

COORDINATING CENTERS AND CRMS

Jessica Wakefield
Coordinating Center Manager

crocc@jhmi.edu

443-287-9377

What is a Coordinating Center?

- Coordinating Centers provide administration, coordination and organizational support in the conduct of a multi-center trial.
- Functions as the central location for multi-center trial documents and patient registrations.
- Monitor the conduct and progress of a clinical trial at participating sites.

Ways CRMS can help run a Multi-Center Trial

- Sites can upload approval letters, ICF's and other regulatory documents to be stored indefinitely.
- Eligibility checklists can be built and eligibility can be confirmed.
- Patient source documents can be stored in the patient specific file allowing a paperless system.
- Remote auditing and monitoring can be performed in 1 location.
- Regulatory documents can be emailed to all study personnel from within CRMS alleviating the need for separate emails and tracking can be performed within the system.

How can external sites receive access?

- External study teams can receive access to CRMS
 - Study teams are provided with a temporary JHED ID which expires every 6 months (this can be renewed with no lapse in access)
 - Study teams then are trained in CRMS by utilizing my learning
 - Site Access is granted to only the study that the team is working on.

What is “Site Access”

- Site access means:
 - The study team will only see tabs that they need (General, Study Team, Sites and Enrollment).
 - The study team will only see the patient information from their site
 - This access allows the system to be a Secure database
- Coordinating Centers then can train staff on the specific study within CRMS

Patient Randomization

- Eligibility checklists can be built in CRMS allowing sites to complete the checklist without printing and these checklists are stored with the patients files.
- In the future we hope to have randomization request forms built into CRMS allowing external sites to fill them out and a notification will be sent to the Coordinating Center.

Patient Data

- Built in Case Report Forms
- Sites have the ability to upload source documents directly into the patients file
- Coordinating Centers can remotely monitor data