the past couple of years, the IR Department has been challenged with the Interventional Radiology Department of MD Anderson Cancer Center. In trials wherein procedures were performed by faculty members of the overview of the management and coordination of intratumoral injection Injecting cancer treatments have shown promise in clinical trials, whether Intratumoral Injection Trials: IR Experience

Time: 2:05 to 2:50   Track: Oncology Research

Oncology Investigator Initiated Clinical Trial Protocols: A Comprehensive Review of Eligibility Criteria and Study Procedures
A clinical trial protocol provides details regarding design, recruitment, treatment plan, regulatory requirements and logistics of a study. Ms. Mukit will go deeper into two specific sections of the protocol: 'eligibility criteria' and 'study procedures'. This presentation will be a beginners level presentation based on oncology investigator initiated interventional clinical trials. Ms. Mukit will focus on the specifics of some universal eligibility criteria and how they can be presented effectively. She will also shed light on the most commonly used study procedures and cover the vital specifics that need to be stated with each study procedure. The impact of these two sections on the ‘Recruitment and Retention’ capacity of a clinical trial will also be discussed. 109
Presenter: Sabeena Mukit, MBBS, MS, Medical Writer, Northwestern University

Time: 2:05 to 2:50   Track: Oncology Research

Intratumoral Injection Trials: IR Experience
Injecting cancer treatments have shown promise in clinical trials, whether through vaccines or direct intratumoral injections. This presentation is an overview of the management and coordination of intratumoral injection trials wherein procedures were performed by faculty members of the Interventional Radiology Department of MD Anderson Cancer Center. In the past couple of years, the IR Department has been challenged with the growing demands of Phase I and Phase II intratumoral injection trials, which were primarily driven by different departments such as Investigational Cancer Therapeutics/Phase I, Melanoma, Sarcoma and others. 111
Presenter: Maria Briones, MD, CCRP, Clinical Research Team Lead, Interventional Radiology, UT MD Anderson Cancer Center

Time: 3:25 to 4:10   Track: Oncology Research

Putting Everything in Perspective: What You Need to Know to Survive in Clinical Trial Management
Ms. Stewart will discuss information from the data management side and regulatory side of managing clinical trials. Ways to navigate requests from sponsors/CROs will also be presented. 113
Presenter: Diandra Stewart, BS, CCRP, Clinical Research Associate, Cancer Centers of SW Oklahoma

Time: 4:15 to 5:00   Track: Oncology Research

Complementary and Alternative Medicine Pros and Cons
Nowadays an increasing number of patients from various age groups are moving to integrative medicine (IM). IM is a coordinated approach that uses Complementary and Alternative Medicine (CAM), and conventional therapies. Patients may not discuss its use with their healthcare providers. These therapies may enhance or interfere with traditional cancer treatments. Healthcare providers should focus on strategies for effective communication with patients to discuss the use of CAM and notify about risks and benefits associated with it. 115
Presenter: Rashmi Pande, BDS, MS, CCRP, Clinical Research Coordinator
Track 2 / Ethics in Research

Time: 1:15 to 2:00   Track: Ethics in Research

Vulnerable Subjects: Challenges of Conducting Research Under Difficult Circumstances

Researchers are often faced with a number of difficult situations during the course of conducting human research. Often, the solutions are not easy or apparent. There are many circumstances where participants are vulnerable to coercion, dependent, and may have decreased autonomy due to developmental disabilities and cognitive impairments, that may violate their freedom to choose and, hence, cannot exercise the right to refuse to participate in research. 209

Presenter: Muhammad Waseem, MD, MS, CCRP, CIP, CHSE-A, Research Director/Professor Emergency Medicine, Lincoln Medical Center

Time: 2:05 to 2:50   Track: Ethics in Research

Words Matter - Dehumanization in the Past...and Today?

Words matter. Historically, words have been used to dehumanize, allowing “researchers” to study “objects” or “animals” instead of humans, which contributed to the atrocities of Nazi Germany and Imperial Japan. Ms. Oeser will review words currently used to describe people who participate in research--are they dehumanizing too? 211

Presenter: Annette Oeser, BS, MLAS, CCRP, Clinical/Translational Research Coordinator III, Vanderbilt University Medical Center

Time: 3:25 to 4:10   Track: Ethics in Research

The Reason Why Emerging Countries are Attractive Places for Clinical Research

Clinical research has become more global in the past few years, therefore the number of conducted clinical trials has increased worldwide, especially in emerging countries. This presentation will discuss reasons for the increasing number of trials in African countries. 213

Presenter: Vanessa Struver, MSc, Research Assistant, University of Applied Sciences and Arts

Time: 4:15 to 5:00   Track: Ethics in Research

Ethics of Placebo Use in Randomized Controlled Trials

An ethical schism amongst placebo use in clinical trials remains, despite the latest revision of the Declaration of Helsinki, to include a systemic approach towards the design of placebo-controlled trials. Disparity in the interpretation of the current international guidelines led to conflicting arguments for and against placebo use in the presence of existing standard treatment. This presentation shall evaluate these differing notions objectively and provide a better understanding of the underlying justifications for the ethical framework supporting placebo use in randomized controlled trials. Alternative study designs which allow comparison of the novel therapy with placebo and active treatment while mitigating existing risks will also be examined. An overview focused on the Declaration of Helsinki revisions shall throw light on the historical perspective of the ethics of placebo use in clinical trials. 215

Presenter: Xinmei Shi, MSc, CCRP, CCRA, Research Manager, National University Cancer Institute, Singapore

Track 3 / Site Management

Time: 1:15 to 2:00   Track: Site Management

Unpacking the FDA Clinical Investigator Inspection Process in order to Maximize the Probability of Successful Inspection Outcomes

Conducting clinical research in an FDA inspection-ready environment is crucial and is arguably the best predictor for a positive FDA inspection outcome. As such, understanding the FDA inspection process should motivate an investigator’s clinical research-related processes. Lastly, navigating the FDA inspection process from inception to complete resolution often relies on a savvy understanding of how to best respond whenever 483-worthy findings are noted. 309

Presenter: T. Che Jarrell, BSPH, MPIA, RAC, Proprietor & Principal Consultant, Milestone Regulatory Experts, LLC

Time: 2:05 to 2:50   Track: Site Management

Source Documentation: Common Pitfalls and Site Monitoring Visit Findings

Source documentation issues is one of the most common findings cited by clinical site monitors. The source document should speak to the patient’s progression in the trial and how the data is initially obtained. Missing or inadequate source documentation jeopardizes the patient’s safety and eligibility, and the accuracy and reliability of the data. To avoid common pitfalls and cited monitoring findings, source documentation should be clearly defined and agreed upon by the site PI, research staff, and sponsor/CRO prior to trial initiation. 311

