## Breakout Session Descriptions

### Track 1  Finance & Billing

**Time:** 1:15 to 2:00  
**Track:** Finance & Billing

### Evaluating Your Protocol - Can We Really Do This Study?

Protocol evaluation is essential to determining the feasibility of a study. Ms. Hapanowicz and Ms. Gaa will discuss the key elements to evaluating protocols. This presentation will discuss financial feasibility according to your institutional policies, potential barriers for recruitment, staffing needs, potential issues and logistical implications, and evaluating staffing and institutional capabilities (departmental access and support). 109

**Presenter:** Monika Gaas, MBA, Senior Feasibility Coordinator  
The Research Institute at Nationwide Children’s Hospital

### Accurately Budgeting for Clinical Research Staff Time

Do you always feel like you never get it right when it comes to budgeting for staff time? Clinical research is complex and dynamic, making study staff time an elusive topic. Our economic climate will no longer allow for inefficiencies and under-budgeting so we must learn techniques to budget and plan for appropriate staffing. 111

**Presenter:** Jennifer Goldfarb, BSN, CCRP, RN  
Senior Director, Clinical Research Support Office, Children’s Hospital of Philadelphia

### RE-Tool: Research Efficiency Tool

UTHealth launched an initiative to improve communication and clinical coordinator satisfaction related to clinical research billing. This talk will address the process of engaging research staff and listening to their concerns. We gathered information from the end users to develop RE-Tool in REDCap to improve their processes. The end result is a product that coordinators want to use versus a mandated complicated system. 113

**Presenter:** Heather Cody, MHA, BBA  
Assistant Director, Clinical Research Finance, University of Texas Health Science Center at Houston

### Medicare Coverage Analysis - the Foundation of Clinical Research Billing

This session will focus on the development of the Medicare Coverage Analysis and its impact on the clinical research billing / patient billing processes. Participants will learn the federal and applicable state regulations impacting the development of the coverage analysis. Ms. Veazie will also inform the participant on best practices and tips on building a compliant program. 115

**Presenter:** Mary Veazie, MBA, CPA, CHC, CHRC  
Executive Director, UT MD Anderson Cancer Center

### Track 2  Device Research

**Time:** 1:15 to 2:00  
**Track:** Device Research

### The State of Innovation in the Canadian Medical Device Industry

Using original research and personal experience leading Canada’s largest medical device design, development, and manufacturing service provider, Mr. Phillips will provide an overview and analysis of the Canadian medical device industry. The presentation will discuss industry size and background, MedTech exits and return on investments, success stories, and serial medical entrepreneur research. Mr. Phillips will contrast Canadian and US MedTech with insights from work with clients in both markets. 209

**Presenter:** Scott Phillips, BSc  
Founder and President Starfish Medical

### First Breath to Death Sensing Analytics: Pathology Informatics in Precision Medicine

Each of us generates billions of bits of data capture over a lifetime. Making sense of this data to predict and prevent disease, personalize our health care and engage us to participate in the management in our own care will be our future. Dr. Corona will discuss building a learning health system using advanced data analytics that extracts patterns from EMRs, gene sequencers, laboratory systems, imaging systems, social media, mobile health and e-health systems is the future of precision medicine. 211

**Presenter:** Robert Corona, DO, MBA, FCAP, FASCP  
John B. Henry Professor/Chair of Pathology & Lab Medicine  
SUNY Upstate Medical University

### Medical Device Directive (MDD): A Case Study Scenario on Clinical Evaluation of a Mechanical Circulatory Support (MCS) Device in Europe for CE Mark

Dr. Munjal will discuss requirements under the amended MDD for demonstration of the safety and clinical performance characteristics of the MCS device. Pertinent regulatory issues, considerations and strategies relating to critical evaluation of relevant scientific literature on a predicate device, if any, will be reviewed. The statistical analyses of data gathered from a prospective clinical study on the investigational MCS device including the side effects, along with the clinical claims and product labeling for submission to the Notified Body for approval of the CE Mark will be discussed. 213

**Presenter:** David Munjal, PhD, MSc, RAC  
President CRC Global Services, LLC
Breakout Session Descriptions

Friday, September 30, 2016

Track 2

**Device Research**

**Time:** 4:15 to 5:00

**Track:** Device Research

**FDA Approval of Humanitarian Use Devices**

Rare diseases collectively affect approximately 30 million Americans and more than 50% affect the pediatric population. However, relatively few medical devices have been developed to specifically address the needs of patients with pediatric or rare diseases. The Humanitarian Use Device/Humanitarian Device Exemption (HUD/HDE) is a unique marketing approval pathway for medical devices targeting diseases affecting small patient populations. This presentation will discuss lessons learned from an analysis of HDE approvals, needs assessment of devices for rare diseases, FDA device initiatives for rare diseases, and other relevant work in this field. 215

**Presenter:** Eric Chen, MS, Director, Humanitarian Use Device Program, Food and Drug Administration

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Track 3

**International Trials & ICH**

**Time:** 1:15 to 2:00

**Track:** International Trials and ICH

**Managing a Multinational NIH Study**

Ms. Thomas will discuss the regulatory requirements for conducting an NIH study in Asia, Europe, and US. 309

**Presenter:** Jessy Thomas, MS
Project Manager, University of Minnesota

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**Time:** 2:05 to 2:50

**Track:** International Trials and ICH

**The Changing Face of Clinical Research: Why Look to Central and Eastern Europe for Qualified Patients**

Many companies spend significant amounts of time and money trying to get patients enrolled in their clinical studies. Central and Eastern Europe (CEE) is a region that is still under-utilized as a venue for clinical research. Why should companies take another look at CEE? 311

**Presenter:** Jeffrey Blum, BS, Senior Director Business Development, EastHORN Clinical Services

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**Time:** 3:25 to 4:10

**Track:** International Trials and ICH

**Clinical Trials in Africa - What is to be Expected - a Case Study**

Cultural barriers, political upheaval and uneven infrastructure are certainly challenges that might create problems in running a clinical trial in accordance with the Western world's legal and ethical expectations. However, Africa offers tremendous expertise and opportunity for cost-effective study sites and appropriate patient populations. What type of challenges are to be expected and how they have been overcome will be presented based on an HIV trial conducted in Nigeria. 313

**Presenter:** Gerhard Fortwengel, PhD, MPH, MSc, Professor, University of Applied Sciences and Arts, Hannover

**Presenter:** Sam Ibeneme, PhD
Consultant Physiotherapist, University of Nigeria

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Track 4

**Data Management / EDC**

**Time:** 1:15 to 2:00

**Track:** Data Management / EDC

**Importance of a Detailed Statistical Analysis Plan in Clinical Study Report Writing**

The presentation will address the importance of the statistical analysis plan and how detailed it should be, including the definition of analyzed populations, the statistical methodology used as well as derived data, the handling of missing data, and most importantly the definition of shells (Tables, Listings and Figures) as per ICH E3, to ease the development of each section of the CSR. 409

