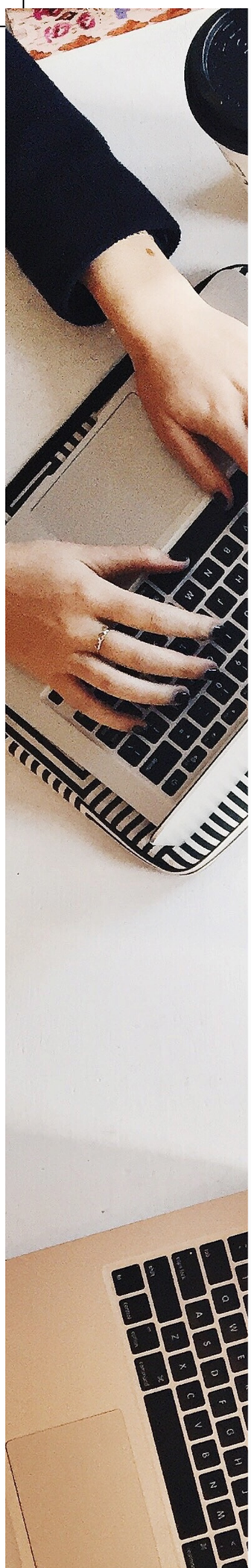
CRE

Clinical Research Enterprise

Research Monitor Informational Packet



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MONITOR WELCOME LETTER

Dear Research Monitor:

Thank you for allowing us to participate in this research endeavor with you and your sponsoring company. Please let us know if there is any way we can assist you during your visit to the Department of Medicine Clinical Research Enterprise (CRE) at the University of Alabama at Birmingham (UAB).

This packet is to assist you in orienting to the CRE. We hope you will take the time to review this material and take the opportunity to clarify any issues or questions you have with the study coordinator assigned to your study.

Sincerely,

Patrick Frazier, MBA, BSN, RN Director of Clinical Research
Department of Medicine Clinical Research Enterprise
UAB University of Alabama at Birmingham
CH20 357 930 20th St. S. Birmingham, AL 35205
thomasfrazier@uabmc.edu

CLINICAL RESEARCH ENTERPRISE (CRE)

The Department of Medicine at the University of Alabama at Birmingham established the Clinical Research Enterprise in August of 2018. The creation of the CRE has allowed us to reorganize staff and provide a new infrastructure to streamline our research processes in the division. We have investigators from numerous divisions and departments around campus including Endocrinology, Gastroenterology/Hepatology, Hematology/Oncology, Rheumatology/Immunology, Cardiology, CV Surgery, Family Medicine, Urology, ENT, Oral Surgery, COVID-19, Emergency Medicine, Radiation-Oncology, Physical Medicine and Rehab, and Orthopaedics who are involved with the CRE at every level of the clinical trials process.

The Department of Medicine and the CRE support the research mission of the University of Alabama at Birmingham by facilitating research funding, helping research teams and investigators manage funded projects, and through ongoing collaboration and communication keeping all research staff current on university, state, federal, and funding-agency specific research policies and procedures. The goal of the department and the CRE is to increase UAB's participation in novel and groundbreaking research.

CLINICAL TRIALS

The CRE provides research support (in varying capacities) to the Department of Medicine as well other Departments ad specialties within the Heersink School of Medicine. There are over 500 trials in a variety of phases and over 100 investigators currently active in the CRE.

STAFF

The CRE has a staff of more than 50 full time research personnel and is overseen by the Department of Medicine (DOM) Vice Chair for Research. The structure of the CRE consists of one Director, three Research Nurse Managers, one Manager of Clinical Research Regulations, numerous Research Coordinators and Research Nurse Coordinators, Regulatory Coordinators, Research Data Coordinators, and student assistants with 100% of their time dedicated to clinical trials.

The CRE research staff are fully trained to perform research procedures and collect data as mandated by study protocol and Federal, State, and Local regulations and guidelines. Many of the Coordinators have 5 years or more of research experience.

SERVICES OFFERED

STUDY START UP

The Clinical Research Enterprise's Benchmark is to have all studies with completed Site Initiation Visit's (SIV) within 90- 120 days from receipt of full regulatory and contract/budget sponsor packets.

CONTRACT, BUDGET & IRB

We utilize WIRB, Adverra, as well as a local IRB and all study start up activities run concurrently.