Presenter: Taylor Swankie, Public Health Analyst/Clinical Research Coordinator, RTI International

Time: 3:25 to 4:10   Track: Site Management

How to Use Excel to Coordinate Your Studies

Learn to use the features in Excel to coordinate studies and patients. Use Excel to manage complicated studies, track patient visits and required observations. Use date fill features, conditional formatting, worksheets, and formulas. 313

Presenter: Amy Rowell, MS, CCRP, Quality Assurance Coordinator, UT Southwestern

Time: 4:15 to 5:00   Track: Site Management

Private Practice Research Culture and Compliance Transformation

Ms. Iovanni will focus on research culture transformation efforts at a community, non-academic, private, medical practice, with a for profit partner. Challenges, successes and strategies that are easily transferrable to a variety of research site types, will also be discussed. 315

Presenter: Linda Iovanni, MBA, BSN, RN, COO, Research Director, Maryland Oncology

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Friday, September 27, 2019  Breakout Session Descriptions
Friday, September 27, 2019

**Track 4**

**GCP and Audit Preparedness**

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

**Track:** GCP and Audit Preparedness

**Investigator / Investigational Site Responsibilities**

Mr. Rashti will highlight the importance of investigator and investigational site responsibilities, and relate Good Clinical Practice compliance to successful completion of clinical studies in support of New Drug Applications. Mr. Rashti will describe how to prepare for an audit by FDA staff, most common deficiencies observed, and how to avoid them. Past audit experiences will be shared.

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

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

**Track:** GCP and Audit Preparedness

**Dealing with an FDA Inspection: Expectations, Outcomes & Consequences**

This session will describe the preparation of a site for an FDA inspection and how to successfully host an audit. Mr. Hamrell will cover the audit from different perspectives and focus on helpful hints and procedural issues regarding what to do if chosen for an FDA inspection. There will be a discussion on how to host the inspection and how best to prepare for the actual event. The audience will be taught some of the dos and don’ts of a successful inspection and will learn from actual case examples and inspections.

**Presenter:** Michael Hamrell, PhD, RAC, FRAPS, RQAP-GCP, CCRA, FACRP, President, MORIAH Consultants

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

**Track:** GCP and Audit Preparedness

**What to Expect from an FDA Inspection**

The FDA notifies you they are coming to inspect. What do you do next? This presentation will go over what to plan for, before the FDA Inspector arrives on site, what to expect when the inspector arrives in person, what to expect during the inspection process, and what to expect at the conclusion of the inspection.

**Presenter:** Donna Williams, BS, CCRP, RN, Project Administrative Officer of Clinical Trials, SUNY Upstate Medical Hospital / Cancer Center

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

**Track:** GCP and Audit Preparedness

**Study Team Training as a Result of Audit Findings in Oncology Trials**

We all love audits. How can we make the results of audits productive and informative? Ms. Rowell and Ms. Chang will help attendees learn how to take oncology clinical trial audit findings and create study team trainings to fulfill the corrective action plan and not have issues in the future.

**Presenter:** Amy Rowell, MS, CCRP, Quality Assurance Coordinator, UT Southwestern

**Presenter:** Jenny Chang, BA, Quality Assurance Coordinator, UT Southwestern

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**Track 5**

**Integrative Medicine / CAM**

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

**Track:** Integrative Medicine/CAM

**Applying Behavioral Science in the Clinical Research Workplace: Tools to Improve Personal and Site Performance**

Clinical research professionals are commonly presented with high stress work situations due to workload, competing priorities, and interpersonal communication challenges within teams. This presentation will outline how various methods can improve an individual’s resiliency, to aid in the ability to focus more effectively and to be more assertive in their roles as they advocate for improved practices in clinical research. Mr. Staios will include a brief guided meditation session and highlight the key principles of emotional intelligence that individuals can incorporate into their daily work and personal lives.

**Presenter:** Gregory Staios, MSc, CCRP, Manager, Research Quality & Privacy, St Michael’s Hospital, Applied Health Research Center

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

**Track:** Integrative Medicine/CAM

**Improving Quality by Using Stress Management in a GCP Environment**

Working in clinical research can be stressful for sponsors, CROs, and sites and have an impact on quality. Ms. Wintering will discuss behavioral and social factors that contribute to errors and reduce quality and performance in research settings and organizational cultures. Learn strategies to recognize stressors and how to build resilience and reduce errors.

**Presenter:** Nancy Wintering, MSW, LCSW, CCRP, Assistant Director of Research, Thomas Jefferson University

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

**Track:** Integrative Medicine/CAM

**Clinical Trials of FDA-IND Natural Bioactive Components for Bone Health**

Bone loss is a natural process of aging. Mitigating the progress of bone loss has become a major public health issue. Nutrition and bone health are closely linked. This session will review the role of dietary natural bioactive components on promotion of bone health. Dr. Shen will discuss how to study dietary natural bioactive components (green tea polyphenols and tocotrienols) for bone health through translational approaches from animal studies to clinical trials. Examples illustrating design of appropriate animal models, FDA IND application, communication between FDA and funding agency (federal and industry), and follow-up IND reports will also be provided.

**Presenter:** Chwan-Li (Leslie) Shen, PhD, CCRP, Professor of Pathology, Texas Tech University Health Sciences Center

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**Breakout Session Descriptions**
**Track 5**
Integrative Medicine / CAM

**Time:** 4:15 to 5:00  
**Track:** Monitoring  
**Acupuncture and Pain Management**
Dr. Zhang will briefly introduce the history of traditional Chinese medicine roots and current practice of acupuncture in the US. Dr. Zhang will also review the clinical research evidences of acupuncture for various pain conditions and examine the issues related to such research. At the end, Dr. Zhang will discuss relevant clinical implications of acupuncture based on the evidences.  
**Presenter:** Yan Zhang, PhD, LAc, Associate Professor, Texas Tech University Health Sciences Center

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**Track 6**
Monitoring

**Time:** 1:15 to 2:00  
**Track:** Monitoring  
**Ensuring Success Through Smarter Site Selection and Study Feasibility**
Site Selection is a complex dance between sponsors and sites. The wrong choice can have serious consequences, impacting quality, time and finances for both the sponsor and investigator. Steps for site selection and feasibility will be discussed. This session will explore best practices for both sponsors and sites during the selection process. Sponsors will learn the most critical questions to ask an investigator and staff to ensure quality and timely data as well as appropriate enrollment for the proposed clinical trial. Sites will learn how they can be proactive in the selection process and how to ensure a study is feasible by considering logistics, resources, and staffing. The whole process of site feasibility and selection will be outlined with key decision points for both sponsors and sites. Sites and sponsors will also learn what tools can help sites become “preferred” and achieve excellence in the execution of a clinical trial.  
**Presenter:** Janet Ellen Holwell, BA, CCRC, CCRA, TIACR, FACRP, Clinical Research Consultant

