The Changing Landscape of Research: Where Do We Go From Here?

Monday, June 20, 2016

4:00 PM - 6:00 PM	**Early Registration**
	Room Assignment: Symphony Ballroom Foyer

Tuesday, June 21, 2016

7:00 AM - 8:00 AM	**Registration and Continental Breakfast**
	Room Assignment: Symphony Ballroom Foyer
8:00 AM - 8:15 AM	**Welcome and Announcements**
	Room Assignment: Symphony Ballroom
	Speakers: Todd Rice, MD, MSc
8:15 AM - 9:15 AM	**How Do You Know What You Think You Know?** (Keynote Address)

Room Assignment: Symphony Ballroom

Course Description:

The management of diseases and conditions for which we currently lack tools to diagnosis, prevent, mitigate, treat or cure carries a huge economic burden. Engaging in poorly conceived, poorly designed, or poorly executed clinical trials impacts future progress in healthcare management. In many cases beliefs, bias, logic, or tradition have directed clinical care rather than data. This presentation will contain a brief overview of methods of collecting data. Offer examples of bias and ignorance that lead to clinical mismanagement. And describe a method of assessing data as a potential mechanism for reducing or eliminating bias.

Speaker for Day 1: Richard Gorman, MD

9:15 AM - 9:30 AM	**Break *** Room Location: Symphony Ballroom Foyer

9:30 AM - 10:30 AM	**A Discussion of the Notice of Proposed Rulemaking (NPRM) of the Common Rule.** (Plenary Session:) Room Assignment: Symphony Ballroom Course Description: The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have announced proposed revisions to the regulations for protection of human subjects in research.The NPRM seeks comment on proposals to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. This proposed rule is an effort to modernize, simplify, and enhance the current system of oversight. The participating departments and agencies propose these revisions to the human subjects regulations because they believe these changes would strengthen protections for research subjects while facilitating important research.The speaker will discuss some of the major proposals and the public comments. Speaker for Day 1: Ivor Pritchard, PhD

10:30 AM - 10:45 AM	**Break *** Room Assignment: Symphony Ballroom Foyer

10:45 AM - 11:45 AM	**OHRP Top 10 Human Research Protection Compliance Risks.** (Track 1 Breakout 1) Room Assignment: Symphony Ballroom I Course Description: OHRP staff will describe the top 10 compliance risks to your institution related to human research protections. OHRP compliance data and common findings of noncompliance will be discussed. Tips on how to protect your institution will be provided. Speaker Day 1 and Day 2: Kristina Borror, PhD

10:45 AM - 11:45 AM	**Advancement of Gene Therapy and the Ethics of "Cure" Strategies.** (Track 2 Breakout 1) Room Assignment: Symphony Ballroom II Course Description: The speaker will review the field of gene transfer research with emphasis on newer methods of genomic editing, some of which are in clinical trials. The field has reached a point where enough examples of patient cures exist, for some diseases, that an emphasis on "Cure" strategies has expanded to many other illnesses. The speaker will describe how this can impact the ethical application of clinical research and what precautions are necessary. Speakers: John Zaia, MD

10:45 AM - 11:45 AM	**Research Using Biospecimens: What Will the NPRM Mean If Adopted?** (Track 3 Breakout 1) Room Assignment: Symphony Ballroom III Course Description: The speaker will describe how the NPRM proposal, if adopted, will radically change the ways in which research using biospecimens and the data derived from them can be used for research in this country and what health care

institutions will need to do.

Speaker for Day 1: Ellen Wright Clayton, MD, JD

| 11:45 AM - 1:00 PM | **Lunch (provided) *** |
| | Room Assignment: Symphony Ballroom Foyer |

| 1:00 PM - 2:00 PM | **Therapeutic Misconceptions: Protocol Violation and Data Falsifications for "The Good of the Patient"** (Track 1 Breakout 2) |

Room Assignment: Symphony Ballroom I

Course Description:

Official Title: "Therapeutic Misconception and the Physician-Researcher: The Repercussions of Purposeful Protocol Violation and Data Falsifications for "The Good of the Patient."

Therapeutic misconception is a concept usually applied to the research subject's misconception that entering a clinical research trial will be of benefit to their health or that participating in research is the same as receiving individualized treatment from a physician. However, physician researchers can also fall victim therapeutic misconception causing not only potential harm to subjects but certain harm to data integrity and in extreme cases may result in findings of research misconduct.

Speaker Day 1 and Day 2: Kristen Grace, MD, PhD

| 1:00 PM - 2:00 PM | **New Challenges in Pediatric Research: Genomics and Drug Development.** (Track 2 Breakout 2) |

Room Assignment: Symphony Ballroom II

Course Description:

In the last decade, with the advent of new scientific technology to interrogate the human genome, there has been dramatic interest in using genomic studies to better understand the biology of chronic and life-threatening diseases and conditions in children. This has led to questions about how this type of research should be conducted in children including practical, legal, ethical, and social considerations. Likewise, through the combined efforts of governmental agencies like the FDA working with industry and pediatric researchers, there are new regulatory mechanisms directed at the inclusion of pediatric studies in drug development. We will review how both of these topics are addressed in current pediatric clinical research.

