Clinical Research Coordinators' Workshop: Study Implementation, Documentation, and Regulations

March 21, 2024

Time: 8:30am – 1:00pm EST
Location: Washington DC Veterans Affairs Medical Center: Clinical Research Center (Building 14)

AGENDA

TIME	TOPIC
8:30am – 9:00am	Breakfast
9:00am – 9:30am **Speaker: Priscilla Adler, MBA**	Introduction • GHUCCTS Overview • Regulations and Where to Find Them • Study Process Overview
9:30am – 10:15am **Speaker: Florencia Gonzalez, MPH**	Important Considerations for Inclusion & Consenting of People with Limited English Proficiency
10:15am – 11:00am **Speaker**: **Kathleen Johnson, NP**	How Can I Obtain Consent for Cognitively Impaired Participants? *Fluctuating Capacity; LAR Qualifications; State Requirements*
11:00am – 11:45am **Speaker: Mary Anne Hinkson, MBA**	Regulatory Binders / Trial Masterfile – What Do I Need to Keep?
11:45am – 12:30pm **Speaker: Neha Mookuparambil, PharmD**	Audit Findings: Avoiding Pitfalls in Source Documentation
12:30pm – 1:00pm	Lunch / Networking Session

Link to Uninsured/Underinsured Medical Resources:
https://docs.google.com/document/d/1tfgaUSmMNw7DoGkJCyn1Stm152_K1XJF/edit?usp=sharing&ouid=115540425773666826278&rtpof=true&sd=true

Other Resources:

Otado, J., Kwagyan, J., Edwards, D., Ukaegbu, A., Rockcliffe, F. and Osafo, N. (2015), **Culturally Competent Strategies for Recruitment and Retention of African American Populations into Clinical Trials**. Clinical And Translational Science, 8: 460-466. https://doi.org/10.1111/cts.12285

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