**Presenter:** Farida Dabouz, PhD, CCRP
President, FB2D Clinical Research Consulting

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**Time:** 2:05 to 2:50

**Track:** Data Management / EDC

**eSource Beyond EDC and Data Management**

eSource is mainly discussed in the context of EDC and from a data management perspective. This may be due to the fact that the FDA guidance on electronic source data in clinical investigations focuses solely on EDC. However, the EMA made it clear in its reflection paper on GCP compliance in relation to trial master files that the concept of electronic source data needs also to be considered in other areas; for example, in the context of trial master files (TMF). This talk will provide an overview on the general aspects of eSource and how they apply to TMFs. 411

**Presenter:** Mathias Poensgen, PhD
Subject Matter Expert, Clinical, Aris Global

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**Time:** 3:25 to 4:10

**Track:** Behavioral Research

**The Language of Behavioral Clinical Trials: A Practical Thesaurus for Clinical Researchers**

Ms. Culp from the National Institutes of Health will give a brief introduction to the most common behavioral interventions tested in clinical trials to improve health, including those meant to educate, teach skills, and boost motivation. Using the drug-development paradigm as a foundation, the presenter will describe key steps in developing and testing behavioral interventions. Among the key steps to be discussed are protocol development, implementation, data capture, and quality control. Commonalities and differences between drug development and behavioral clinical trials at each step will be highlighted. 413

**Presenter:** Michelle Culp, BSN, MPH, CCRP, RN
Director of Clinical Operations
National Center for Advancing Translational Science, NIH

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**Time:** 4:15 to 5:00

**Track:** Behavioral Research

**Challenges in Behavioral Health Research in Health, Fitness, and Weight Management**

The speaker will discuss challenges that are unique to behavioral health research that involve cognitive or behavioral change in health, fitness, and weight management. Challenges to be addressed include privacy, social stigma and reliability in self-reporting; interpersonal dynamics and how this may affect self-care and protocol compliance, impact of relationship dynamics in the participant’s social support in the home and workplace; motivation in relation to incentives and behavior economics and whether the expected results are consistent with the subject’s effort and (cont’d on next page)
### Track 4
#### Behavioral Research

readiness for change. Attendees will gain an understanding of challenges faced in behavioral health research and will be able to develop realistic study protocol procedures for future behavioral health interventions. 415

**Presenter:** Beth Auguste, MS, RD
Registered Dietitian Nutritionist, EXOS

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### Track 5
#### Project Management

**Time:** 1:15 to 2:00  
**Track:** Project Management

#### Tools for Effective Project and Risk Management

The overall goal of this session is to review a few tools/skills that will enhance one's project and risk management skills such as flow charts, Gantt charts, and risk registers. Having a clear understanding of these tools will allow a project manager to effectively manage clinical research resources and timelines including milestones and risks while properly linking them back to the project plan. Examples will be reviewed throughout the presentation. 509

**Presenter:** Susan Leister, PhD, MBA, BS, COA, CSSBB
Director of Quality Assurance, Technical Resources International, Inc.

**Time:** 2:05 to 2:50  
**Track:** Project Management

#### Using PMI Project Management Principles When Considering a CTMS Implementation

Implementation of a clinical trials management system at any site is a complex and risky endeavor. Using PMI project management principles and tools will fortify implementation and sustained success. 511

**Presenter:** Elizabeth Micalizzi, MBA, CCRP, PMP
Director, Strategic Projects and Integrated Technology
Virginia Commonwealth University

**Time:** 3:25 to 4:10  
**Track:** Project Management

#### Challenges and Benefits of Consortium Led Clinical Trials

Collaborative efforts, combining expertise and oversight for clinical trials, are becoming more common. However, multi-organizational and multi-funder efforts provide their own inherent set of challenges and rewards. Adding in collaborators and sites from around the world only increases the scope of work and magnitude of challenges. Providing early and carefully laid out structure and expectations are key to success. Here we explore the pros and cons of working in these large consortium efforts and outline some strategies for creating and maintaining successful structures that are linked to the success of the clinical trial. 513

**Presenter:** Stephanie Combes, MA, CCRP, PMP
Clinical Research Project Manager, FHI360

**Time:** 4:15 to 5:00  
**Track:** Project Management

#### Remaining OPTIMISTIC: Project Management for New Funding Mechanisms

This talk will provide an overview of the Centers for Medicare and Medicaid Services Innovations grant as a newer funding mechanism and describe the differences from other traditional behavioral research studies. In addition, the presenter will describe unique project management tools and strategies to successfully manage a large, multi-facility implementation program funded by this mechanism. 515

**Presenter:** Laura Holtz, BS, CCRP, Research Manager
IU Center for Aging Research, Regenstrief Institute

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### Track 6
#### Pediatric Research

**Time:** 1:15 to 2:00  
**Track:** Pediatric Research

#### Pediatric Clinical Research: Informed Consent and Assent Considerations for High Risk Studies

Ms. Talley will explore the ethics involved in children participating in studies that may be invasive, high risk, early phase, or have limited understanding or diminished cognitive capacity. Human subject protections regarding children participating in clinical research, with special attention given to the informed consent and assent process, will be reviewed. The rationale of why children should be included in clinical trials and, as a group, the many factors that can influence participation will be explored. 609

**Presenter:** Christina Talley, MS, CCRP, RAC, Clinical Research Project Manager, Baylor College of Medicine

**Time:** 2:05 to 2:50  
**Track:** Pediatric Research

#### Justifying the Choice of a Control Arm in Pediatric Clinical Trials

An evidence-based tool to justify the selection of a control arm (placebo, active) in pediatric clinical trials will be presented. Dr. Kelly will discuss the challenges in selecting a control arm in pediatric trials using real empirical data on evaluated Pediatric Investigation Plans adopted by the European Medicines Agency. 611

**Presenter:** Lauren Kelly, PhD, PhD, MSc, BMSc, CCRP
Research Fellow, Hospital for Sick Children

**Time:** 3:25 to 4:10  
**Track:** Pediatric Research

#### Conducting Pediatric Clinical Trials with Rare Diseases

Managing pediatric clinical trials for patients with rare diseases takes special considerations. This presentation will discuss the challenges of early detection of rare diseases, recruitment and retention issues, and the impact of family life. The speaker will explore the best ways to serve the patients and their families. 613

**Presenter:** Kandice Roush, BSN, RN, CCRC, Research Nurse, The Research Institute at Nationwide Children’s Hospital

**Time:** 4:15 to 5:00  
**Track:** Pediatric Research

#### Recruiting Healthy Controls in the Pediatric Population

This session is aimed at site staff that will be engaged in or looking to start projects that involve healthy controls. The speakers will discuss the importance of enrolling healthy controls and tactics for successful study completion. Objectives include defining why healthy controls are critical in pediatric research, identifying recruitment strategies in the healthy control population, and discussing challenges when recruiting healthy children. 615

**Presenter:** Michael Lawson, BSN, RN, CCRC
Clinical Research Nurse Coordinator
The Research Institute at Nationwide Children’s Hospital

**Presenter:** Shelli Farley, ADN, RN, CCRC, Clinical Research Nurse, The Research Institute at Nationwide Children’s Hospital

**Presenter:** Rachel Heffern, BSN, RN
Clinical Research Nurse Coordinator
The Research Institute at Nationwide Children’s Hospital

