



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

March 21, 2025

Time: 8:30am – 3:00pm EST

Location: Washington DC Veterans Affairs Medical Center: Clinical Research Center (Building 14)

AGENDA

TIME	TOPIC
8:30am – 9:00am	Breakfast / Networking Session
9:00am – 9:40am Speaker: Priscilla Adler, MBA	• Introduction / GHUCCTS Overview • Regulations and Where to Find Them • Updates on Regulatory Issues
9:40am – 10:30am Speaker: Priscilla Adler, MBA	Informed Consent Process • Updated FDA Guidance • Common Rule and FDA Requirements
10:30am – 10:45am	Break
10:45am – 11:15am Speaker: Heidi Maloni, PhD	Telehealth Technology
11:15am – 11:45am Speaker: Hiwot Guebre-Xabiher, BS	De-Centralized Clinical Trials
11:45am – 1:00pm	Lunch / Networking Session
1:00pm – 1:45pm Speaker: Mary Anne Hinkson, MBA	• Remote Monitoring and Pitfalls to Avoid • Source Documentation
1:45pm – 2:00pm	Break
2:00pm – 2:45pm	Jeopardy Session
2:45pm – 3:00pm	Evaluation and End of Workshop

Additional References/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>
- Adler P, Otado J, and Kwagyan J. (2020) **Satisfaction and perceptions of research participants in clinical and translational studies: An urban multi institution with CTSA**. Journal of Clinical and Translational Science 4: 317–322. <https://doi.org/10.1017/cts.2020.20>

Link to Uninsured/Underinsured Medical Resources:

https://docs.google.com/document/d/1tfgaUSmMNw7DoGkJCyn1Stm152_K1XJF/edit?usp=sharing&ouid=115540425773666826278&rtpof=true&sd=true

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