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**Track 7**
Device Research

**Time:** 1:15 to 2:00  
**Track:** Device Research  
**Top 5 Clinical Trends in the Medical Device Industry in 2019**
New trends in technology are transforming the medical device industry, particularly in the way data is managed during clinical trials. Advanced technology is making clinical data management easier, so regulatory agencies are raising their expectations regarding clinical studies, primarily with trial master file (TMF) management. Specifically, more regulatory focus will be on accuracy, security, integrity, and inspection readiness of all TMF components. Also, the industry is trending toward managing all clinical activities electronically, making it more critical for companies to establish the TMF as a single point of truth.  
**Presenter:** Patricia Santos-Serrao, RAC, Director, Product Strategy-Pharma and Biologics, MasterControl, Inc.
Breakout Session Descriptions

**Track 7 / Device Research**

**Managing Risks for Medical Device Clinical Trials and Their Products**
Medical device clinical trial managers must manage risks (i.e., things that could potentially go wrong) in their trials, and may also be involved in the product risk management process (as per ISO 14971, the harmonized standard for medical device in vitro diagnostic product risk management) for the device under evaluation. This session will provide an overview of a) Project Management Institute's® project risk management process and how it can be executed to achieve clinical trial objectives, b) the ISO 14971 product risk management process and how it is executed, and c) the vital roles of clinical data and the clinical trial manager for the product risk management process. 711

**Presenter:** Claudia Campbell-Matland, MS, PMP, Consultant & Managing Member, CNCM Consulting LLC

**Clinical Validation for a Medical Device Design Update**
Ms. Downing will describe the R&D efforts that were required to enhance the capabilities of the Welch Allyn Spot Vision Screener (a device that objectively screens for the 6 risk factors of amblyopia). She will also cover the clinical validation that was required to prove that the updates were effective and that the device was still accurate. 713

**Presenter:** Lindsay Downing, BS, MS, CCRP, Senior Specialist, Clinical Affairs, Welch Allyn

**Building Quality Clinical Data into Premarket Approval (PMA) Applications**
Devices that present the highest risk (Class III) to patients are generally regulated under the Premarket Approval (PMA) Program. The PMA review process is a scientific and regulatory review to evaluate the reasonable safety and effectiveness of a new Class III medical device. This evaluation is based on valid scientific evidence. It is critical that valid scientific evidence is supported with high quality data. This session will provide an introduction to the premarket program, valid scientific evidence and elements, and strategies of quality data. 715

**Presenter:** Donna, Headlee, RN, BSN, CCRP

**Track 8 / International / ICH**

**Being Prepared - The EU General Data Protection Regulation (GDPR)**
The EU GDPR has been constituted to harmonize European data protection regulations. It has an impact on any company worldwide with revenue-generating processes based on using personal data of EU citizens. The GDPR protects data of every EU citizen, no matter where in the world the data is processed and stored. GDPR protects a broad variety of types of data, including health and research related data! GDPR was officially released in April 2016. After a two-year transition phase, the date of enforcement was May 25 in 2018. Unlike most EU regulations, GDPR is in effect without undergoing ratification of the EU member states first. The presentation covers in short, what you should know about the new regulation and how and where it affects your daily business. 811

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

**International Variations in the Uptake and Governance of Genetic Research, Research on Gametes and Stem Cells and Cloning**
The past two decades have witnessed huge leaps in medical research. While genetic research is now paving the way for personalized medicine, stem cell research continues to promise life and a cure for patients with a wide spectrum of disorders such as cancer and multiple sclerosis. Cloning has opened a whole new gate for restorative medicine and, as the case has always been in history, science and research confront traditions, beliefs and societal norms. Dr. Elmorsy will focus on the international differences in dealing with new areas of medical research, utilizing examples from countries with varying cultural and religious backgrounds. Regulations governing stem cell research, cloning, and genetic research will be compared among the USA, Europe, Saudi Arabia, a country from the Far East and another from Latin America. Such information is very important when planning multinational research in the current era when new clinical research frontiers are badly needed. 813

**Presenter:** Soha Elmorsy, MD, PhD, Associate Professor, Faculty of Medicine, Cairo University

**European Union Medical Device Regulation (EU MDR) and Its Impact on Clinical Investigations**
This session will look at how implementation of the European Union Medical Device Regulation (EU MDR) will impact clinical investigations performed by manufacturers. Topics to be discussed will include: 1) What is a clinical evaluation/CER under EU MDR? 2) When are you required to update a product’s CER? 3) What constitutes the requirement for performing a clinical investigation to support a CER submission to your notified body? 4) What impact does this have on the ability to support the safety and efficacy claims for your products? 809

**Presenter:** Dona Occhipinti, MPH, CCRP, EU MDR Clinical Evaluation Lead, Welch Allyn (A Hill-Rom Company)

**Quality Control Principles and Practices to Oversee Research Projects in South America**
This presentation will address the importance of a commitment to Total Quality principles and practices as the key to successful research projects in Latin America. It provides an overview of training and general elements for running a quality control program and offers recommendations for addressing the unique challenges encountered in multisite projects. Creating a culture of quality through commitment, training, and continual improvement can enhance team performance from site selection to study closeout. Tips, tools, and best practices will be shared, along with suggestions on how to apply them in different scenarios. Ms. Wright will discuss strategies, common barriers and opportunities, and the role of the United States in partnerships for leading and monitoring investigation projects. This presentation will be based on tuberculosis trials conducted in Peru and Brazil since 2008, drawing from insights gained through training and leading clinical research personnel in multisite projects in both countries. 815

**Presenter:** Alicia Wright, MS, CCRP, Program Manager, Vanderbilt University Medical Center
**Track 1 / Poster Session**

**Time:** 8:30 to 10:05  
**Track:** Poster Session

**Poster Session Presentations**
Selected poster presenters will present a synopsis of their work related to Clinical Trials and Clinical Research Management. 117/119

**Moderator:** Joanne Goldberg, MSc, phd, CCRP, Assistant Director, CIHR Institute of Aging  
**Moderator:** Bryce Warren, PhD, Chairman, L.H. Warren Foundation for Science

**Track 1 / Risk Management**

**Time:** 10:50 to 11:35  
**Track:** Risk Management

**The State of Industry Adoption of Risk-Based Monitoring: Survey Results**
OmniComm represents the eClinical Forum in reporting survey results of diverse organizations that currently have, or plan to, adopt risk-based monitoring related to clinical research risk based planning, analytics, and data monitoring. Mr. Light will share those findings. 121  
**Presenter:** Kenneth Light, MS, BS, Executive Vice President, Corporate Strategy