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<th>Track 7</th>
<th>Ethics in Research</th>
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<tr>
<td><strong>Time:</strong></td>
<td>1:15 to 2:00</td>
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<tr>
<td><strong>Session Overview:</strong></td>
<td>Working to Eliminate Disparities in Clinical Trials: One Site's Experience</td>
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<tr>
<td><strong>Presenter:</strong></td>
<td>Dr. Jackson will achieve the following four objectives: 1) Explain why inclusion of minorities is critical in clinical research; 2) Describe legislative background such as the NIH Revitalization Act and its amendments; 3) Provide examples of what some funding agencies expect of minority inclusion in trials; and 4) Review a large clinical study site's challenges in and potential solutions to meeting inclusion requirements. 709</td>
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<tr>
<td><strong>Instructor:</strong></td>
<td>Jonathan Jackson, Phd</td>
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<td><strong>Institution:</strong></td>
<td>Harvard Medical School</td>
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<td><strong>Time:</strong></td>
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<td><strong>Session Overview:</strong></td>
<td>Revisiting the Syphilis Study: What Really Happened at Tuskegee?</td>
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<td><strong>Presenter:</strong></td>
<td>Quincy Byrdsong, EdD, CIM, CCRP, CIP</td>
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<td><strong>Institution:</strong></td>
<td>VP for Academic Planning &amp; Strategic Initiatives, Augusta University</td>
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<th>Track 8</th>
<th>GCP Audit Preparedness</th>
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<td><strong>Time:</strong></td>
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<td><strong>Session Overview:</strong></td>
<td>Investigator/Investigational Site Responsibilities</td>
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<td><strong>Presenter:</strong></td>
<td>Mike Rashti, BS</td>
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<td><strong>Institution:</strong></td>
<td>President</td>
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<td><strong>Time:</strong></td>
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<td><strong>Session Overview:</strong></td>
<td>Preparing for Successful Sponsor Audits</td>
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<td><strong>Presenter:</strong></td>
<td>Lauren Kelley, BA, CCRP</td>
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<td><strong>Institution:</strong></td>
<td>Associate Director, GCP Compliance</td>
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<td><strong>Time:</strong></td>
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<td><strong>Session Overview:</strong></td>
<td>Ethical Considerations in Consenting for Lab Protocols</td>
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<td><strong>Presenter:</strong></td>
<td>Susan Tse, BSN, CCRP</td>
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<td><strong>Institution:</strong></td>
<td>Research Nurse Manager, MD Anderson Cancer Center</td>
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<td><strong>Session Overview:</strong></td>
<td>Research with Respect: Family Advocacy in Pediatric Clinical Trials</td>
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<td><strong>Presenter:</strong></td>
<td>Lauren Bird, BA, BSN, RN, CCRC</td>
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<td><strong>Institution:</strong></td>
<td>Clinical Research Nurse</td>
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<td><strong>Presenter:</strong></td>
<td>Mallory Rowell, MS, CCRC</td>
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<td><strong>Institution:</strong></td>
<td>Clinical Research Coordinator</td>
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<th>Track 8</th>
<th>Risk Management</th>
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<td><strong>Session Overview:</strong></td>
<td>Risk Management: How Are Sponsors Managing Risk?</td>
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<td><strong>Presenter:</strong></td>
<td>Joanne Malia, BS, MS, MS</td>
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<td><strong>Institution:</strong></td>
<td>Director, Medical Research Process Management</td>
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<td><strong>Time:</strong></td>
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<td><strong>Session Overview:</strong></td>
<td>Implementing Quality by Design in Clinical Trials</td>
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<td><strong>Presenter:</strong></td>
<td>Vatche Bartekian, BSc, MSc</td>
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<td><strong>Institution:</strong></td>
<td>President</td>
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Friday, September 30, 2016
Breakout Session Descriptions

Saturday, October 1, 2016

**Track 1 - Poster Session**

**Poster Session Presentations**

Selected poster presenters will present a synopsis of their work related to Clinical Trials and Clinical Trials Management. 117

**Track 1 - Responsible Conduct of Research**

**Can Clinical Research Learn from the Patient Safety Movement?**

Since 1999, the patient safety movement in the USA has made important advances in preventing patient harm by learning from its mistakes, identifying the quality gap between best practices and care as it is commonly given, and developing structured systems that track and analyze risk, harm, and potential harm. This presentation will identify lessons from these reports that could be applied to the responsible conduct of research. 121

Presenter: John Kessler, BS Pharm, PharmD
Chief Clinical Officer, SecondStory Health, LLC

**Time:** 10:50 to 11:35

**Track: Responsible Conduct of Research**

**Case Studies in the Responsible Conduct of Research**

Dr. Cookmeyer will use case studies and lessons learned to discuss research integrity and the consequences of a scientific enterprise that relies solely on a "self-correcting" model of peer review and independent validation of results. An updated model of actively promoting research integrity and encouraging the safe reporting of problems will be presented that is based on tools and strategies adopted from patient safety movement and a "just culture." Approaches will be discussed for moving beyond a "reactive" mode of responding to questionable research practices and more serious issues of research misconduct to a "proactive" setting where all components of the research enterprise are involved in, responsible for, and accountable to a community standard of integrity. A focus on remediation not only of individuals but also of factors in the institutional setting where questionable practice or misconduct may have been facilitated or gone undetected will be discussed. 123

Presenter: Donna Cookmeyer, PhD
Research Integrity Officer, Duke University

**Time:** 11:40 to 12:25

**Track: Responsible Conduct of Research**

**The Journey from Point A to Point B: How to get from Clinical Inquiry to Conducting Nursing Research**

This presentation will define three types of clinical inquiry: evidence based practice (EBP), quality improvement (QI), and research. Steps nurses can take to move from having a practice idea or question to making a decision about conducting nursing research will be described. Information provided will include how to identify a problem/topic, how to view a problem/topic from a variety of practice angles, key sources of evidence to consider when conducting a literature review, making a decision to conduct research, and steps of the research process. The role of nurses in EBP, quality improvement, and research will be described in terms of how nurses can contribute to the body of knowledge that guides nursing practice. 125

Presenter: JoAnn Mick, PhD, RN, NEA-BC, Nurse Researcher
Memorial Hermann - Texas Medical Center

**Time:** 2:30 to 3:15

**Track: Nurse as Researcher**

**Want to Write a Research Protocol? What to Consider, Where to Start & How to Create a Protocol Draft**

Dr. Mick will provide information on the purpose and components of a research protocol and helpful strategies for writing a protocol draft with an Institutional Review Board reviewer's perspective in mind. Three steps to writing an abstract, the difference between a study purpose and research question, and how to synthesize a review of literature that includes justification for conducting a study will be described. Other information will include a description of a critical thinking path for selecting appropriate data collection methodologies, describing risks and benefits to human subjects, and inclusion of a dissemination plan in study design. 127

Presenter: JoAnn Mick, PhD, RN, NEA-BC, Nurse Researcher
Memorial Hermann - Texas Medical Center

**Time:** 3:45 to 4:30

**Track: Training**

**Important Insights for Team Building within Clinical Trials in Oncology**

Ms. Grant will explore approaches to team building in the workplace with a focus on adult education principles. Insights learned from teaching and leading clinical research personnel within a large Canadian oncology centre will be shared. The audience will be invited to join in on an interactive discussion so that we can learn from each other's experiences. 129

