHRP</p>
2:45 – 3:00 p.m.	<p>Break</p>	

3:00 – 4:15 p.m.	Roundtable Moderator: Chris Byrne, LLNL <ul style="list-style-type: none"> • ORHP Review Report • AAHRPP Status • Outside Review DOE Human Subjects Program Report • Other 	Speakers: Terry Reser, Sandia Betsy Ellis, ORISE Darcy Mallon, BNL Libby White, DOE/SC 23.2 All
4:15 – 4:45 p.m.	Wrap up	Libby White, DOE/SC23.2
5:45 p.m.	Meet in Hotel Lobby for Dinner	