**Time:** 11:40 to 12:25  
**Track:** Risk Management

**Risky Business: Successfully Using a Risk-Based Approach to Clinical Trial Management**
Ms. Wiskow will examine using the ICH E6 Good Clinical Practices (GCP) guidance as a road map to identify, evaluate, and manage critical areas of risk for your clinical trials to help you focus on activities essential to ensure human subject protection and reliability of trial results. Practical approaches will illustrate successful risk mitigation and management strategies for sponsors and sites, and common pitfalls to avoid will be discussed. Ms. Wiskow will also explore why, when and how to regularly review risks, ensuring continual improvement in the quality of your clinical trials. 123  
**Presenter:** Susan Wiskow, BS, CCRP, Senior Clinical Project Manager, Regulatory & Clinical Research Institute Inc

**Track 1 / Finance and Billing**

**Time:** 2:30 to 3:15  
**Track:** Finance and Billing

**Business Building Blocks of a Billing Process**
This session will discuss the purpose of having a good business practice in place for doing trials. Understand the elements needed and how your site can better provide the infrastructure necessary for revenue integrity. 127  
**Presenter:** Kelly Willenberg, DBA, RN, CHRC, CHC, CCRP, CEO, Kelly Willenberg LLC

**Time:** 3:45 to 4:30  
**Track:** Finance and Billing

**Leveraging Data to Drive Decisions & Maximizing the Health System Revenue Cycle**
Data is a powerful tool that can be leveraged to drive key decisions for the health system. Ms. Veazie will discuss various data elements, metrics, and key performance indicators that aid the health system with making key decisions about their research portfolio. Using denials management is one example of leveraging the data to build robust Medicare coverage analysis; thus, increasing revenue for the health system. The presentation will provide attendees with information to develop staffing models and productivity models. 131  
**Presenter:** Mary Veazie, MBA, CPA, CHC, CHRC, Executive Director, Clinical Research Finance, The University of Texas MD Anderson Cancer Center

**Breakout Session Descriptions**

**Track 2 / Responsible Conduct of Research**

**Time:** 8:30 to 9:15  
**Track:** Responsible Conduct of Research

**Lessons Learned from Case Studies in Research Misconduct**
This presentation will use case studies and lessons learned to discuss research integrity and the impact of wrongdoing on the research enterprise. Proactive interventions aimed at raising awareness, promoting a culture of integrity, and encouraging the early detection and reporting of problems will be presented. Approaches will be discussed for moving beyond a “reactive” mode of responding to misconduct to a “proactive” setting where all components of the research enterprise are engaged in, responsible for, and accountable to a community standard of integrity. 217  
**Presenter:** Donna Kessler, PhD, Research Integrity Officer, Duke University
Track 2 / Investigator Initiated Research

Time: 1:40 to 2:25  Track: Investigator Initiated Research
Investigator Initiated Trials - The Tale of Two Roles in One
Unlike industry sponsored trials focused on regulatory approval of new medications, investigator initiated trials (IITs) are developed and executed under the direction of 3rd party investigators who are physician researchers, often within an academic institution. Biopharmaceutical companies are using them as a creative and cost-effective way to innovate and further improve patient safety. Yet, these trials do come with some risks, potentially for the investigator and institutions. What is the guidance available and what are ways to ensure subject protection, data integrity, and ethical quality research? 225

Presenter: Cynthia Clark, PhD, MSN, CRNP, CCRC, Director of Research Operations Dermatology, Perelman Center for Advanced Medicine, Hospital of the University of Pennsylvania

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Time: 3:45 to 4:30  Track: Investigator-Initiated Research
Investigational Product Management: Understand Your Responsibilities as a Sponsor/Investigator to Ensure Compliance
Ms. O’Malley will review the responsibilities of the sponsor-investigator related to investigational product management, when performing investigator-initiated research. Ms. O’Malley will include a discussion of tools to manage investigational products and considerations around dose management/escalation, and the decision to utilize an investigational pharmacy. 229

Presenter: Jennifer Gaskin, BA, CCRP, CMQ-OE, Director, Karyopharm

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Time: 4:35 to 5:20  Track: Investigator-Initiated Research
Meeting with Regulatory Authorities
Early, proactive, and productive communication with regulatory agencies can benefit many areas of investigator-initiated research. Many times, sponsor-investigators may have questions about IND or IDE related investigations that require a more detailed review or discussion than the information found in procedural guidance. Ms. Talley will review what types of mechanisms are available to request a meeting with specific centers or offices at the FDA and the purposes of each, how this relates to different types of IITs or investigator-driven technology development, and the benefit of doing so. The following meeting and communication types will be discussed: administrative, product-related (CDER, CBER, CDRH), safety/product inquiries. 231

Presenter: Christina Talley, MS, RAC, CCRP, CCRC, Director, Regulatory Affairs & Translational Management, Houston Methodist Research Institute
### Breakout Session Descriptions

#### Track 3: Advanced Management

<table>
<thead>
<tr>
<th>Time</th>
<th>Track</th>
<th>Session Title</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>8:30 to 9:15</td>
<td>Advanced</td>
<td>Retention Rates of Clinical Research Associates – A Global Perspective</td>
<td>Mike Brunet, PhD, ATC, CHRISTUS Regional Director of Research, CHRISTUS Health</td>
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<tr>
<td>9:20 to 10:05</td>
<td>Advanced</td>
<td>How To Motivate and Retain Your Clinical Research Staff</td>
<td>Ramon Adams, BA, CCRP, Clinical Research Associate, University Hospitals Cleveland Medical Center</td>
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<td>10:50 to 11:35</td>
<td>Advanced</td>
<td>The Benefits of a Cooperative and Functional Interdepartmental Relationship at Your Site</td>
<td>Takisha Adair, MBA, CCRP, Clinical Operations Manager, Covance</td>
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<tr>
<td>11:40 to 12:25</td>
<td>Advanced</td>
<td>The Leadership Mindset</td>
<td>Samuel Jones, President, Innovative Learning Society</td>
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<tr>
<td>1:40 to 2:25</td>
<td>Advanced</td>
<td>Using Simulation for Research</td>
<td>Muhammad Waseem, MD, MS, CCRP, CIP, CHSE-A, Research Director/Professor Emergency Medicine, Lincoln Medical Center</td>
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<tr>
<td>2:30 to 3:15</td>
<td>Advanced</td>
<td>Expanded Access Drug: From Bench to Bedside</td>
<td>Sara Ingersoll, MS, CCRP, Regulatory/Data Coordinator, St. Barnabas Medical Center</td>
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#### Track 3: Compliance/Noncompliance

