Clinical Research Enterprise (CRE)

Standard Operating Procedures

Responsibilities/Duties of the Research Team

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Approval:

Approved By		**Date**
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Revision History:

Version	Effective Date	Description
1.1	2.19.2020	Changes made to reflect additional staff
1.2	5.26.2021	Changes made to reflect additional staff
1.3	9.1.2022	Changes made to reflect additional staff
1.4	1.20.2024	Changes made to reflect additional documentation

Purpose

The purpose of this SOP is to provide a description of the CRE team member roles and responsibilities. The research program is organized to conduct multiple clinical trials. Each protocol is treated individually and requires varying degrees of involvement from team members.

References

- CRE Roles and Responsibilities Documents

Scope

This SOP applies to all member of the CRE staff.

Allowable Exceptions

This SOP is meant to be followed without deviation.

I. Roles and Responsibilities

a. Director of Clinical Research: Assess the ongoing needs of the CRE and collaborators; Lead and implement strategic planning for the CRE; Resource and primary contact for CRE; Develop CRE leadership team; Oversee CRE processes and projects

b. Research Nurse Manager (Coordination): Manage all study coordinator team members and activities; Resource and primary contact for coordination issues in the CRE; Manage CRE support team members and activities; Lead coordinator/enrollment portions of required meetings

   i. Clinical Research Coordinator and Research Nurse Coordinator I: Manage the "life cycle" of a study; Accurately record all study activities in source chart, EMR, OnCore, and EDC; Accurately account for all stipends in a study; Know when to escalate items to PI and/or CRE Leadership; Attend regular meetings with PI; Complete all CRE record keeping

      See Study Coordinator Roles and Responsibilities Document for further details

   ii. Clinical Research Coordinator and Research Nurse Coordinator II: In addition to items listed under CRC/RNC I; Participate in study feasibility process; Provide guidance on study activities; Appropriately engage ancillary support teams; Schedule and conduct SIV independently; Understand ancillary team requirements and complete independently; Identify potential barriers to success in a project and proactively engage leadership or address

      See Study Coordinator Roles and Responsibilities Document for further details

   iii. Clinical Research Coordinator and Research Nurse Coordinator III: In addition to items listed under CRC/RNC I and II; Act as team leads and provide support to team members; Independently manage all aspects of the project; Complete feasibility review on all protocols assigned to your team; Review monitor letters for major concerns/findings and report to Research Nurse Manager

      See Study Coordinator Roles and Responsibilities Document for further details

c. Research Nurse Manager (Contracts/Finances): Management of contracts, financials, and special project team members and activities; Oversee CRE and study financials; Resource and primary contact for contracts/finances; Lead contracting and financial portions of required meetings; Negotiate study budgets

   i. Business Officer II: Request effort reports and reclass all staff effort; Oversee utilization of FBS, including invoicing and reconciliation, Manage CRE Finance and CRE Invoice inboxes; Prepare monthly CRE fiscal analysis reports

      See Contracts/Finances Roles and Responsibilities Document for further details

   ii. Clinical Trials Administrator II: Oversee accounts payable including internal bill pay and participant stipend payment; Primary contact for Greenphire/ClinCard items; Place and reconcile P-Card purchases; Enter and manage clinical trials in OnCore Financials; Perform upgrades and maintenance on CRE dashboards

      See Contracts/Finances Roles and Responsibilities Document for further details

   iii. Program Manager I: Oversee CH20 clinic; Primary contact for facilities items in CH19 and CH20; Liaison with other clinics and ancillary areas; Support other financial processes

      See Contracts/Finances Roles and Responsibilities Document for further details

   iv. Research Nurse Coordinator III (Education/Special Projects): Onboarding of new clinical staff, including residents and fellows as required; Instruct BLS and organize CEU courses for CRE; Oversee Pre-Site Selection process including CDA's and feasibility assessment; Submit contracts and amendments to OSP and track appropriately

      See Contracts/Finances Roles and Responsibilities Document for further details

d. Manager of Clinical Research Regulations: Management of regulatory team members and activities; Resource and primary contact for regulatory items; Track all regulatory processes and effort; Lead regulatory portions of required meetings; Manage regulatory documents, including long term storage

    i. Clinical Research Regulatory Coordinator I: Maintain ISF documentation for projects; Prepare industry sponsored submissions to IRB; Submit continuing review approvals and amendments to IRB; Route training and DOA logs to appropriate staff; Submit amended RPLs to OSP; Prepare for and attend monitoring visits; Ensure appropriate tracking and document upload in all systems

        See Regulatory Roles and Responsibilities Document for further details

    ii. Clinical Research Regulatory Coordinator II: In addition to items listed under CRRC I; Assist with initial drafts of ICF and information sheets on IITs; Populate ePortfolio for IIT; Schedule and perform audits on clinical trials; Prepare CAPAs when required; Escalate and present major audit findings

        See Regulatory Roles and Responsibilities Document for further details

    iii. Clinical Research Regulatory Coordinator III: In addition to items listed under CRRC I and II; Assist with implementing and evaluation of quality assurance processes; Resource for CRRC I and II; Oversee QA compliance with study protocols and ensure accordance with GCP

        See Regulatory Roles and Responsibilities Document for further details

e. Research Nurse Manager (Grants Management): Manage grants management team members and activities; Manage DOM grants inbox; Resource and primary contact for grants management and post-award federal, foundational, and non-profit projects; Oversee post-award finances on federal, foundational, and non-profit projects; Lead grants management portions of required meetings

    i. Grant Administrator I; II; and III (Education/Special Projects): Provide support to faculty with grant submissions; Complete/Update Biosketch and Other Support Documents; Manage JIT and Annual Progress Reports for faculty; Serve as liaison between OSP and faculty

        See Grants Administrator Roles and Responsibilities Document for further details

f. Principal Investigator: Ultimately responsible for the conduct of the study. Bears final responsibility for the safety and welfare of study participants and the integrity of study findings.

g. Sub-Investigator: Performs study-related medical duties under the supervision of the principal investigator. Listed on the FDA 1572.

h. Supporting Physician: Used when services of various specialties (radiologist, surgeon) are needed to perform essential assessments and functions required by the protocol. Not listed on the FDA 1572. Does not sign CRFs or administer study drugs.

i. Pharmacist: Responsible for the storing and dispensing of study drug. Knows the protocol and ensures proper storage conditions and adequate security accordingly. Only authorized persons have access to study drugs. Maintains forms necessary for drug accountability. Drafts a study specific prescription for use during the study.

II. Study Back-Up

a. CRE policy is that a primary coordinator is assigned to each study. At least one back up coordinator are assigned to each study. When the primary coordinator is not available or is in need of additional assistance, the backup coordinator can assist.

b. Research Nurse Manager: Assigns at least two coordinators to each trial to form a coordinator team. Listed on the delegation log as a backup coordinator. Completes eCRF training for trials.

c. Coordinator Team: At least two coordinators on the team will work to understand each other's studies well enough to give assistance concerning study procedures in the absence of the primary study coordinator. When possible within the constraints of patient schedules and protocol requirements, team members will see each other's patients.

    i. If the primary coordinator has a planned absence, all patient visits that can be rescheduled, within the constraints of the patient's schedule and the protocol requirements, should be rescheduled for when the primary coordinator returns.

    ii. If the backup coordinator needs to see patients in the primary coordinator's absence, the primary coordinator is responsible for making sure the patient visits are covered and the covering personnel have enough knowledge about the study to carry out the visits.