
Clinical Research Enterprise (CRE)

Standard Operating Procedures

CRE Study Coordinator Team Meetings

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Date



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Revision History:	Version	Effective Date	Description

Purpose

The purpose of this SOP is to outline how CRE study coordinator teams are to operate and how inter-team meetings are to be conducted

References

- N/A

Scope

This SOP applies to all members of the CRE staff who are part of a CRE study coordinator team.

Allowable Exceptions

There are no allowable exceptions to this SOP.

I. Team Hierarchy and Composition

- a. A team is made up of a single Team Lead, either a Research Nurse Coordinator III or Clinical Research Coordinator III, and assigned CRNCs and CRCs

II. Responsibilities of Team Leads and team members

- a. The Team Lead is responsible for scheduling meetings and its associated correspondence as well as reserving space for in-person meetings
- b. The Team Lead is responsible for proactively assessing study enrollment, identifying logistical concerns and addressing barriers across all trials within their team
- c. All team members are required to attend all meetings unless prior written arrangement is made with Team Lead

- d. All team members are responsible for completing assigned tasks given at meeting, or in person if member was unable to attend the meeting, within given designated time frame
- e. A designated team member must take meeting minutes using template. These minutes must be distributed to all team members and to Sue Ellen within 3 business days. CRE Team Meeting Agenda and Meeting Minutes Form is saved in the General Channel in the CRE Study Coordinators Microsoft Teams group.
- f. The Team Lead is responsible for knowing when and how to escalate study coordinator issues to the leadership team
- g. Team members who miss a meeting must arrange a debrief with the Team Lead within 2-3 business days. Outstanding tasks remain due at that time.

III. Timelines

- a. Team Leads must send out proposed meeting at least one week before the intended meeting. Team members must confirm their availability at least 48 hours before the scheduled time.
- b. Any tasks given during meetings will have a clear deadline for study coordinators, individualized per coordinator if needed
- c. Each team must hold one in-person meeting and one Zoom meeting per month, scheduled approximately two weeks apart (i.e. in-person on 1st, zoom on 14th)
- d. Each meeting should last at least 30 minutes but no longer than 1 hour unless prior arrangement made with all team members

IV. Agenda

- a. CRE Team Meeting Agenda and Meeting Minutes Form will be completed at every team meeting
- b. Team leader will relay any correspondence from the CRE managers and the DOM leadership to the team
- c. Review CREEL and make any necessary updates
- d. Review all upcoming sponsor visits through to next meeting and assess if assistance is needed
- e. Review any challenging studies and/or complicated areas with team members and assess if assistance is needed
- f. Review of study specific topics that require escalation to CRE leadership, including but not limited to:
 - i. Lower than anticipated enrollment
 - ii. Logistic/coverage issues with a trial
 - iii. Compliance concerns
- g. Conduct individual check-ins (i.e. highs and lows of the week, celebrations, personal distractions, study related questions)
- h. Include helpful information sharing, such as learning opportunities, team building, leadership events
- i. Pending tasks/action items from last meeting

- j. Review upcoming team member time off and ensure it is reflected on the shared calendar
- k. Review items discussed at staff meetings and all pertinent updates
- l. Any additional concerns not specified above

V. Goals

- a. All team members actively participate and engage in meetings
- b. Ensure all team members feel adequately supported
- c. Create an environment where team members feel safe voicing concerns openly, without fear of judgment or retaliation
- d. Ensure team leaders foster a supportive, professional, and inclusive environment
- e. All needed information shared