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<tr>
<td>3:45 to 4:30</td>
<td>Compliance</td>
<td>Beyond the Matrix - A Quantitative Approach to Compliance Program Management</td>
<td>Kevin Smith, MS, MBA, CCRP, Research Administrator, Cleveland Clinic</td>
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<td>4:35 to 5:20</td>
<td>Compliance</td>
<td>The FDA Is Here - Now What</td>
<td>Sylvia Johnson, BS, MS, MBA, President/CEO, JI-Solutions LLC</td>
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<tr>
<td>5:35 to 6:20</td>
<td>Compliance</td>
<td>The Importance of Quality Management in Behavioral Research</td>
<td>Jessica Rowe, MA, MS, CCRP, Research Quality Improvement Manager, University of Maryland, Baltimore</td>
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#### Track 4: Quality Management

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<tr>
<td>8:30 to 9:15</td>
<td>Quality</td>
<td>The Importance of Quality Management in Behavioral Research</td>
<td>Jessica Rowe, MA, MS, CCRP, Research Quality Improvement Manager, University of Maryland, Baltimore</td>
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**Additional Information:**
- **Universities and Hospitals:** University Hospitals Cleveland Medical Center, St. Barnabas Medical Center, Cleveland Clinic, Lincoln Medical Center, University of Maryland, Baltimore
**Track 4 / Quality Management**

**Time: 9:20 to 10:05**  
Track: Quality Management

*Creating a Comprehensive Quality Assurance Program for Human Subject Research*

This session will evaluate investigator/site performance, IRB performance, and address complaints and concerns from the research community. Managing reports of investigator and IRB performance will also be discussed. 419

**Presenter:** Jessy Thomas, DMFT, MS, Assistant Director, Quality Assurance, University of Minnesota

**Time: 10:50 to 11:35**  
Track: Quality Management

*Deviations, CAPA, and Root Cause Analysis*

Developing an effective system to track deviations, implement CAPAs, and identify root causes will be presented. 421

**Presenter:** Monika Schmuck, BSc, Quality Assurance Coordinator, University Health Network

**Time: 11:40 to 12:25**  
Track: Quality Management

*How to Create a Culture of Quality at a Research Site*

Sites are so busy nowadays that quality assurance is often overlooked and is only a focus when issues arise or when there is an audit. Creating a culture of quality using an integrative approach in a team environment will be discussed. Easy to implement techniques include quality assurance checks, office guidelines, checklists, and lessons learned. Challenges of implementing a quality management system and how to overcome any setbacks will be explored. 423

**Presenter:** Sergey Nikitin, MBA, BSc, President and Director, Prime Site Research Solutions, Inc.

**Presenter:** Jessica Pinder, BSc, CCRP, PMP, Research Coordinator, Prime Site Research Solutions

**Track 4 / Pediatric Research**

**Time: 1:40 to 2:25**  
Track: Pediatric Research

*Developing a Pediatric Clinical Research Center – Lessons Learned at the University of Minnesota*

In 2018 the University of Minnesota Department of Pediatrics began an effort to open an outpatient research center for pediatric research visits. Key stakeholders included not only researchers and research staff, but also hospital administration, clinic operations, university research leadership, and the medical school dean’s office. In 2019 much work continues to be done to ensure the PedCRC is successful. In this talk Ms. Galster will share with you the steps taken in planning, parties involved, challenges faced, structure developed, and what the team would have done differently. 425

**Presenter:** Amanda Galster, MPH, CCRP, Clinical Research Program Director, University of Minnesota

**Time: 2:30 to 3:15**  
Track: Pediatric Research

*The Community Basis of Optimal Pediatric Recruitment*

Ms. Allen will present an overview of recruitment in pediatric trials. Recruitment is a challenging endeavor, and this seminar will help attendees best utilize their system to aid in useful recruitment. This talk will stimulate discussion around helpful community-based recruitment tactics. 427

**Presenter:** Janelle Allen, BS, MS, CCRP, Director, Clinical Research Operations, Quality & Education, Institute for Advanced Clinical Trials for Children

**Track 5 / Enrollment/Retention and Informed Consent**

**Time: 3:45 to 5:20**  
Track: Pediatric Research

*Transforming the Informed Consent Process into a Quality Experience: Innovative Strategies to Adapt your Communication Style*

CRAs are called upon to discuss clinical trials in a variety of situations, ranging from crisis interventions to long term clinical trials. Each discussion must be tailored to the potential enrollees, families, or legally authorized representatives in order to present fair, balanced information for an informed consent. This session will highlight the impact of verbal cues, body language, situational context and small group dynamics within the context of role play during illustrative case scenarios. A group debriefing will conclude the session. 429/431

**Presenter:** Margaret McCormick, MS, RN, CNE, Clinical Associate Professor, Towson University

**Presenter:** Mary Catalaletto, MD, MMM, Professor of Clinical Pediatrics, NYU Winthrop Hospital

**Time: 8:30 to 9:15**  
Track: Pediatric Research

*Building a Referral Partner Network – Developing Partnerships with Primary Care Physicians, Specialists and Other Medical Professionals to Support Enrollment into your Clinical Trial Program*

Clinical trial centers often reach out to primary care providers, specialists, and other medical professionals to provide information about open and enrolling clinical trials in the hope they will receive potential participant referrals. Ms. Jackson-Pope will review how to create successful referral partner relationships and provide tips for building engagement opportunities that will ensure success in the referral process. Examples of how referral networks have been built to support a clinical trial site will be discussed. 517

**Presenter:** Lenore Jackson-Pope, ADN, BSN, MSM, RN, CCRP, Co-Director of Primary Care Outreach at the Center for Alzheimer Research and Treatment (CART), Brigham and Women’s Hospital

**Time: 9:20 to 10:05**  
Track: Enrollment/Retention and Informed Consent

*Knowing Your Study Subjects on Day One: Artificial Intelligence (AI) with Clinical Trials*

Anyone involved in clinical research today understands that clinical trial recruitment is expensive, making up to one-third of the total cost of trial costs. Clinical recruitment is also slow, expensive and inefficient. With 86% suffering delays (11 months on average), and 50% of trial sites failing, in any other industry this would be unacceptable. AI is a game-changer when evaluating clinical trial feasibility. Mr. Brusselaers will provide case study examples illustrating how applying AI to medical records can pinpoint eligible patients for clinical trials in minutes not months, and will explore the effectiveness of analytics versus AI. Mr. Brusselaers will also show how combining different techniques drastically speeds up subject identification and augments patient recruitment. 519