Presenter: Jasmine Grant, MEd, BHSc, CCRP, Education Specialist Lead, Princess Margaret Cancer Centre

**Time:** 4:35 to 5:20

**The Joint Task Force Harmonized Core Competencies in Clinical Research: Formation, Survey Results, and Application**

In 2014, the Harmonized Core Competencies were published as a result of work groups within the Consortium of Academic Programs in Clinical Research (CoAPCR) and the Joint Task Force for Clinical Research Competencies that sought to harmonize multiple competency statements that had simultaneously evolved from clinical research stakeholders. These competencies have been embraced as a standard for curriculum development and program accreditation for academic programs in clinical research and have also been applied to clinical research training programs across sites awarded by NIH Clinical and Translational Science Awards (CTSA). Results from a 2015 global survey of the core competencies provide a broader understanding of clinical research practitioner learning needs across competencies. Ms. Jones will discuss the results of the 2015 survey. 131

Presenter: Carolyn Jones, DNP, DNP, MSPH, RN
Assistant Professor, Ohio State University

**Time:** 1:40 to 2:25

**Track: Nurse as Researcher**

**Where to Start & How to Create a Protocol Draft**

Where to Start & How to Create a Protocol Draft: Dr. Mick will provide information on the purpose and components of a research protocol and helpful strategies for writing a protocol draft with an Institutional Review Board reviewer's perspective in mind. Three steps to writing an abstract, the difference between a study purpose and research question, and how to synthesize a review of literature that includes justification for conducting a study will be described. Other information will include a description of a critical thinking path for selecting appropriate data collection methodologies, describing risks and benefits to human subjects, and inclusion of a dissemination plan in study design. 127

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Presenter: Carolyn Jones, DNP, DNP, MSPH, RN
Assistant Professor, Ohio State University

**Time:** 1:40 to 2:25
SESSION OVERVIEWS

Breakout Session Descriptions

Saturday, October 1, 2016

Track 2 | Device Research

Time: 8:30 to 9:15

Human Factors Testing and Clinical Research
Presenter: Tim Reeves, PhD, CHFP
Founder and Managing Director, Human Factors MD, Inc.

Medical Device Classification System: A Canadian Perspective
Presenter: Donna Headlee, BSN, RN, CCRP
Global Manager, Site Activation & Maintenance, ECD Covance

Track 2 | Research Subject Advocacy

Time: 1:40 to 2:25

We’re All Participant Advocates
Presenter: Cheryl Thomas, MS, CGC
Research Subject Advocate
Mayo Clinic

Research Participant Advocacy - Functions and Forms of Advocacy in Clinical Research Settings
Presenter: Elizabeth Martinez, BSN, CCRC, RN
Research Participant Advocate
Johns Hopkins University-ICTR

Track 2 | Investigator-Initiated Research

Time: 3:45 to 4:30

Building a Quality Assurance Program for Investigator-Initiated Research
Presenter: Abby Statler, MPH, MA, CCRP
Research Regulatory Quality Assurance Coordinator
Cleveland Clinic

Establishing a Quality Control Program for Investigator Initiated Studies
Presenter: Grace Wentzel, BA, CCRP
Director Clinical Research Services
The Research Institute at Nationwide Children’s Hospital

Track 2 | Device Research

Time: 9:20 to 10:05

Medical Device Classification System: A Canadian Perspective
Presenter: Valerie Cronin, HBA, MA, CCRP, RN, SCM
Clinical Nurse Research Coordinator
The Ottawa Hospital, Kidney Research Centre

Experiences of Monitoring via Remote Access to Electronic Medical Records
Presenter: Kristi Pinkston, BS, MABC, CCRP, RN
Senior Field Clinical Research Associate, St. Jude Medical, Inc.
Presenter: Michelle Wetherby, BS, CCRP
Senior Manager, Field Monitoring, St. Jude Medical

Track 2 | Research Subject Advocacy

Time: 2:30 to 3:15

Research Participant Advocacy - Functions and Forms
of Advocacy in Clinical Research Settings
Presenter: Cheryl Thomas, MS, CGC
Research Subject Advocate
Mayo Clinic

What are the ways that a designated Research Participant Advocacy Program (RPAP) or individual advocacy efforts may benefit participants and institutions? Discussion of specific things that an RPAP or investigator may consider implementing to promote the interests of their research participants and provide optimal human subjects protection will take place.

Presenter: Elizabeth Martinez, BSN, CCRC, RN
Research Participant Advocate
Johns Hopkins University-ICTR

Track 2 | Investigator-Initiated Research

Time: 4:35 to 5:20

Establishing a Quality Control Program for Investigator Initiated Studies
Presenter: Grace Wentzel, BA, CCRP
Director Clinical Research Services
The Research Institute at Nationwide Children’s Hospital

Research subject advocacy is everyone’s responsibility, regardless of their role on the study team. This talk will use participant stories and feedback to highlight actions that study teams can take to serve as advocates for their participants.

Presenter: Cheryl Thomas, MS, CGC
Research Subject Advocate
Mayo Clinic

We’re All Participant Advocates
Presenter: Cheryl Thomas, MS, CGC
Research Subject Advocate
Mayo Clinic

Research Participant Advocacy - Functions and Forms of Advocacy in Clinical Research Settings
Presenter: Elizabeth Martinez, BSN, CCRC, RN
Research Participant Advocate
Johns Hopkins University-ICTR

Track 2 | Device Research

Time: 10:50 to 11:35

Remote monitoring is the wave of the future. Medical facilities are now required to use an electronic medical records system. Most research studies use electronic data capture/remote data capture systems now instead of the paper case report forms. With many electronic medical record systems, sponsors now have the ability to monitor studies remotely. Sites’ IT departments assign ID/passwords and a link to the monitor and give monitors read-only access to a cohort of study patients. The cohort of patients is requested by the coordinator, and with the link/ID/password can be monitored without the field CRA having to travel to the site. Remote monitoring decreases travel costs for the sponsor, and assists the sites by not having to keep office space available for field monitors. Remote monitoring can also be done by in-house CRAs so that adverse events may be reviewed more quickly, as well. Remote monitoring is time saving and cost effective.

Presenter: Kristi Pinkston, BS, MABC, CCRP, RN
Senior Field Clinical Research Associate, St. Jude Medical, Inc.
Presenter: Michelle Wetherby, BS, CCRP
Senior Manager, Field Monitoring, St. Jude Medical

Track 2 | Device Research

Time: 11:40 to 12:25

Medical Device Case Study - Lessons Learned
Presenter: Donna Headlee, BSN, RN, CCRP

This presentation will be an interactive session discussing aspects of medical device investigational studies, applications, and lessons learned. Topics will include IDEs, PMAs, compliance strategies, and device GCP.
### Track 3: Canadian Regulations/Inspections

#### Negotiating Canadian Clinical Trial Agreements: Key Issues and Practical Tips

This session will address key elements to consider when reviewing and negotiating a clinical trial agreement involving a Canadian site. How to ensure all applicable parties are properly bound and how to ensure your CTA does not jeopardize the PI’s medical malpractice coverage or the site’s insurance coverage will be discussed. Mr. Rajakaruna will explain why governing law and jurisdiction language really matter and why you need to understand local laws. 317