SCOPE OF SERVICES

Phase I, IIa Studies

- **First Time in Human Safety/Tolerance**
- **Pharmacokinetics (PK)**
- **Pharmacodynamics (PD)**
- **PK/PD Correlations**
- **Pharmacogenetics**

Phase IIb-IV

- **Clinical Safety and Efficacy**
- **Dose Ranging and Dose Definition**
- **Labeling and Claims Support**
- **Post Marketing Surveillance**

Ancillary Services

- **Protocol Preparation**
- **Study Design**
- **Source Document Form Design**
- **Database design**
- **IRB Preparation and Submission**
- **Budget Analysis and Negotiation**
- **Study Coordinator Effort**

Category B devices

Clinical Research Enterprise (CRE)
Standard Operating Procedures
Monitor Visits (On Site or Remote)

SOP #: 3.04

Version: 7.0

Author(s): Patrick Frazier, Felice Cook, Jane E. S. Vines, Ronald Prevatt

Approval:

Approved By		Date
	Electronically signed by: Thomas Patrick Frazier Reason: I am the approver. Date: Apr 26, 2025 14:29 CDT	04/26/2025
	Electronically signed by: Felice Cook Reason: signature needed on regulatory documents Date: Apr 26, 2025 15:04 CDT	04/26/2025

Revision History:

Version	Effective Date	Description
7.0	04/26/2025	

Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the required processes for monitoring clinical research studies to ensure compliance with sponsor, Contract Research Organization (CRO), and Clinical Research Enterprise (CRE) requirements. This SOP is designed to support the accuracy, integrity, and timely resolution of data queries and any other findings identified during monitoring visits. It is intended to align with applicable U.S. Food and Drug Administration (FDA) regulations and Good Clinical Practice (GCP) guidelines.

Scope

This SOP applies to the following: all CRE staff, Sponsors/CROs.

Allowable Exceptions

On a case to case basis with prior approval from CRE Executive Leadership.

I. Scheduling

a. **Monitor Informational Packet**
New monitors must be provided with the Monitor Informational Packet prior to any remote or onsite monitoring visit. This packet is designed to assist the monitor in preparing for and conducting their visit. The Study Coordinator is responsible for sending the packet once the primary monitor for the study has been identified.

b. **Monitoring Visit Timing and Coordination**
Monitoring visits must be scheduled in advance and conducted on regular business days between 8:30 AM and 4:00 PM CST. The Study Coordinator and the monitor share responsibility for coordinating these visits. If the monitor requests meetings with the Principal Investigator (PI), pharmacy, or other

departments, the Study Coordinator must coordinate and confirm those appointments prior to the visit.

c. Scheduling Process and EMR Access
Monitoring visits are scheduled using the **Fillable Monitor Request Form**. Once submitted, the Regulatory Coordinator (Ronald Prevatt) will send a calendar invitation to all regulatory personnel and the Study Coordinator, with key details included in the subject line. If EMR access is required, Ronald will initiate the access request process. The Study Coordinator will be cc'd on all related correspondence to ensure timely follow-up on all tasks and monitor-related needs. **Form Link:** Fillable Monitor Request Form
Monitoring visits should be requested a **minimum of four (4) weeks in advance** for **new monitors** and **at least three (3) weeks in advance** for **established monitors**.

d. **Work Space and Access**
If applicable, a designated work location will be provided for the monitor with access to appropriate research staff. The Study Coordinator is responsible for securing this space, reserving it, and notifying the regulatory team of the location.

e. **IMV Letter Requirement**
It is expected that monitors will submit the IMV (Interim Monitoring Visit) letter to the Study Coordinator **no later than two (2) weeks prior** to the scheduled visit, to ensure sufficient preparation time.

f. **EMR Access Verification**
Monitors must submit a screenshot showing successful access to **CERNER/IMPACT** at least **one (1) week prior** to the visit. It is the monitor's responsibility to install all the required software and confirm access independently. Failure to do so will result in the visit being canceled and rescheduled.

g. **Follow-up for EMR Access**
If the Study Coordinator has not received the required screenshot one week prior to the visit, they must contact the monitor to confirm access setup (e.g., username, password, token, etc.). If the monitor does not respond within **two (2) business days**, the visit will be canceled and rescheduled.
Please note: **Over-the-shoulder EMR viewing is not permitted**. In addition, **printing or certifying source documents available in the EMR will not be accommodated.**

II. Day(s) of Monitor Visit

a. Study Coordinator Support
During the monitoring visit, the Study Coordinator will ensure that all relevant study documentation is available for review. The Study Coordinator will be present in the morning to welcome the monitor, assist with room setup, and provide general guidance on navigating the EMR system if required. Note that

this support does not include technical troubleshooting or extended IT assistance. Monitors are encouraged to refer to their training materials for EMR navigation as needed.

