

Agenda for UCSD RCF Workshop Day
Feb 27, 2018
Hyatt Regency Mission Bay, San Diego, CA

7:30 – 8:30 a.m.	Registration and Breakfast	
8:30 – 8:45 a.m.	Welcome and Introductions	15 min
8:45 – 10:00 a.m.	Applying the Regulations: Revised Common Rule OHRP staff will provide an overview of applying and implementing the revised Common Rule, including changes to the exemptions.	75 min
10:00 – 11:00 a.m.	Secondary Research and the Revised Common Rule OHRP staff will present the changes to the Common Rule relevant to secondary research with identifiable biospecimens and identifiable private information, including applicable exemptions and aspects of informed consent.	60 min
11:00 – 11:15 a.m.	Break	15 min
11:15 – 12:45 p.m.	Local perspectives: the Common Rule This could be a speaker or panel (or combination of) focused on local perspectives of an aspect of HHS regulations or policy, presumably related to the revised Common Rule.	90 min
12:45 – 1:45 p.m.	Networking lunch	60 min
1:45 – 2:30 p.m.	What happens to incident reports and complaints to OHRP OHRP staff will review the requirements for reporting to OHRP and what OHRP does with these reports and public complaints. They will discuss how OHRP works with institutions to resolve issues and improve subject protections.	45 min
2:30 – 2:45 p.m.	Break	15 min
2:45 – 4:15 p.m.	Informed Consent: Improving the Process OHRP staff will discuss improving the informed consent process in light of requirements in the revised Common Rule. This will be an interactive session with audience engagement and lessons learned from real-world examples.	90 min
4:15 – 4:30 p.m.	Wrap-up and Q&A	15 min

8:00-9:00 **Registration & Breakfast**

9:00 - 9:15 **Welcome & Introduction**

Gary Firestein, MD
 UC San Diego

9:15-10:00 *What is 'Ethical' Today?*

Joseph Garner, DPhil
 Stanford University

10:00-10:15 *Break*

10:15-11:00 *Revised Common Rule: A Product of Rethinking What's Ethical*

Julie Kaneshiro, MA
 Deputy Director, OHRP

11:00-11:15 *Break*

11:15-12:00 **Break-Out Sessions**

A *Flexible approaches to the Common Rule*

BAYVIEW I

Susan Rose, PhD
 USC

Kip Kantelo
 UCLA

James Riddle
 Kinetic Ideas

B *Tech-Enabled Public Health Research: Challenges & Opportunities*

BAYVIEW II

Linda Hill, MD, MPH
 UC San Diego

Camille Nebeker, EdD, MS
 UC San Diego

C *Telemedicine, Research & the Learning Healthcare Environment*

BAYVIEW III

Anthony Magit, MD, MPH
 Rady Children's Hospital
 UC San Diego

Brett Meyer, MD
 UC San Diego Stroke Center

12:00-1:00 *Lunch & Networking*

1:00-1:45 *Taking off the blindfold: Genetic testing for babies born with mysterious ailments*

Stephen Kingsmore, MD, DSc
 Rady Children's Institute for Genomic Medicine

1:45-2:30 *Four Decades in Clinical Research: Risks & Rewards*

Jane Burns, MD
 UC San Diego

2:30-2:45 *Break*

2:45-3:45 *Questions Raised by the iCompare Study ...Ethical considerations in the world of single IRBs*

Jim Gearhart
 Quorum IRB Review

Stephen Rosenfeld, MD, MBA
 Quorum IRB Review

Jonathan Green, MD
 Washington University

Cynthia Hahn
 Feinstein Research Institute

3:45-4:00 *Break*

4:00-4:45 *Ask the Feds: Clinical research & human research protections Q&A*

OHRP

4:45-5:00 **Wrap-Up | Next Steps for Guidance | Networking**