Speaker for Day 1: Victor Santana, MD

| 1:00 PM - 2:00 PM | **From Recruitment to Capturing Data: Using Amazon Mechanical Turk and REDCap.** (Track 3 Breakout 2) |

Room Assignment: Symphony Ballroom III

Course Description:

The speakers will provide an introduction to recruiting participants and administering survey-based studies online. An overview of how to recruit participants using a widely-used subject pool - Amazon's Mechanical Turk (MTurk) will be detailed. The speakers will explain how to set up your study on MTurk, how to identify participants (also known as "workers"), direct participants to your online study, compensate participants, and verify their participation. An example of how to build and administer online surveys using software that's available to researchers – REDCap will be provided. Ways to create different types of questions for surveys, with built-in field verification, and how to export your data to multiple data analysis software will also be discussed.

Speaker for Day 1: Natalia Jiminez-Truque, PhD, Jonathan Lane, PhD

| 2:00 PM - 2:15 PM | **Break *** |
| | Room Assignment: Symphony Ballroom Foyer |

| 2:15 PM - 3:15 PM | **Facing the Challenges of Reviewing Comparative Effectiveness Research.** (Track 1 Breakout 3) |

Room Assignment: Symphony Ballroom I

Course Description:

In 2013 a determination of noncompliance by the Office for Human Research Protections (OHRP) regarding the information provided in the informed consent forms for the SUPPORT Trial precipitated a vigorous debate about the correctness of OHRP's determination and its implications for future comparative effectiveness research. This presentation will review the original determination and the issues raised in the subsequent controversy, to explain how that

controversy arose and what it implies for the review of comparative effectiveness studies, including the assessment of research risks and the implications for whether and when informed consent is required.

Speaker for Day 1: <u>Ivor Pritchard, PhD</u>

2:15 PM - 3:15 PM	**Can Parental Perspectives on Biobanks,Genomic Sequencing,and Early Phase Research Enhance Respect** (Track 2 Breakout 3)

Room Assignment: Symphony Ballroom II

Course Description:

Official Title: "Research Ethics: Can Parental Perspectives on Biobanks, Genomic Sequencing, and Early Phase Research Enhance Respect for Persons in the Context of Pediatric Research?"

While children play an increasing role in health-care decisions as they age and mature, parents (or legal guardians) must almost always provide informed permission before a minor can be enrolled in a research study. As such, parents are key stakeholders whose voices and opinions should be solicited for the purpose of improving the research experience and honoring the basic principles of the Belmont Report. The speaker will examine parental feedback from published and ongoing research involving the parents of children with cancer who were offered an early phase, bio-banking, or next generation genomic sequencing research study. The optimal process for the protection of children offered research studies in these areas is a source of debate among the academic research ethics community. She will discuss how these parental perspectives might influence our oversight and review of pediatric studies involving the aforementioned technologies.

Speakers: <u>Liza-Marie Johnson, MD, MPH, MSB</u>

2:15 PM - 3:15 PM	**Alternative IRB's: Panel Discussion of OneIRB, IRBrely and IRBchoice.** (Track 3 Breakout 3)

Room Assignment: Symphony Ballroom III

Course Description

Moderator: Rebecca Abel

Each IRB will highlight their respective IRB. Following the IRB descriptions the moderator will entertain questions from the audience regarding each IRB.

Speaker: Julie Martin

OneIRB is a single IRB of record model with a coordinating center component designed to assist study teams and institutions in implementation of single IRB review for multi-site research. With OneIRB, the coordinating center collects information from study teams, submits IRB applications to the single IRB of record on their behalf, and disseminates IRB approval letters and consent forms to study teams and relying institutions. In addition to relieving the administrative burden on study teams, OneIRB also relieves administrative burden on the IRB of record by managing the flow of documents to relying institutions

Speaker: Nichelle Cobb

The IRBrely initiative seeks to ease common challenges and burdens associated with initiating multisite research and thereby support and encourage collaboration across a national network of institutions. By facilitating the conduct of multisite studies, IRBrely aims to help investigators obtain trial results faster, speeding development of new diagnostics, treatments, and preventative measures for

patients, while continuing to maintain a strong level of human research protections, oversight, and regulatory compliance.

Speaker: Emily Sheffer

IRBchoice is a national IRB reliance platform with the goal of providing faster and more consistent IRB approvals for multisite sites studies, as well as significant support for IRBs and investigators around the use of IRB reliance. Supported by

NHLBI (grant # 1R01HL126492-01), IRBchoice goes beyond traditional IRB

reliance models to support the full spectrum of human research protections by offering flexible reliance options to a national network of collaborators; transparency between IRBs to promote the sharing of best practice and help identify collaborators; centralized tracking of different reliance relationships; and study-specific support and notifications for study teams to promote understanding and regulatory compliance.

