Northwest Association for Biomedical Research 2017 IRB Conference
"Staying Ahead: Disruption & Ethics Review"

Thursday, July 20, 9 am - 5 pm (EST)
Miami CTSI Collaboration Space
Don Soffer Clinical Research Center
1120 NW 14th St., Suite 710

Conference Replay Agenda

9:00 - 10:00 AM	**Keynote: Social Disruption: Science, Technology, Research, and Paradigmatic Shifts**
10:00 - 10:45 AM	**Immuno-Oncology - Disrupting Traditional Approaches to Clinical Trials and Revolutionizing Cancer Care**
10:45 - 11:30 AM	**Embracing Electronic Informed Consent in the Electronic Age**
12:00 - 12:45 PM	**Clinical Research vs. Clinical Care: Blurring the Lines** ***Brown Bag Lunch**
12:45 - 1:30 PM	**Maintaining Human Subjects Protections in Today's Changing Healthcare Environment**
2:00 - 2:45 PM	**Ethical And Regulatory Considerations For International Product Development Research**
2:45 - 3:30 PM	**Errors of Enthusiasm: Responsible Communication of Research Findings**
3:30 - 4:15 PM	**Implementing the sIRB Mandate: Implications for Institutions**
4:15 - 5:00 PM	**Overview of the Revised Common Rule**

Session Details

Title: Keynote: Social Disruption: Science, Technology, Research, and Paradigmatic Shifts

Presenter(s): Elizabeth Buchanan, Ph.D.

Abstract: The theme of this conference is "Staying Ahead: Disruption and Ethics Review." What does that mean to you? What is disruption and do we welcome it? Who decides what is disruptive, and to what norms? What happens if we resist disruption? Can we resist disruption? These questions will set the stage for this presentation, which will provide an overview of scientific disruption and its impact on human subject research.

Title: Immuno-Oncology - Disrupting Traditional Approaches to Clinical Trials and Revolutionizing Cancer Care

Presenter(s): Eslie Dennis, MD

Abstract: The past decade has witnessed a revolution in our understanding of the role of the immune system in oncology, and with it our ability to develop safer and more effective immunotherapies. This presentation will review the CDx-relevant science of immuno-oncology including the role of the tumor microenvironment, identify the challenges in biomarker development, discuss the impact on clinical trial design, and new regulatory developments.

Title: Embracing Electronic Informed Consent in the Electronic Age

Presenter(s): Cheryl Grandinetti

Abstract: The clinical research community is showing increasing interest in using electronic media to supplement or replace paper-based informed consent processes. For this reason the FDA and OHRP published a joint final guidance on electronic informed consent (eIC). This session will delve into this guidance and provide a first-hand account of the FDA's perspective on eIC.

Title: Clinical Research vs. Clinical Care: Blurring the Lines.

Presenter(s): Stephen Rosenfeld, MD and Jennifer Byrne

Abstract: Participation in clinical research is increasingly being seen as a patient clinical care option. This session will debate the acceptability of such a view, discuss the opposing forces at play, and determine whether a new definition of therapeutic misconception is on the horizon.

Title: Maintaining Human Subjects Protections in Today's Changing Healthcare Environment (The Non-OHRP/FDA Stuff)

Presenter(s): David Vulcano

Abstract: Whether dealing with the repeal and replacement of the Patient Protection and Affordable Care Act, the newly passed 21st Century Cures Act, or economic incentives such as "pay for performance" and "meaningful use" of electronic health records, each of these (and more) have an impact on the recruitment, retention and protection of human subjects in research. This session reviews many new and proposed healthcare regulations and their intended and/or unintended consequences.

Title: Ethical And Regulatory Considerations For International Product Development Research

Presenter(s): Renee Holt (Moderator), Darin Zehrung, and Jane Cover

Title: Errors of Enthusiasm: Responsible Communication of Research Findings

Presenter(s): Gary Schwitzer

Abstract: For 11 years, HealthNewsReview.org has systematically reviewed and graded leading news organizations' stories about biomedical research. In 2015, they also started systematically reviewing health care PR news releases by government agencies, academic institutions, industry, medical journals

and others. The report card is not good, suggesting that there is a polluted stream of research information from the sources to the public. This session will discuss this report card and its implications.

Title: Implementing the sIRB Mandate: Implications for Institutions

Presenter(s): Ada Sue Selwitz

Abstract: The NIH has issued a new policy mandating the use of a Single Institutional Review Board (sIRB), which goes into effective in September, 2017. The new Common Rule also includes an sIRB mandate. Consequently, institutions and their IRB administrators are scrambling to revise their Human Research Protection Programs in response. This session will discuss challenges institutions are facing and strategies being used at the institutional level to meet the new mandate.

Title: Overview of the Revised Common Rule

Presenter(s): Jaime O. Hernandez, J.D., M.B.E.

Abstract: OHRP staff will provide a brief background and summary of the major changes in the new Common Rule, which was published in January 2017. This presentation will also address implementation dates and the transition provision for the revised rule. Additionally, the session will present key changes intended to better protect human subjects and to reduce administrative burden on the review process.