The New Research Landscapes

2019 Research Community Forum and IRB Conference

Session Details

July 24, 2019

8:30am | 0.25 hours | **Welcome**

8:45am | 1.25 hours

Applying the Regulations

OHRP staff will engage the audience in considering how the HHS regulations are applied, particularly with regard to changes in the exemption categories.

Misti Ault Anderson , MS, MA

10:00am | 0.25 hours | **Break**

10:15am | 1 hour

Secondary Research with Data and Bio-specimens

OHRP staff will focus on options for conducting secondary research activities under the revised Common Rule, including relevant changes to exemptions.

Yvonne Lau , MBBS, MBHL, PhD

Session Details

11:15am | 0.25 hours | **Break**

11:30am | 1 hour

What's New in Informed Consent

OHRP staff will discuss the improvements to and flexibilities in informed consent.

Misti Ault
Anderson , MS, MA

12:30pm | 1 hour | **Networking Lunch**

1:30pm | 1.5 hours

Incorporating Plain Language into Informed Consent Documents

This session will engage the audience in discussion about and training in plain-language writing related to the technical information in informed consent documents

Sean Horkheimer

Session Details

3:00pm | 0.25 hours | **Break**

3:15pm | 0.75 hours

Informed Consent: Putting it into Practice

This interactive session will discuss the informed consent process, and focus on how to increase understandability of information to support good decision making. Discussion will include organizational tips and key information requirements.

Yvonne Lau , MBBS, MBHL, PhD

4:00pm | 0.25 hours | **Wrap-up and Q&A**

4:15pm | **Happy Hour**

Session Details

July 25, 2019

7:45am | 0.25 hours

Welcome

8:00am | 1 hour

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

Mark Barnes, JD, LLM

As it becomes cheaper to collect, store, and re-analyze large datasets, it has become clear that informed consent at the beginning of research cannot adequately capture the possible benefits and (potentially unknown) risks of consenting to the uses of one's data. This presentation will outline the ethical challenges posed by Big Data in human subjects' research and both US and international perspectives being addressed.

9:00am | 0.75 hours

Update on Common Rule

Lauren Hartsmith, JD

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.

Session Details

9:45am | 0.25 hours | **Break**

10:00am

0.5 hours

St. Kitts Live Herpes Vaccine trial - What Went Wrong

Christian Westby, PhD

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.

10:30am

1 hour

Ethical and Practical Issues in Conducting Research During a Bioemergency

Bruce Gordon, MD

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.

Session Details

10:30am

1 hour

Breakout Session: The new Common Rule

Room 2A

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

Meghan Scott, BA

11:30am

0.5 hours

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

Following on from the opening keynote this presentation will take a deeper dive into the issue of what constitutes identifiable information. Social media and the onslaught of terms of use agreements requires us to rethink how we can best address the issue of privacy in research and ensure transparency and communication in all research.

Michele Russell-Einhorn, JD

11:30am

1 hour

Breakout Session: Small Research Programs

Room 2A

Challenges and Opportunities for Institutions with Small Research Programs

Andrea McDowell, PhD

12:00pm 1 hour **Lunch**

Session Details

12:30pm

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.

OHRP
Office for Human Research Protections

1:15pm

1.5 hours

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.

Rebecca Dresser, JD

Keith Eaton, MD, PhD

1:15pm

1.5 hours

Breakout Session: Small group discussion for IRB Leaders

Room 2A

Facilitated discussion for IRB Leaders

David Forster, JD, MA, CIP

Session Details

2:45pm | 0.25 hour | **Break**

3:00pm | 1 hour

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

4:00pm | 1 hour

ClinicalTrials.gov Requirements

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

Jan Hewett

5:00pm | **Happy Hour**