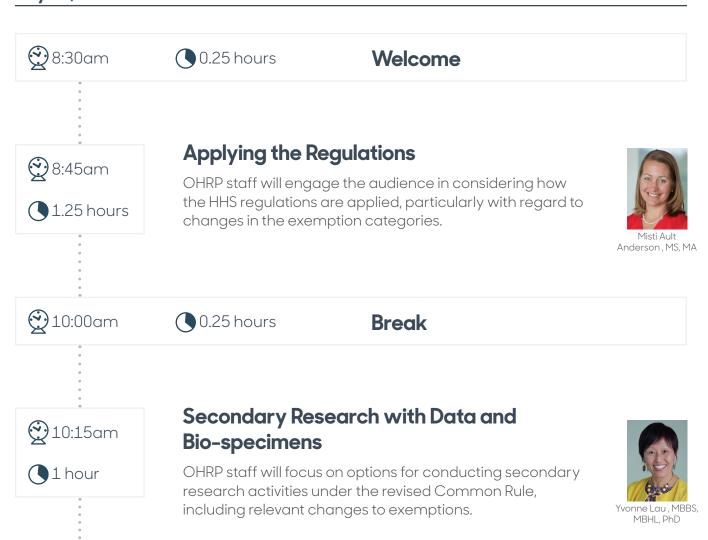
The New Research Landscapes

2019 Research Community Forum and IRB Conference

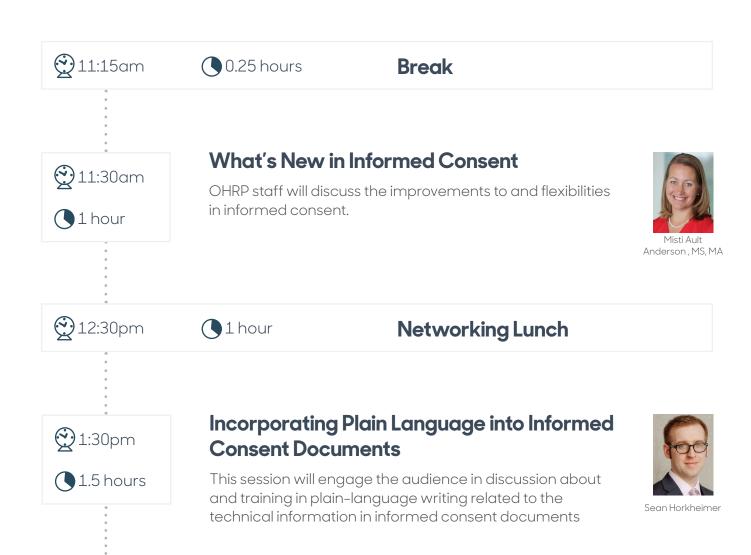
Session Details



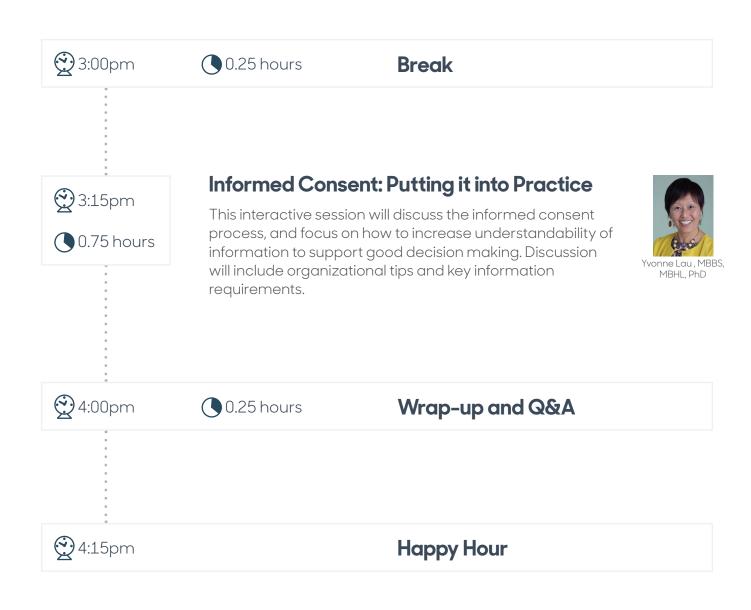


The New Research Landscapes





Session Details



The New Research Landscapes



July 25, 2019



0.25 hours

Welcome





Keynote Address: Regulatory and Ethical Challenges in "Big Data" Research: U.S. and International Perspectives.





Mark Barne JD 111





Update on Common Rule

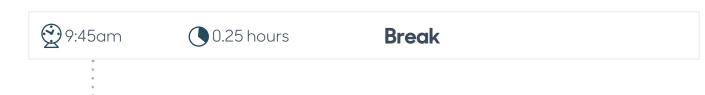
perspectives being addressed.

The new Common Rule was fully effective as from January 20, 2019. In this session OHRP staff will update the progress that they are seeing in relation to the implementation of the CR and highlight areas that may still need to be further addressed.



auren Hartsmitl JD

Session Details







St. Kitts Live Herpes Vaccine trial - What **Went Wrong**

The St. Kitts Live Vaccine Trials highlighted the risks associated with an ambitious researcher and potential oversight gaps with certain "international" studies. This presentation will examine both what went wrong with the oversight of this experiment and consider how an IRB could have brought this work back under control.



Westby, PhD



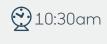


Ethical and Practical Issues in Conducting Research During a Bioemergency

Research during natural bioemergencies (such as Ebola virus disease in western and central Africa) poses unique challenges for institutional review boards. Such situations require careful consideration of informed consent, confidentiality, fair subject selection, risk-benefit, study design and independent review. IRBs (and investigators) must balance the necessity to develop and test potential treatments with the need to protect the rights and welfare of subjects of the research.









Breakout Session: The new Common Rule Room 2A

Tools and techniques for IRB operations under the changes to the Common Rule.







Re-envisioning the definition of private identifiable information in the information age









Breakout Session: Small Research Programs Room 2A

Challenges and Opportunities for Institutions with Small Research Programs



12:00pm



1 hour

Lunch

Session Details



0.5 hours

Lunch Session: Ask the Feds

This lunchtime session will be a moderated Q & A with representatives from OHRP. Attendees will be encouraged to write questions in advance of the session.





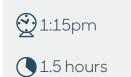


Keynote address: What Patients (or Participants or Subjects) Can Teach Us about Research Ethics

This co-presented session will consider the impacts of research on patients from the perspective of two renowned speakers who have been involved in research and have had significant experience, also, as patients who are in clinical trials.







Room 2A

Breakout Session: Small group discussion for IRB Leaders Facilitated discussion for IRB Leaders JD, MA, CIP









Break





The IRB's role in Research on Gun Violence

For many years in the United States research and training in the field of firearm injury prevention has been essentially absent. The speaker is part of a collaboration aimed at providing data to fill this critical knowledge gap. This presentation will both outline this vital work and also consider the IRB's role in this realm which crosses historical, social behavioral and medical research fields.



Patrick M. Carter, MD





Clinical Trials.gov Requirements

The session will review and discuss the FDA's role and responsibilities with ClinicalTrials.gov



Jan Hewett



Happy Hour