**Presenter:** Wout Brusselaers, MA, CEO, Deep 6 AI
Breakout Session Descriptions

Track 5 / Enrollment/Retention and Informed Consent

**Time: 10:50 to 11:35**
Track: Enrollment/Retention and Informed Consent
**We Are the Champions: Using a Systems Approach to Research Recruiting**
Ms. Holtz will present systems level approaches to facilitate recruitment and enrollment of participants in an innovative clinical demonstration project for long-stay nursing home residents in 40 Indianapolis nursing facilities. Ms. Holtz will describe the strategies for a systems approach to recruiting at the nursing facility level, including navigating the IRB, and educating non-research staff to describe the program to potential subjects. The talk will discuss recruiting activities, communicating patient eligibility, using an opt-out informed consent approach, and managing rolling enrollment. Ms. Holtz will share experiences illustrating successes and challenges in enrollment, retention, data collection, tracking deviations, and how the knowledge will be used in future projects, including National Institutes of Health pragmatic trial grants. 521
**Presenter:** Laura Holtz, MS, CCRP, Senior Research Manager, IU Center for Aging Research, Regenstrief Institute

**Time: 11:40 to 12:25**
Track: Enrollment/Retention and Informed Consent
**Rethinking Recruitment**
The Recruitment Enhancement Core model deploys novel recruitment and retention strategies for direct study recruitment while actively engaging the public and the research community to change the way research participation is viewed. This talk will provide an overview of the structure of an REC and the best practices that dramatically improve recruitment and retention. 523
**Presenter:** Christopher Gantz, MBA, Senior Director, Research Liaison Office, TJU Sidney Kimmel Cancer Center

**Time: 1:40 to 2:25**
Track: Enrollment/Retention and Informed Consent
**How to Leverage Social & Digital Media to Recruit Patients for Clinical Trials**
Eighty percent of clinical trials in the United States are delayed by at least one month due to enrollment delays [Tolve A 2017]. Ms. Hernandez will discuss how social media marketing can accelerate clinical trial enrollment and ultimately help bring medicine to patients earlier. 525
**Presenter:** Heather Hernandez, BA, Director, Seeker Health

**Time: 2:30 to 3:15**
Track: Enrollment/Retention and Informed Consent
**The Social Media Blueprint: Top 3 Tips for the New Patient Advocacy and Recruitment**
Social media has been a new highly innovative and disruptive technology to many industries, but most importantly clinical trials. Mr. Shields will discuss how social media breaks down the latest techniques for patient recruitment, retention, and advocacy across new and old platforms including Snapchat, Instagram and Facebook. 527
**Presenter:** Justin Shields, Director of Site Relations, StudyKIK

Track 5 / Project Management

**Time: 3:45 to 4:30**
Track: Project Management
Define the meaning of the word ‘project’ as per PMI. Review the 10 knowledge areas and 5 processes of PMI Project Management. Illustrate and discuss the interactions of the processes and how they work together to provide best practices/guidelines for managing individual projects. 529
**Presenter:** Barbara Kosky, MASc, CCRP, PMP, Clinical Trials Project Management Consultant

**Time: 4:35 to 5:20**
Track: Project Management
**Implementing Integrated Project Management Framework: Lessons Learned from Ebola Rapid Response Efforts in West Africa**
At a large clinical research organization, project management approaches can vary greatly across many functional groups. Functional project and program management approaches under fragmented organizational structures can result in many different solutions to similar problems, each with its own pros and cons. While these functional group-specific PM approaches are often a key priority within each function to maintain excellent clinical research support services, program-wide planning, operational, and administrative support can stagnate significantly. However, integrating the most effective project management approaches from all involved at the functional and program level can have an immediate impact. The LBR/CMRP project team will share its experience and lessons learned from key customers while implementing and expanding the best integrated project management framework in support of a dozen Ebola clinical trials initiated by NIAID’s Division of Clinical Research Program during and after the outbreak Ebola virus disease in West Africa in 2014. 531
**Presenter:** Jiwan Giri, MSPM, MSIS, PMP, Clinical Project Manager II, Leidos Biomedical Research, Inc.
**Presenter:** Sara Albert, MPH, Clinical Project Manager II, Leidos Biomedical Research, Inc.
Saturday, September 28, 2019

**Track 6 / Training**

**Leadership and Line Management in Clinical Research**

Why's and what's of line management through leadership will be discussed using real life examples to show how it can support clinical research and you.

**Presenter:** Anatoly Gorkun, MD, PhD, Chartered MCIPD, Senior Manager, Global Clinical Development, PPD UK

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

**Track 6 / Training**

**Workforce Resource Management: Managing Onboarding and Training for Key Functional Area Roles**

In today's fast-paced clinical research industry with heightened expectations of quality and qualified staff, effective on-boarding (beyond company orientation) requires a systematic review and analysis of key functional roles to strategically align and allocate resources for the development of efficient on-boarding practices across the enterprise. Management of resources to effectively meet competing clinical research activities necessitates a quality systems approach. Creating a process of continuous improvement to actively engage and positively impact the organization requires realignment, re-deployment and restructuring. This session reviews methods and analysis practices for deployment of on-boarding and training to include realignment when necessary, based upon organizational needs.

**Presenter:** Erika Stevens, MA, BA, Principal, Recherche Transformation Rapide

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

**Track 6 / Training**

**From Clinical Trials Poster to Peer-Reviewed Publication**

This session is designed to teach poster presenters how to convert their poster content into a manuscript suitable for submission to a peer-reviewed journal. It is particularly suited for those presenting in the clinical trials track who are inexperienced at composing articles for publication. Dr. Selfe will cover choosing an appropriate journal, structuring the manuscript according to International Committee of Medical Journal Editors (ICMJE) recommendations (i.e., introduction, methods, results, and discussion), finding and using the applicable reporting standard (e.g., CONSORT for randomized controlled trials) as a blueprint to make composing a manuscript with the appropriate content a clear-cut task and attainable goal.

**Presenter:** Terry Selfe, PhD, DC, CCRP, Translational Research & Impact Librarian, University of Florida HSC

**Time:** 10:10 to 10:55

**Track 6 / Training**

**Optimizing Personal Communication in the Clinical Research Arena: Passive, Aggressive, Assertive, Which Are We and When?**

Collaborative communication with colleagues of all levels is a critical professional skill as the clinical research enterprise expands. This presentation will provide an overview of the aggressive, passive, and assertive communication styles, including characteristics, impact on professional progression, and how it looks in a professional environment as well as an inventory tool that allows the participant to adjust their communication style to support their professional goals.