b. **Communication During Visit**
The Study Coordinator will establish the preferred method of communication for the duration of the visit and coordinate how queries and follow-ups will be addressed throughout the day.

c. **Exit Interview and Oversight**
If requested, the Research Nurse Manager will review monitoring findings. The Study Coordinator will ensure that an adequate time is reserved at the end of the visit for an exit interview with the monitor if needed. The exit interview will be conducted after all CRFs, and regulatory documents have been reviewed by the monitor.

d. **Building Access**
Monitors are restricted to their assigned monitoring room and the restrooms. Access to any other areas of the research facility requires accompaniment by a staff member.

e. **Additional Access Charges**
A monitoring visit fee will be assessed to the sponsor/CRO for any non-routine visit that includes access to the e-regulatory binder outside of standard monitoring visit scope.

III. Regulatory documents

a. **Issue Resolution**
The Clinical Research Regulatory Coordinator is responsible for addressing any regulatory deficiencies identified during the monitoring visit.

b. **Preparation and Access**
The Regulatory Coordinator will prepare the regulatory binders and place them in the monitor room either the day before or the morning of the visit. For studies utilizing the Florence e-regulatory system, the Regulatory Coordinator will confirm the monitor's access to the platform prior to the visit. The Regulatory Coordinator will also meet with the monitor during the visit to review any concerns and work to resolve them before the monitor departs.
Monitors are not permitted to remove any original regulatory or study-related documents from the research offices.

IV. Participant documents

a. **Issue Management**
The Study Coordinator is responsible for resolving monitoring findings related to the clinical conduct of the study. Any major deviations or significant findings must be promptly communicated to and reviewed with the Research Nurse Manager.

b. **Document Preparation**
The Study Coordinator must ensure that participant source documents and CRFs are complete, current, and accessible. Prior to the visit, the Study Coordinator will organize and place all requested participant documents in the monitor room for review.

V. Conclusion

a. **Post-Visit Summary**
Upon completion of the visit and the exit interview, the monitor is expected to provide a written summary of all findings—both clinical and regulatory—within two (2) weeks. This summary must be sent to the Study Coordinator, Regulatory Coordinator, and Principal Investigator.

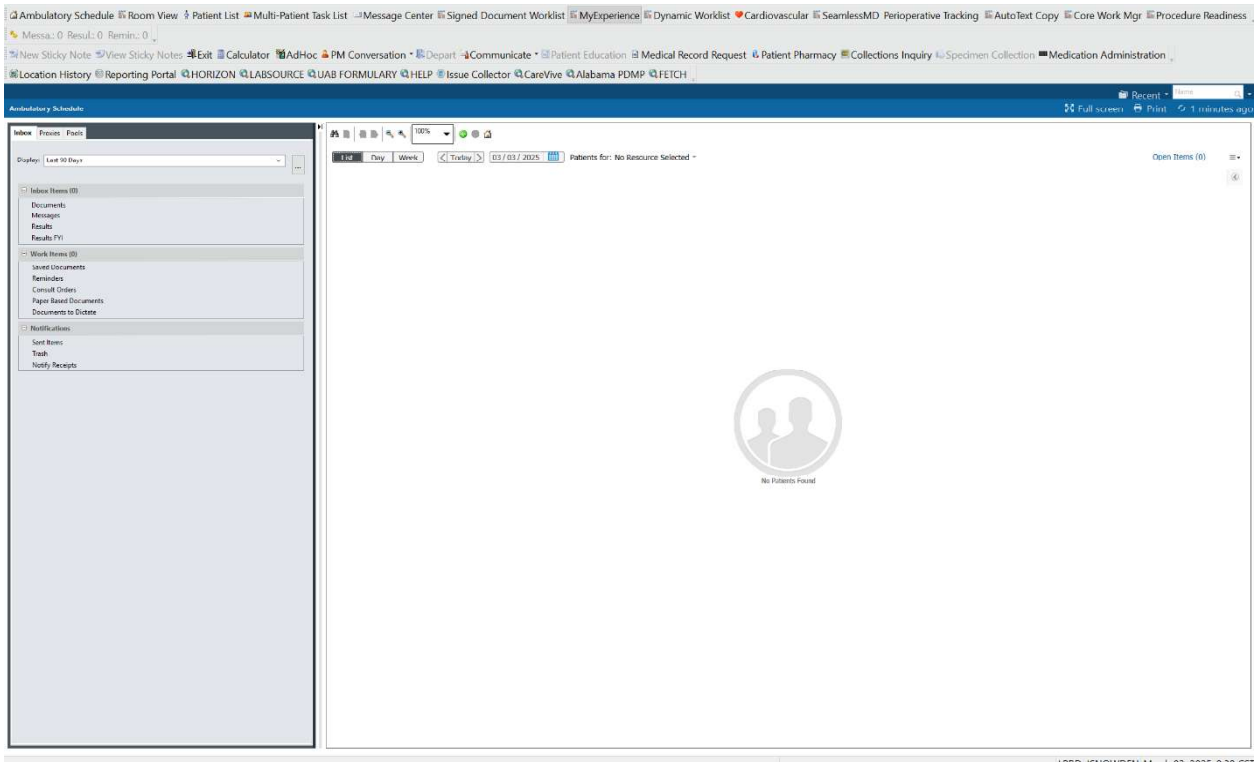
b. **Document Return**
Following the visit, the Regulatory Coordinator will return all regulatory documents to their appropriate location, and the Study Coordinator will do the same for participant and study documentation.

