Ethics, Regulations and Study Implementation for Research Involving Human Subjects: An Advance face-to-face Course

JUNE 2020

Course Descriptions

Presenter: **Sarah Vittone**

Research Ethics and Informed Consent- Challenges: While informed consent is one of the most basic applications of human subject protection, enhancing their autonomy and agency in research can be complex. Our obligations to beneficence and justice in this application is sometimes challenged. We will use case studies to examine challenges in informed consent including language barriers, religious influence, false expectations, patient perceptions and vulnerable populations. We will consider implications for emergency vaccine research, equitable compensation and issues around research errors.

Presenters: Shannon Gopaul &Yejide Obisesan

Contract Management: Contract negotiation and management are essential to the implementation and successful execution of clinical research. This presentation will highlight the steps for effective management during the grant lifecycle using a case study, tools, and processes at Howard University as a backdrop. Research staff will gain a clearer understanding of the benefit of stakeholder engagement, budget development, and fiscal management in overall management of clinical research.

- Kickoff Meeting; Shadow budgets; and Case Study (Dr. Sanses)

Presenter: **Candice Vance**

Billing Compliance: This course will provide an overview of the research billing requirements and the process for ensuring compliance. In order to comply with federal, state and institutional regulations and standards for clinical trial billing, research sites are responsible for establishing effective processes to ensure that all services for a study are billed properly. These processes can be complex because clinical trials often involve multiple entities that are responsible for costs incurred during the course of a trial. During a single visit a research participant may receive routine medical care in addition to services or procedures conducted purely for research purposes.

Presenter: **Petros Okubagzi**
Mobile Technology: Mobile technologies offer the potential to increase the quality and efficiency of clinical trials—from reducing barriers to participation and improving the participant experience, to capturing more informative real-world data and lowering costs associated with conducting clinical trials. This use of mobile technology to collect data, in addition to traditional efficacy data, can lead to improved assessment of response to treatment and thereby support more efficient development of new therapies for patients.

Presenters: **Emily Paku & Allison Moses**
Study Recruitment Support (re-GHUCCTS core): GHUCCTs and the MedStar Health Research Institute Recruitment Center collaborate to provide a variety of recruitment support services. "The Lunch and Learn" session presentation will cover the recruitment support tools available to study teams, including outreach, advertising options, and technology-based programs to identify and enroll research subjects.

Presenter: **Florence Gonzalez**
Integrating/Inclusion of Diverse Populations in clinical trials: The importance of including diverse populations in clinical and translational research is widely accepted and it is critical for better understanding diseases and condition-related in diverse groups of individuals. Despite multiple national level efforts in the past two decades, individuals from diverse racial and ethnic groups, persons with disabilities, and those aged 65 years or older remain under-represented in clinical and translational research. This presentation will highlight approaches for research team members to consider in their efforts to increase recruitment of diverse groups into health research

Presenter: **Amy Loveland**
Risk-Based Monitoring: With the costs of clinical trials skyrocketing, sponsors and sites are looking for more effective and efficient ways to ensure a study is being conducted according to protocol and regulatory requirements. Risk-based monitoring has been identified as one approach that can reduce errors, lower cost, and lead to cleaner data. This course will describe the different types of risk-based monitoring strategies a sponsor may employ, as well as tips for coordinators to ensure success with a risk-based monitoring model.

Presenter: **Mary Anne Hinkson**
Source Documentation: Source Documentation lies at the heart of clinical research workflows for investigative sites. Documentation could be thought of as creating a story of patient activity over the duration of the protocol. Research staff should look at their documentation and ask if it will make sense four years from now when someone inspects the records. This course will be a mix of didactic, active and collaborative learning activities regarding the leading practices with implementing the regulatory requirements for source documents.

Presenter: **Mary Anne Hinkson**
Hot Topics: Clinical Trials: "Conducting Research during COVID-19 Outbreak"