**Presenter:** Marlon Rajakaruna, BA, MBA, LLB, CRCP
Partner, Global & National Co-Leader of Life Sciences Dentons Canada LLP

**Time:** 8:30 to 9:15

#### Negotiating Canadian Clinical Trial Agreements: Key Issues and Practical Tips

#### Conducting Clinical Trials in Canada

Mr. Rashti will explain to the audience how FDA selects their clinical study sites, differences between US and Canadian sites, FDAs foreign cadre, Bioresearch Monitoring Program, deviations observed in Canadian sites, and how to be prepared for the agency audit. 319

**Presenter:** Mike Rashti, BS
President, BIMO Auditor and Trainer, LLC

**Time:** 9:20 to 10:05

#### Controlled Substances in Clinical Research: Perspectives from an Academic Research Centre

This presentation will give the attendees a greater understanding of the regulatory framework surrounding the use of controlled substances in research, provide guidance regarding completion and submission of a Controlled Drugs and Substances Act Section 56 Exemption and learn about drug sourcing and importation procedures for academic studies. 321

**Presenter:** Gregory Staios, MSc, CCRP
Research Monitor
Centre for Addiction and Mental Health

**Time:** 10:50 to 11:35

#### Why I Believe in Testimonials

Mr. Tulley will present a first-hand experience of the role a clinical trial played when a loved one was threatened by a terminal illness. This is an intimate view of participating in a clinic study and how it impacts the patient and family. 323

**Presenter:** Marty Tully, Publisher

**Time:** 11:40 to 12:25

#### GCP Compliance Program

Ms. Kasina will discuss frequent compliance questions and highlight more recent initiatives. 325

**Presenter:** Alicja Kasina, MSc, PhD
Drug Specialist, Health Canada

**Time:** 1:40 to 2:25

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**Breakout Session Descriptions**

**Saturday, October 1, 2016**

**Track 3: Canadian Regulations/Inspections**

**Time:** 2:30 to 3:15

**“Lost in Translation” - Conducting Transnational Research in Canada and the United States**

Although Canada has a long history of research collaboration with the United States, there is growing concern about divergent regulatory approaches. Such divergent approaches can have a direct impact on the interpretation of concepts commonly used on each side of the 49th parallel. Mr. Letendre will explore and navigate these divergent regulatory approaches through the review of expressions that carry different meanings in Canada and the United States including placebo-controlled, investigator, safety reporting, and compliance. 327

**Presenter:** Martin Letendre, LLB, LLM
Managing Director
Veritas IRB, Inc.

**Time:** 3:45 to 4:30

**Practical Applications of the Initiative to Streamline Clinical Trials**

Researchers from across Canada came together to create the Initiative to Streamline Clinical Trials, a document that provides ideas for making clinical research easier while maintaining participant safety and the scientific integrity of the study. The Initiative was made public in the spring of 2014, and Ms. Bosch will focus on the uptake of information in the Canadian clinical trials community as well as suggestions for improvement and for further streamlining.

**Presenter:** Jackie Bosch, PhD, MSc, BSc.
Director, Project Management PHRI
Population Health Research Institute / McMaster University

**Time:** 4:35 to 5:20

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Breakout Session Descriptions
Saturday, October 1, 2016

Track 4
Complementary & Alternative Medicine

Time: 8:30 to 9:15

FDA and Health Canada Perspectives on Homeopathic Products as Drugs
Homeopathic products are widely used in the US and Canada. Homeopathic products in the US are regulated as drugs; in Canada they are regulated as natural health products. In traditional medicine pharmacologically active agents are used to suppress symptoms or pathophysiologic processes of diseases. The treatment of disease in homeopathic medicine is to use diluted substances that produce symptoms in healthy individuals similar to those of the diseases that they treat. Scientific and regulatory similarities and differences will be presented for discussion. 417
Presenter: Harvey Arbit, PharmD, MBA, CCRP, RAC
President, Arbit Consulting, LLC

Time: 9:20 to 10:05

When There Is No Place to Turn, I’ll Try Integrative Medicine Research Too
Integrative medicine and CAM research is sought by persons facing potentially devastating illnesses. Ms. Wintering will discuss integrative medicine research conducted with persons with Alzheimer’s disease, Parkinson’s disease and Cancer. Project planning, collaboration, risk management and psychological considerations will be presented. Challenges and opportunities of successful integrative medicine research will be discussed. 419
Presenter: Nancy Wintering, MSW, LCSW, CCRP
Research Program Manager
Thomas Jefferson University

Time: 10:50 to 11:35

Monitoring

Blind Dating: Ways to Successfully Select Clinical Sites for Lasting Relationships
The speakers will present effective tips, forms, templates, and tools to ensure selection of only sites that have quality data and subjects, as well as sites that meet or exceed goals. Practical, real-world examples of how not to fall for the “glitz and glam”, but how to spot the red flags and dig deeper will be offered. Site selection is imperative to ensure successfully meeting enrollment milestones. With quality sites, sponsors will see a very low number of avoidable protocol deviations and the overall number of queries. 421
Presenter: Wendy Ko, BS, CCRP
Clinical Team Lead
Rho, Inc.

Presenter: Joella Kittrell, MPH, CCRP, MCRP
Senior/Lead Clinical Research Associate
Rho, Inc.

Time: 11:40 to 12:25

Monitoring

The Sawyer Effect: Impacting Recruitment from a Sponsor/CRO Perspective
As clinical trials become increasingly complex, looking to recruit a more selective patient, and draw more conclusions, an increased load has been placed on the site staff. This often translates into sluggish recruitment and site demotivation. With over 80% of clinical trials not meeting recruitment targets, change is overdue in how sponsors and CROs approach the topic of patient recruitment. In this presentation, psychology and evidence based research reveal what truly motivates clinic site staff, from study coordinators to principal investigators. Scientists have recognized the importance of intrinsic motivation for decades. The shifting paradigm in clinical research will be discussed, as the traditional “fact checking” CRA becomes the site manager. The shift to a “heads up” approach to site monitoring and management will allow CRAs to begin to build these principals of intrinsic motivation in to their relationship with sites, resulting in more productive clinical sites. 423
Presenter: Fraser Gibson, BSc, CCRA
Senior Clinical Research Associate/Operations Specialist
Spectral Medical Inc

Time: 1:40 to 2:25

Monitoring

Why Does this Problem Keep Happening Over and Over?
In examining clinical trial findings, we may discover that very often they highlight the same type of problems which arise year after year. Have you ever wondered why the same issues occur repeatedly despite the implementation of quality systems, compliance training, and CAPA plans? Dr. Gorkun will look into the root cause and make sure the corrective and preventative actions are addressing the actual problem rather than its symptoms. Case study examples will be provided. This presentation was developed in collaboration with April Bishay, Senior Manager Clinical Compliance at MedImmune. 425
Presenter: Anatoly Gorkun, MD, PhD, Associate CIPD
Senior Manager, Scientific & Compliance Training
MedImmune

Time: 2:30 to 3:15

Monitoring

Risk-Based Monitoring - Is Everyone on the Same Page?
Ms. Boakye will present a review to assess if CRO, pharma, and academia are all seeing if risk-based monitoring is truly transforming clinical trials and if they are cohesive in their approach. 427
Presenter: Golda Boakye, MSc, BSc, CCRP
Sr Clinical Research Associate
Naantu Research, Inc/PRAHS