**Presenter:** Barbara van der Schalie, MS, Clinical Training Manager, Leidos Biomedical Research Inc

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

**Track 6 / Training**

**Research Investment and Staff Enrichment (RISE)**

A core objective of RISE is to “develop a highly trained, innovative, and skilled workforce” and “legitimize” research staff as a valued and career-worthy pathway. Currently there is no defined advancement strategy, and one’s advancement through existing career pathways is often restricted because of reasons unrelated to merit or knowledge, skills, and abilities. RISE is a formal mentorship platform to help individuals identify personal strengths and work toward career goals. The result will be a diverse network of knowledgeable and skilled staff dedicated to producing high-quality research. Anticipated benefits are 1) job satisfaction and retention among research staff by providing career advancement guidance and professional development opportunities, 2) demonstrated value of contributions and professional development of research staff, and 3) legitimize research staff careers.

**Presenter:** Gloria Harrington, MBA, LMSW, CCRP, Research Operations Manager, University of Michigan

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

**Track 6 / Training**

**Career Progression in Clinical Research: Transitioning from a CRC to a sponsor CRA**

Mr. Boothby will focus on the direct experiences of the what, how, and when to make the transition from CRC to a sponsor CRA. With over 15 years of clinical research experience as both a CRC and a CRA, Mr. Boothby will provide individuals attending this presentation with a checklist that will act as a roadmap to help make this a smooth transition.

**Presenter:** Thomas Boothby, MSc, CCRP, Clinical Research Associate II, Boston Scientific

**Time:** 12:25 to 1:10
### Track 6 / Training

**Time**: 8:30 to 9:15  
**Track**: Training  
**How Do You Ensure Clinical Trial Quality in Investigator-Initiated Studies? Training for Research Professionals in Monitoring Concepts!**  
Establishing and maintaining a rigorous quality management system in clinical trials helps to protect human subjects and ensures data collected is accurate and valid. Monitoring, an essential and routine quality function in industry-sponsored trials, is often lacking in investigator-initiated trials conducted in academia. We find that only approximately 65% of investigator-initiated trials are monitored when we poll research professionals locally and nationally. Findings from literature and web-based searches revealed that although numerous GCP training resources are available, most require fees or institutional affiliations. Moreover, many lack the practical approaches to meet the complex requirements of monitoring. To address this gap, the University of Southern California is developing a series of self-study modules that will be readily accessible by all research professionals to be used to establish a pool of research coordinators who can cross-monitor and cross-audit studies they do not coordinate. Ms. Spinrad will share her approach, experience, and findings in an interactive session. 631  
**Presenter**: Amelia Spinrad, Regulatory Knowledge Support Administrator, University of Southern California

**Time**: 9:20 to 10:05  
**Track**: Device Research  
**Integrating Clinical Research Data Collected Through Divergent Software Applications**  
The use of electronic health record data in clinical investigations presents new challenges for source verification. This talk will discuss the challenges and review the FDA guidance documents surrounding the use of electronic health record data and electronic source data. 719  
**Presenter**: D. Maria Rhoades, MSN, CCRP, RN, Clinical Project Manager, AtriCure, Inc.

**Time**: 10:50 to 11:35  
**Track**: Device Research  
**Medical Device Studies: How to Consent and More from a Monitor and Study Coordinator Perspective**  
The monitor and the site research coordinator are a team. Fully take advantage of your monitor’s knowledge on how to make your site have a smooth study execution which will help minimize your work and your stress level. When the monitor is happy, the PI and site team will be happy with a clean monitor report and future studies will come your way as a result. Ms. Diehl will review study etiquette, most common problem areas, how to overcome challenging study situations, and you will get inside intel of what the sponsor is focusing on during visits. 721  
**Presenter**: Julie Diehl, BSc, CCRP, CMA, Senior Clinical Research Monitor, Medtronic

### Track 7 / Device Research

**Time**: 11:40 to 12:25  
**Track**: Device Research  
**How Do You Ensure Clinical Trial Quality in Investigator-Initiated Studies? Training for Research Professionals in Monitoring Concepts!**  
Establishing and maintaining a rigorous quality management system in clinical trials helps to protect human subjects and ensures data collected is accurate and valid. Monitoring, an essential and routine quality function in industry-sponsored trials, is often lacking in investigator-initiated trials conducted in academia. We find that only approximately 65% of investigator-initiated trials are monitored when we poll research professionals locally and nationally. Findings from literature and web-based searches revealed that although numerous GCP training resources are available, most require fees or institutional affiliations. Moreover, many lack the practical approaches to meet the complex requirements of monitoring. To address this gap, the University of Southern California is developing a series of self-study modules that will be readily accessible by all research professionals to be used to establish a pool of research coordinators who can cross-monitor and cross-audit studies they do not coordinate. Ms. Spinrad will share her approach, experience, and findings in an interactive session. 631  
**Presenter**: Amelia Spinrad, Regulatory Knowledge Support Administrator, University of Southern California

**Time**: 1:40 to 2:25  
**Track**: Emergency Research  
**Somebody Call 911! The Challenges of Emergency Medicine Research**  
An overview of the typical challenges faced in emergency medicine research will be provided, as well as examples of studies that have posed unique hurdles and how those hurdles were jumped (or fumbled) over. 725  
**Presenter**: Natalie Bidaj, BSN, RNCC, ENPC, MOAB, Assistant Director of EMRAP, University of Vermont Medical Center

**Time**: 2:30 to 3:15  
**Track**: Emergency Research  
**Ways of Knowing**  
Dr. Blohm will present an introduction to clinical epistemology. This presentation will cover the differences between belief, knowledge, and truth as it pertains to emergency medicine research. 727  
**Presenter**: Eike Blohm, MD, Emergency Medicine Physician, The University of Vermont Medical Center

**Time**: 3:45 to 4:30  
**Track**: Data Management / EDC / 21 CFR 11  
**Where Did My Data Go and Who Does it Concern, Anyway? Using Results from Pharmaceutical Clinical Research Trials Beyond the NDA**  
Ms. Elsaid will demonstrate how pharmaceutical organizations use results obtained from Phase I – III clinical trials other than for the purposes of obtaining NDA and product monograph publishing. Several industry-initiated, medical and commercial programs will be reviewed. The examples of such programs will include medical education programs, advisory board meetings, medical ambassador programs, speaker tours, detail aids, patient focus groups, and educational initiatives. Furthermore, Ms. Elsaid will discuss how the pharmaceutical industry interacts with healthcare workers, key opinion leaders (KOLs) and patients. Clinical research professionals who attend the presentation will also be able to learn and understand how their expertise can be used beyond clinical operations. 729  
**Presenter**: Sonja Elsaid, MSc, CCRP, Medical Affairs Consultant, MaRS

**Time**: 4:35 to 5:20  
**Track**: Data Management / EDC / 21 CFR 11  
**Succeeding with CTMS**  
Integrating clinical research data collected through divergent software applications can be a challenge. Knowing how and when to use clinical trial management software/systems (CTMS) and how to integrate data from other e-clinical systems can help ensure successful trial execution. This presentation will highlight what you can expect from a modern CTMS including successful integration ideas and techniques. 731  
**Presenter**: Jan Nielsen, BS, PMP, Senior Project Manager & Community Manager CTMS, BSI Business Systems Integration AG
Negotiating a CTA is often a challenging task for CTA negotiators. This presentation will identify and describe key mistakes commonly made when drafting and negotiating CTAs. Topics covered will include CTAs with foreign sponsors, CTAs with CROs, privacy, indemnification, insurance and limitation of liability. For attendees not involved in CTA negotiations this presentation may still be of value, especially for study personnel who want to know if the CTA properly protects their interests.