Panelists: <u>Nichelle Cobb, PhD</u>, <u>Julie Martin, R.N., M.Ed., CCRP</u>,

Emily Sheffer, MPA

Moderators: Rebecca Abel, MA,CIP

3:15 PM - 3:30 PM	**Break *** Room Assignment: Symphony Ballroom Foyer
3:30 PM - 4:30 PM	**Ask the Feds Panel** (Final Plenary/Wrap Up) Room Assignment: Symphony Ballroom Course Description: You've got questions, we have answers. In this concluding session, the representatives of the Federal agencies participating in the RCF will be available to answer your questions. RCF staff will collect your questions on cards throughout the day for this session and/or you may ask your questions "in real time" at this closing session.
4:30 PM - 5:00 PM	**Closing Remarks** Room Assignment: Symphony Ballroom Speakers: Todd Rice, MD, MSc
6:00 PM - 8:00 PM	**Welcome Reception hosted by St. Jude Children's Research Hospital *** Location: Ballroom Foyer
	* OHRP staff and resources were not used to develop, promote, or otherwise support this portion of the event.

Wednesday, June 22, 2016

8:00 AM - 8:01 AM	**Maximum Registration has been reached for day two. Registration for day one is still available.** PRESENTATIONS FOR THE WORKSHOP WILL BE MADE AVAILABLE DURING THE WORKSHOP
8:00 AM - 8:30 AM	**Registration and Continental Breakfast** Room Assignment: Symphony Ballroom Foyer
8:30 AM - 8:40 AM	**Welcome and Announcements** Room Assignment: Symphony Ballroom I and II Speaker: Yvonne Lau, MBBS, MBHL, PhD and OHRP staff
8:40 AM - 10:40 AM	**Let's Review a Protocol Together** Room Assignment: Symphony Ballroom I and II Course Description: The speaker will present one or more research protocols and invite the audience to review them together using the principles and guidance provided by the HHS regulations and OHRP policies. Speakers: Yvonne Lau, MBBS, MBHL, PhD
10:40 AM - 11:00 AM	**Break *** Room Assignment: Symphony Ballroom Foyer
11:00 AM - 12:00 PM	**When to Rally the Troops and When to Move Findings Up the Food Chain.** Room Assignment: Symphony Ballroom I and II Course Description: As you are reviewing a study in continuing review, something catches your attention that is not consistent with the protocol. Or there is a complaint from a research participant. When do you "rally the troops" to perform a "for cause" audit? What options are there if an issue is identified with a study during the audit? When does an incident need to be reported to the OHRP? Using case based examples, this session will discuss some of the triggers that should alert your team to compliance issues and when reporting to the OHRP is mandatory. Speakers: Saralyn Williams, MD, FACEP, FACMT
12:00 PM - 1:00 PM	**Lunch (provided) *** Room Assignment: Symphony Ballroom I and II

1:00 PM - 2:15 PM	**Beyond Protocol Deviations: The Unmasking of Data "Fudging" in Human Research Studies.**
	Room Assignment: Symphony Ballroom I and II
	Course Description:
	Dr. Grace will discuss what constitutes research misconduct in clinical research studies and how is this different from IRB protocol deviations, what are the red flags indicating there may be data integrity problems, what to look for during audits and who to contact with concerns. We will review the research misconduct investigation procedures as defined by 42 C.F.R 93 and how these relate to investigations also involving human subject protection violations. Participants are encouraged to come with questions.
	Speakers: <u>Kristen Grace, MD, PhD</u>
2:15 PM - 2:45 PM	**The Overlapping Roles of Human Subjects Protection and Research Misconduct: OHRP's Experience, Oversight Role, and Expectations**
	Room Assignment: Symphony Ballroom I and II
	Course Description:
	This session will describe how OHRP approaches a case of serious non-compliance that might involve research misconduct. This will include a discussion of what OHRP would look for, what kind of findings and actions might it reach, as well as reporting to OHRP.
	Speakers: <u>Kristina Borror, PhD</u>
2:45 PM - 3:00 PM	**Break ***
	Room Assignment: Symphony Ballroom Foyer
3:00 PM - 4:15 PM	**Improving With Time: Lessons Learned from Historical Cases**
	Room Assignment: Symphony Ballroom I and II
	Course Description:
	Mr. Hernandez will present one or more historical case(s) and invite the audience to explore what was done well, what improvements could have been made, and how the regulations and policies might have facilitated human research protections. In addition, the group will consider how the case(s) might be evaluated by contemporary standards and regulations.
	Speakers: <u>Jaime Hernandez, JD, M.Be</u>
4:15 PM - 4:30 PM	**Wrap up/ Q & A**
	Room Assignment: Symphony Ballroom I and II
	Speakers: Yvonne Lau, MBBS, MBHL, PhD and OHRP staff
	* OHRP staff and resources were not used to develop, promote, or otherwise support this portion of the event.