Time: 3:45 to 4:30

Monitoring

BULLSEYE: What is Targeted Monitoring All About?
“Targeted monitoring” has become a popular catch phrase. Where did it come from? What is targeted monitoring all about, and how is it done? Is it any good? Come hear a monitor's experience with this newfangled way of doing source/data verification. 429
Presenter: Jane Ferguson, RN, MN, CCRP
Clinical Research Associate III
PrECOG, LLC
**Breakout Session Descriptions**

**Saturday, October 1, 2016**

**Track 4: Monitoring**

**Remote Monitoring - How Can a Data Warehouse Help?**
The presentation summarizes a research project at Medical School Hannover. The objectives of the project are to investigate options for remote monitoring activities, in particular related to data verification and identification of safety issues, both mainly in IITs. The internal data warehouse is used as basis to validate data and to reconcile safety information as reported in the trials. The research project is ongoing and will be completed by April 2016. 431

Presenter: Gerhard Fortwengel, PhD, MPH, MSc
Professor
University of Applied Sciences and Arts, Hannover

**Track 5: Advanced Management**

**A Site Perspective on Study Budget / Feasibility**
Review of the clinical trial cost assessment / feasibility review process and key points with real examples will be presented. Planning the logistics and performing a thorough cost analysis lead to successful management and execution of studies. 517

Presenter: Serpil Tutan, MBA, CCRP
Operations Manager
Baylor College of Medicine

**Organization for Smooth Site Start Up**
Ms. Allen will present successful and helpful organizational tactics to assist in managing important aspects of the start-up of clinical research trials, whether a single-site or a multi-site study. These tactics will promote success in recruitment and retention, communication with the IRB, and oversight of regulatory needs and participant safety, as well as encourage teamwork and ease in workflow for site research staff. 519

Presenter: Janelle Allen, MS, BS, CCRP
Project Manager and Senior CRC
Cincinnati Children’s Hospital Medical Center

**Is Your Site Prepared for an FDA Inspection? Learn How Through Lessons Learned!**
What can your site expect during an FDA Inspection? Learn How Through Lessons Learned!

Presenter: Lisa Benson, BS, CCRP, CRCP
Senior Director, Research Operations and Sponsored Programs
Connecticut Children’s Medical Center

**I’m Just a Coordinator**
Ms. Derr will discuss helpful topics for small sites where coordinators and assistants are also performing research administration duties such as budgets, contracts, finance, and billing. 523

Presenter: Jessica Derr, BA, CCRP, CRCP
Director, Research Administration
Texas Health Resources

**Successful CTMS Roll-Out: Lessons Learned from an Academic Medical Center**
Academic medical centers can be complex environments with numerous stakeholders and a decentralized management structure. The field of clinical research and large clinical trials is similarly becoming more complex and rigorous, requiring comprehensive systems to ensure quality, efficiency, and productivity. This talk will discuss the decisions of a large academic medical center to implement an institution-wide CTMS. Ms. McCue will discuss the approaches taken to successfully implement a comprehensive CTMS, including project management, change management, culture change, and strategic planning requirements. 525

Presenter: Rebecca McCue, BA
Associate Director
Site Based Research, Stanford University School of Medicine

**Simple Data Gathering Tools Can Greatly Improve Research Quality Management**
In order to manage the diverse activities that make up a clinical research program, it is essential to be able to identify trouble spots, assess and correct deficiencies, and continually monitor process improvements for efficacy. While this can seem like a monumental task, it can be broken down into simple constituent steps. This can be carried out with a minimal expenditure of effort and without the purchase of expensive custom software packages. This session will demonstrate a process for developing simple tools to leverage existing information, organize collection of additional information, analyze the dataset, and drive lasting improvements using standard office productivity software. 527

Presenter: Kevin Smith, MS, MBA, CCRP
Research Program Manager
Cleveland Clinic Foundation

**The Process of Conducting Emergency Protocols**
Ms. Larson will discuss how we brought up multiple emergency protocols and treated patients with an investigational drug within 24 hours of receiving notice of their arrival. Discussion will include, but not be limited to, emergency INDs, calling an emergency IRB meeting, getting an IRB application/consent written in <24 hours, developing source documents, study drug administration in a bioccontainment unit, special consenting issues, how to get data out of a bioccontainment unit, and sharing data. 529

Presenter: LuAnn Larson, BSN, CCRP, RN, CCRC
Nurse Manager
University of Nebraska Medical Center

Assuring Research of Today Improves Outcomes of Tomorrow
**Session Overviews**

### Track 5: Advanced Management

**Time: 8:30 to 9:15**

**Identifying Effective Community Consultation Methods for 21 CFR 50.24 Compliance**

Research in emergency environments involves interventions administered to patients at a time when no intervention may result in death or permanent disability. In these circumstances, patients are considered vulnerable since they may be unconscious, in shock and alone. These are not the ideal conditions to obtain informed consent from the patient. In order to address these issues, the FDA and DHHS introduced 21 CFR 50.24, entitled Exception from Informed Consent (EFIC) for Emergency Research. The regulation is vague and researchers use various methods to conduct community consultations as a means to engage the community’s opinions prior to conducting emergency research. This presentation will review current published methods of community consultation including an in-depth look at the purpose and intention of community consultations as they apply to 21 CFR 50.24, the methods utilized, and their effectiveness in communicating with the appropriate potential target study population and potential improvements to the current processes.

Presenter: **Skeeta Sobrian, BHA, MScHQ, CCRP, RN**
Consultant ReQuE

### Track 6: Oncology Research

**Time: 9:20 to 10:05**

**Narrow the Focus - Open the Aperture**

The protocol says this, my study team wants that, and my study participant needs something else; so where do I even begin to know where to start? Surprisingly the starting point is not the protocol or your team but the study participant. The new CRC need not become overwhelmed by everything that everyone says, wants, or needs done and done NOW. By narrowing the focus to the primary objective of protecting the study participant and then the study team, the CRC will then be better able to open the aperture of prioritizing tasks to meet the protocol’s parameters.

Presenter: **Jennifer Kay, BSN, CCRP, CCRC, WALS, ACLS, BCLS-1**
Clinical Research Coordinator
University of Virginia Health System

**Time: 4:35 to 5:20**

**Identifying Effective Community Consultation Methods for 21 CFR 50.24 Compliance**

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Presenter: **Skeeta Sobrian, BHA, MScHQ, CCRP, RN**
Consultant ReQuE

**Time: 10:50 to 11:35**

**Moving Beyond Paper: Implementing an Electronic Source (eSource) Platform**

Ms. Cole will share the Princess Margaret Cancer Centre’s experience of implementing an electronic source (eSource) system; the process, challenges, and advantages of working electronically.

Presenter: **Heather Cole, BSc**
Manager, Cancer Clinical Research Unit
Princess Margaret Cancer Centre

**Time: 1:40 to 2:25**

**Identifying and Validating Recruitment and Retention Trends Utilizing a Web-Based Data Capture System**

Ms. Hoepner will demonstrate how the transition from using Excel spreadsheets to a secure web-based data capture system assisted in early identification of trends that hinder the recruitment process leading to improvements to the overall study conduct.