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

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Health Canada has recently released GUIDE-0100 to help researchers conducting clinical drug trials to be compliant with regulations and guidelines, specifically Part C, Division 5 of the Food and Drug Regulations and ICH E6(R2). This talk will give an overview of the new GUIDE-0100. Methods to integrate Part C, Division 5 and ICH E6(R2) into practice to ensure compliance will be discussed.

**Presenter:** Velma Marzinotto, BScN, RN, CCRP, Senior Research Compliance & Education Specialist, St. Michael’s Hospital

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Investigational Drug Services (IDS) is a specialized area of pharmacy practice that requires adherence to standard best practices and regulations governing both the pharmacy profession and clinical trial conduct. This talk will provide an overview of the practical challenges and solutions in applying Division 5 requirements to everyday practice of an IDS pharmacy, covering topics that include drug labeling and preparation for audits/inspections.

**Presenter:** Jeffrey Doi, HonBSc, BScPharm, RPh, BCPS, Clinical Trials Pharmacist, Princess Margaret Cancer Centre, UHN

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Ms. Kasina will present an overview of Health Canada’s Clinical Trial Compliance Program, including compliance trends, program updates, transparency, Canada’s implementation of ICH E6 (R2) and GUI-0100.

**Presenter:** Alcia Kasina, PhC, MSc, Senior Regulatory Advisor, Clinical Trial and Biological Product Compliance

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Health Canada’s Clinical Trial Compliance Program

Ms. Kasina will present an overview of Health Canada’s Clinical Trial Compliance Program, including compliance trends, program updates, transparency, Canada’s implementation of ICH E6 (R2) and GUI-0100.

**Presenter:** Alcia Kasina, PhC, MSc, Senior Regulatory Advisor, Clinical Trial and Biological Product Compliance

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Conducting cross-border/international clinical trials increases the complexity of an already complex task exponentially. Key differences in areas such as clinical, regulatory, ethical, and operational, must all be clearly identified as early as possible. Ensuring that these (and more) issues are addressed appropriately across all sites helps secure the rigor of your trial data while simultaneously ensuring participant safety.

**Presenter:** Amr Sharaf, HBSc, CCRP, Clinical Site Monitor, Bristol-Myers Squibb

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Faculty will give brief historical background on the founding principles and scandals that led to the current HHS Federal Regulations and give an overview of the regulations that protect research participants.

**Presenter:** Elyse Summers, JD, President and CEO, AAHRPP

**Presenter:** Michelle Feige, MSW, LCSW-C, Executive Vice President, AAHRPP

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Ms. Souliere will discuss how the IRB functions and what CRCs and regulatory personnel can do to create better applications and anticipate what the IRB is going to look at.

**Presenter:** Rebecca Souliere, BA, CCRP, Team Lead Certified Clinical Research Coordinator, Mayo Clinic

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SAVE THE DATE

2020 Annual Conference
Las Vegas NV
September 25 - 27
Applying the Principles of the Science of Safety to Improve Subject Safety in Clinical Research: Actionable Practices to Identify and Minimize Risk

Dr. Kessler will use case studies to illustrate and describe 1) selected practices in the management of investigational drugs and the consent process that are potentially unsafe and increase the risk to subjects, 2) enhanced reporting strategies to identify potential risks, and 3) enhanced ways to learn from deviations/mistakes that occur.

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

The Evolution of Vulnerability – The Ethics of Equitable Subject Selection

In April of 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published the Belmont Report. The Report summarized ethical principles and guidelines for research involving human subjects. Three core principles were identified: respect for persons, beneficence, and justice. While all three principles consider the rights of the research subjects, the justice principle focused primarily on subject selection. The spirit of the justice principle describes the protection of subjects vulnerable to unethical research. However, vulnerability in 1979 is markedly different from vulnerability today. This talk will chronicle the history of vulnerability in human subjects research and compare and contrast how this vulnerability is now manifested in today’s research environment.

Presenter: Quincy Byrdsong, EdD, CCRP, CIP, Executive Director for Research Administration, WellStar Research Institute

Including Vulnerable Subjects with Cognitive Impairment in Research

This talk will review the new common rule definition of vulnerable subjects including “individuals with impaired decision making ability.” It will discuss why inclusion of this vulnerable population is needed in research studies, especially for diseases such as Alzheimer’s research. Finally, it will review the ethical guidelines and discuss practical strategies for obtaining informed consent for subjects who may lack decision making capacity.

Presenter: Laura Holtz, MS, CCRP, Senior Research Manager, IU Center for Aging Research, Regenstrief Institute

Sharing De-Identified Data

Ms. Balch will discuss Count Me In, a nonprofit that allows researchers to work directly with patients and advocacy groups, along with software engineers and computational scientists, to collect, analyze, and share de-identified data in order to transform cancer care.

Presenter: Sara Balch, BS, Project Manager, Count Me In and the Broad Institute of MIT and Harvard

The Reality of Enrollment Expectations

Louis Lasagna was the founder of the Tufts Center for the Study of Drug Development at Tufts University where he became Dean of the Sackler School of Graduate Biomedical Sciences. Lasagna’s Law states “The incidence of patient availability sharply decreases when a clinical trial begins and returns to its original level as soon as the trial is completed.” Why is this true? Can it ever be changed? If not, why not?

Presenter: Harvey Arbit, PharmD, MBA, CCRP, RAC, President, Arbit Consulting, LLC

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2019 ANNUAL CONFERENCE NIGHT OUT

SAN ANTONIO

FRIDAY, SEPTEMBER 27TH | 6:00 TO 9:00 PM

Join us for a night out on the world famous San Antonio Riverwalk! Enjoy a narrated river cruise to a group dinner with fellow conference attendees.

Please note, this event requires separate registration. Availability is limited. See www.socra.org/annualconference for details