# Clinical Research Enterprise (CRE)

Standard Operating Procedures

Relocating Research Staff and Offices, Process for accounting for and moving Research study data, Research patient files, and Regulatory Files

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| ***Version:*** | 1.0 | |
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| ***Approval:*** | **Approved By** Patrick Frazier<br>Patrick Frazier (Jan 30, 2023 11:33 CST) | **Date** 01/30/2023 |

| ***Revision History:*** | **Version** | **Effective Date** | **Description** |
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## Purpose

The purpose of this SOP is to explain the process for packing and relocating patient data and research files in the event that research staff or the entire research office has a change in physical location.

## References

- none

## Scope

This SOP applies to all member of the CRE staff involved with handling or moving patient data, regulatory information, and research files including but not limited to- Study Coordinators, Regulatory Affairs, Administrative staff, and student assistants.

## Allowable Exceptions

This SOP is meant to be followed without deviation. If a deviation from this SOP occurs, a description of this event will be written and presented to the CRE Manager for further inquiry, process improvement measures, and disciplinary actions if warranted.

## I. Roles and Responsibilities during personnel or office change of location

a. Nurse Research Manager: The manager will oversee the moving process as a whole coordinating moving activities. Will be the primary point of contact for any issues that may arise during this process.

b. Clinical Research Regulations Manager: The manager will oversee the moving process for regulatory records and information only. Will be the primary point of contact for any issues that may arise during this process with these documents

during this process. Will confer with the nurse research manager to correct any issues that may arise.

c. Clinical Research Coordinators (I, II, & III's) & Clinical Research Nurse Coordinators I, II, & III's): The primary coordinator for each research study is responsible for the accounting of and verification of patient related research documents in the event of a move or relocation. The Primary Coordinator is also responsible for notification of Sponsor/CRA at least 1 week prior to planned move. All study documents must be reconciled and accounted for prior to relocation using a log or spreadsheet. These documents must then be packed securely and taken directly from their current location to the new research office or coordinator location. Upon arrival, primary coordinator will again reconcile all patient related research documents utilizing the prior mentioned log or spreadsheet to verify that all documents have been accounted for and received at new location. If a discrepancy is noted the primary coordinator must notify the Research Nurse Manager as soon as possible and no more than 24hr upon awareness so that actions can be taken to rectify the situation and recover any misplaced research patient data. Primary research coordinator may delegate the physical movement of documents to other ancillary staff but must complete the reconciliation prior to and after the physical move. This action cannot be delegated unless the primary coordinator is out of the office for an unexpected absence in which case the backup coordinator for the study will take over the responsibility of the primary coordinator. Planned vacation or PTO does not constitute an unexpected absence and unless otherwise approved by the manager the primary coordinator must be onsite the day of the move to perform designated assigned tasks.

d. Regulatory Personnel: The primary regulatory person for each research study is responsible for the accounting of and verification of regulatory related research documents in the event of a move or relocation. The primary regulatory person is responsible for notifying applicable sponsor at least 1 week prior to schedule move. All documents must be reconciled and accounted for prior to relocation using a log or spreadsheet. These documents must then be packed securely and taken directly from their current location to the new research location. Upon arrival the primary regulatory person will again reconcile all patient related research documents utilizing the prior mentioned log or spreadsheet to verify that all documents have been accounted for and received at new location. If a discrepancy is noted the primary regulatory person must notify the Clinical Research Regulations Manager as soon as possible and no more than 24 hrs after awareness so that actions can be taken immediately to rectify the situation and recover any misplaced regulatory research data. The primary regulatory person may delegate the physical movement of documents to other ancillary staff but must complete the reconciliation prior to and after the physical move. This action cannot be delegated unless the primary coordinator is out of the office for an unexpected absence in which case the backup coordinator for the study will take over the responsibility of the primary coordinator. Planned vacation or PTO

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