Presenter: **Amy Hoepner, RN**
Research Nurse III/Quality Manager
Cincinnati Children’s Hospital Medical Center

**Time: 2:30 to 3:15**

**The University Health Network Genitourinary (GU) BioBank**

Since the date of its inauguration in 2008, the GU BioBank has accrued hundreds of thousands of specimens from more than 10,000 consenting patients. The GU BioBank aims to facilitate the discovery of new diagnostic and prognostic biomarkers to achieve the ultimate goal of personalized medicine and improved outcomes for GU oncology patients. The GU BioBank has garnered an incredible amount of interest in recent years, and we would like to share our experience in setting up and maintaining this patient-centered research program. Ms. Laszlo will touch on biobanking challenges including but not limited to data quality (accuracy and completeness).

Presenter: **Sandra Laszlo, MHM candidate, BS, CCRP**
GU BioBank, QA, and Projects Lead
UHN Princess Margaret Cancer Centre

**Time: 10:40 to 12:25**

**The Role of the Specialized Oncology Nurse in Clinical Trials**

This session will provide an overview of applying the ambulatory model of nursing care to clinical trials in oncology as well as training and orientation of new trial nurses. Strategies for working with clinical staff, provisions of protocol training for supporting departments, and transfer of accountability will also be discussed. Finally, innovations in clinical trial nursing that have been implemented at Princess Margaret Cancer Centre will be reviewed.

Presenter: **Skeeta Sobrian, BHA, MScHQ, CCRP, RN**
Consultant ReQuE

**Time: 4:35 to 5:20**

**Trends Utilizing a Web-Based Data Capture System**

Ms. Hoepner will demonstrate how the transition from using Excel spreadsheets to a secure web-based data capture system assisted in early identification of trends that hinder the recruitment process leading to improvements to the overall study conduct.

Presenter: **Amy Hoepner, RN**
Research Nurse III/Quality Manager
Cincinnati Children’s Hospital Medical Center

**Time: 1:40 to 2:25**

**Academic Community Collaboration to Improve Access to Cancer Clinical Trials: One State’s Journey**

Ms. Stewart will discuss the organizational structure, governing agreements, and operations to develop a statewide oncology research network. The talk will provide the actual steps taken to build the network and lessons learned.

Presenter: **Teresa Stewart, MS, CRCP (MTASCP)**
Executive Director, Clinical Trials , New Mexico Cancer Care Alliance

**Time: 9:20 to 10:05**

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**Narrow the Focus - Open the Aperture**

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Presenter: **Jennifer Kay, BSN, CCRP, CCRC, WALS, ACLS, BCLS-1**
Clinical Research Coordinator
University of Virginia Health System
Informed Consent: Participants Just Don’t Understand…or Do They?

This presentation will discuss one institution’s experience in implementing institutional-wide simplified ICFs. 717

Presenter: Michelle Dickey, MS, CFNP, CPNP, CCRC, Assistant Professor of Pediatrics/Director of Infectious Diseases, Cincinnati Children’s Hospital Medical Center

Informed Consent Documentation - Is It Really Necessary?

Ms. Lloyd will discuss possible policy and procedure requirements and regulations regarding consent documentation as well as warning letters regarding improper consent documentation. Suggestions for improved documentation will be provided. 723

Presenter: Wendy Lloyd, BA, CCRP, LPN, CIP, Regulatory Compliance Analyst, Vanderbilt University Medical Center

Emergency Research: Exception from Informed Consent

This presentation explores both the regulatory requirements and practical implementation of 21 CFR 50.24, exception from informed consent requirements for emergency research. Emergency research, per IRB policy, is research that is conducted in participants who are in a life-threatening or emergent situation, where available treatments are unproven or unsatisfactory, and the collection of scientific evidence (which may include randomized, placebo-controlled trials) is necessary to determine the safety and efficacy of the intervention under study. Added requirements for such research and the safeguards implemented for public safety and awareness will be explored. 725/727

Presenter: David Hiller, BSN, RN, AEMT, CIP, Regulatory Compliance Manager, Vanderbilt University Medical Center

Regarding the Immortal Life of Henrietta Lacks

This presentation will start by providing a timeline of events of the story of Henrietta Lacks and her family as they relate to informed consent including the Nuremberg Code, the Declaration of Helsinki and the Belmont Report. Ms. Kosky will discuss the impact that HeLa cells have had on research and informed consent. Ms. Kosky will conclude by asking people what part of Henrietta Lacks’ story had the most impact on them personally and why. 729

Presenter: Barbara Kosky, MAsC, CCRP, Clinical Research Coordinator, University Health Network
### Breakout Session Descriptions

**Saturday, October 1, 2016**

#### Track 7
IRB Issues - Solutions - Methods

**How to Eliminate Overreporting**
IRBs continue to be overburdened with reports not required by federal regulation. It is important to understand what is required by regulation and what has become an industry standard. Additionally, study sites are often confused regarding reporting requirements and err on the side of conservatism by overreporting. By clearly identifying regulatory requirements versus what has become standard operating procedure, our industry may well become more efficient and eliminate unnecessary work for sites as well as IRBs. 831

**Presenter:** Sarah Attwood, Director of Business Development IntegReview IRB

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#### Track 8
Quality Management

**Incorporation of Quality Data for Research Purposes**

**Time:** 10:50 to 11:35

**Presenter:** Velma Marzinotto, BScN, CCRP, Research Compliance and Education Specialist, St. Michael's Hospital

**Summary:** This session will provide an overview of how to incorporate quality data in research. It will cover the importance of quality data in research, the role and expectations of the researcher in the conduct of quality research, and how to use quality data to improve research outcomes. Participants will learn how to incorporate quality data into their research projects and how to use quality data to improve the quality of their research.

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**Track 8**

**Quality Management**

**Time:** 8:30 to 9:15

**Research Quality Audits: Internal Risk-Based Auditing in a Large Academic Research Hospital**

This talk will outline the development of an internal research quality audit process for clinical trials conducted in an academic research hospital. An overview of the research quality audit objectives, selection process, audit procedures, audit report, and follow-up will be provided. Ms. Marzinotto will also discuss the role and expectations of the researcher in the conduct of quality research. 817

**Presenter:** Velma Marzinotto, BScN, CCRP, Research Compliance and Education Specialist, St. Michael's Hospital

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**Site Management**

**Time:** 2:30 to 3:15

**Developing Effective Study Start Up Processes**

Through a series of exercises and templates, the speaker will guide coordinators, PI's and other site staff through the study start up process with tools developed to ensure successful implementation. 827

**Presenter:** Sara Albert, BA, MPH
**Clinical Project Manager**
**Leidos Biomedical Research, Inc.**

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**Centralized Enrollment - Staying Audit Ready**

There are several benefits to having a centralized enrollment office. 100% of eligibility checklists and consents submitted to our institution are reviewed for accuracy and completion upon receipt. The coordinators then enter the enrollment date into our database which then prompts them to verify their eligibility. 100% of our eligible research participants receive a second verification within five days of enrollment. This helps the institution to be audit ready as it pertains to consents and eligibility criteria. 829

**Presenter:** Steven Hirsh, DPM, RPh, DPM, MHSA
**Director of Clinical Research, Life Extension Clinical Research, Inc.**

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**Time:** 1:40 to 2:25

**Protocol Implementation Logistics**

Ms. Albert will identify when applicable HHS and FDA regulations apply. Study logistics and the steps for protocol implementation will also be discussed as well as the required approvals needed for study start up. 825

**Presenter:** Sara Albert, BA, MPH
**Clinical Project Manager**
**Leidos Biomedical Research, Inc.**

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**Time:** 3:45 to 4:30

**Dispensing and Accountability Can Affect the Quality of a Clinical Trial**

Dr. Hirsh will initially review the development process with discussion of clinical trial design which will impact the study product distribution. There will be a review of the dietary supplement and pharmaceutical receipt, preparation and dispensing procedures with examples of the documentation. A review of the importance of accountability and regulatory compliance will be discussed as well as the requirements for study product retention, return, and destruction. 823

**Presenter:** Steven Hirsh, DPM, RPh, DPM, MHSA
**Director of Clinical Research, Life Extension Clinical Research, Inc.**

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**Time:** 11:40 to 12:25

**Dietary Supplement and Pharmaceutical Preparation: How to Eliminate Overreporting**

**Presenter:** Janet Holwell, CCRC, CCRA, TIACR
**Clinical Research Consultant**

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**Time:** 4:35 to 5:20

**Lean and Continuous Improvement in Clinical Research**

Ms. Knight will introduce Lean methods and tools used in healthcare and how we used these tools to organize a continuous improvement process at our institution. Actual examples will be shared, as well as successes and challenges along the way. 831

**Presenter:** Susan Knight, MBA, CNMT, Director, Medical Sciences

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**Time:** 9:20 to 10:05

**Centralized Enrollment - Staying Audit Ready**

**Presenter:** Janet Holwell, CCRC, CCRA, TIACR
**Clinical Research Consultant**

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**Time:** 2:30 to 3:15

**Incorporation of Quality Data for Research Purposes**

Special considerations may be needed when using site specific quality data in research. Institutional regulatory agencies may require full board approval where others may approve through an exemption process. Publication of data sets may also require full board approval where others may approve through an exemption process. By clearly identifying regulatory requirements versus what has become standard operating procedure, our industry may well become more efficient and eliminate unnecessary work for sites as well as IRBs. 731

**Presenter:** Sarah Attwood, Director of Business Development IntegReview IRB

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**Presenter:** Velma Marzinotto, BScN, CCRP, Research Compliance and Education Specialist, St. Michael's Hospital

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**Time:** 4:35 to 5:20

**Lean and Continuous Improvement in Clinical Research**

Ms. Knight will introduce Lean methods and tools used in healthcare and how we used these tools to organize a continuous improvement process at our institution. Actual examples will be shared, as well as successes and challenges along the way. 831

**Presenter:** Susan Knight, MBA, CNMT, Director, Medical Sciences

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**Time:** 10:50 to 11:35

**How to Eliminate Overreporting**

**Presenter:** Janet Holwell, CCRC, CCRA, TIACR
**Clinical Research Consultant**

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**Time:** 1:40 to 2:25

**Protocol Implementation Logistics**

Ms. Albert will identify when applicable HHS and FDA regulations apply. Study logistics and the steps for protocol implementation will also be discussed as well as the required approvals needed for study start up. 825

**Presenter:** Sara Albert, BA, MPH
**Clinical Project Manager**
**Leidos Biomedical Research, Inc.**

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**Time:** 3:45 to 4:30

**Dispensing and Accountability Can Affect the Quality of a Clinical Trial**

Dr. Hirsh will initially review the development process with discussion of clinical trial design which will impact the study product distribution. There will be a review of the dietary supplement and pharmaceutical receipt, preparation and dispensing procedures with examples of the documentation. A review of the importance of accountability and regulatory compliance will be discussed as well as the requirements for study product retention, return, and destruction. 823

**Presenter:** Steven Hirsh, DPM, RPh, DPM, MHSA
**Director of Clinical Research, Life Extension Clinical Research, Inc.**

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**Time:** 4:35 to 5:20

**Lean and Continuous Improvement in Clinical Research**

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Closing Plenary

Sunday, October 2, 2016

Time: 8:40 to 9:25
Track: Closing Plenary

**Integrative Oncology: Combining High and Low Tech Cancer Care**

Dr. Lawenda will discuss the core concepts of an important new trend in oncology care: "integrative oncology." This is an evidence-based whole systems approach to the care of patients, which combines state of the art treatments with complementary therapies and lifestyle counseling. The goals of integrative oncology are: 1) improve outcomes, 2) improve quality of life, and 3) patient empowerment.

Presenter: Brian Lawenda, MD
Clinical Director, Radiation Oncologist
21st Century Oncology

Time: 9:25 to 10:10
Track: Closing Plenary

**How the Common Rule Notice of Proposed Rule Making Will Affect Clinical Research**

This presentation will provide an overview of the Common Rule Notice of Proposed Rulemaking (NPRM) published in September 2015 and explain the NPRM proposals relevant to clinical research involving human subjects. Some of the most significant NPRM proposals would mandate that US institutions engaged in cooperative research utilize a single IRB to review a study conducted at multiple sites, impose limitations on the transfer and subsequent research use of biospecimens collected in research regulated by the Common Rule, and expand the regulatory scope to apply to certain clinical trials that are not currently regulated under the Common Rule. Ms. Odwanzy will summarize the public comment received on these proposals and address the implications of these proposals, if adopted.

Presenter: Laura Odwanzy, JD, MA, BA
Senior Attorney
US Department of Health and Human Services

Time: 10:30 to 11:00
Track: Closing Plenary

**Why the “Protocol” Is the Key to a Clean Audit**

This talk will center on why following the study protocol is how you avoid a Form 483 and warning letters. Not following the protocol is one of the main problems identified by regulatory inspectors during trial audits. To start, the written protocol must be pharmacologically, ethically, and medically sound. The principal investigator, on whom full responsibility for the conduct of the study falls, signs thereby agreeing to follow this document to the letter. Any deviations are fodder for negative inspectional findings. The warning letters that will be shown are scary.

Presenter: Charles Pierce, MSC, MD, PhD, FCP, CPI
Director
Pierce One Consulting

Time: 11:00 to 11:30
Track: Closing Plenary

**L-Glutamine Therapy for Sickle Cell Anemia**

Proper design and execution of a clinical trial can enhance and save the lives of many. On the other hand, poor design and execution of a clinical trial can deprive society of good products. These points will be demonstrated by reflecting on our experience in developing L-glutamine therapy for sickle cell disease.

Presenter: Yutaka Niihara, MD
President and CEO
Emmaus Life Sciences, Inc.

Time: 11:30 to 12:00
Track: Closing Plenary

**Between Visits: The Use of Mobile Health Apps for Patient Self-Care and Outcomes Research**

Our mobile phones are embedded within our daily lives and are actively collecting tons of data about us, such as our physical activity levels, eating habits, and even our socializing patterns. These smart devices present a unique opportunity to deliver real-time personalized health care to individuals across the globe.

Presenter: Shivani Goyal, B.Eng, MASc
Project Manager
University Health Network

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**Thursday, September 29, 2016**
6:00 p.m. - 7:00 p.m.