c. **Room Clean-Up**
The Study Coordinator and Regulatory Coordinator are responsible for ensuring that the monitoring room is cleaned and restored to its original condition after use.

d. **Distribution of Follow-Up Communication**
Once the monitoring follow-up letter is received, the Study Coordinator will forward it to their Lead Coordinator and copy the Regulatory Coordinator, Regulatory Manager, and Nurse Manager.

e. **PI Review and Documentation**
The monitor's follow-up letter must be reviewed and signed by the Principal Investigator (PI), either in person or electronically (e.g., Adobe Sign), depending on the sponsor's requirements. The Regulatory Coordinator will file the signed letter and submit any necessary corrective actions to the IRB as applicable.

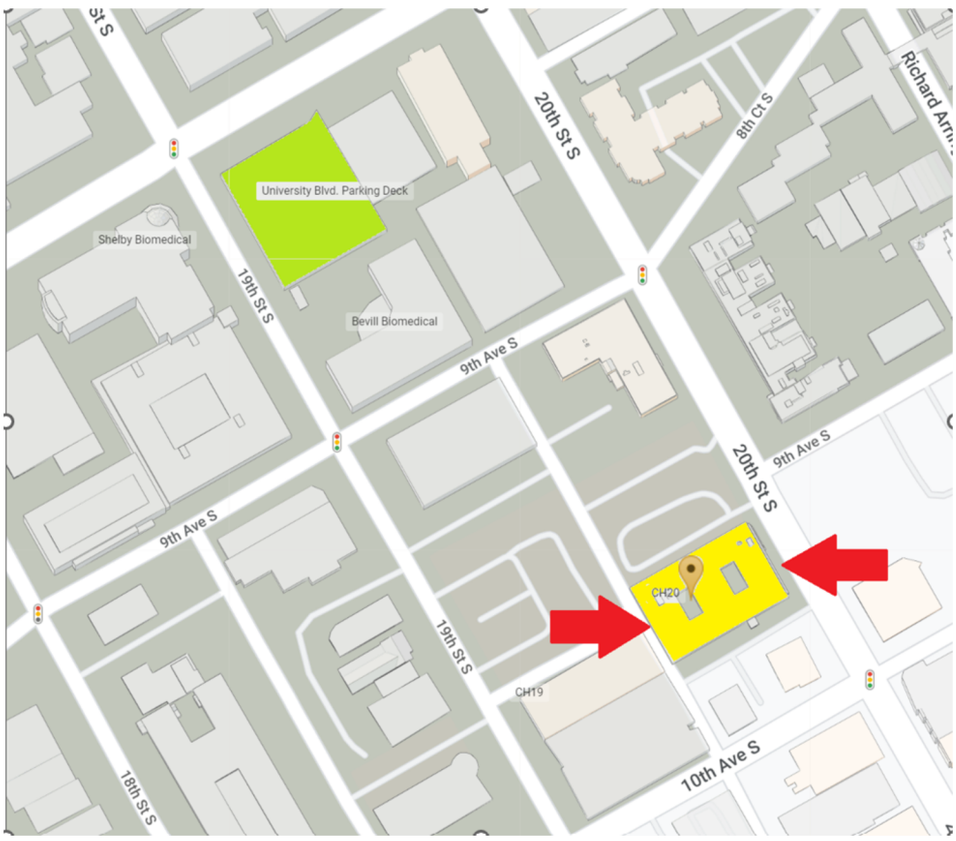
VI. Screenshot Example



PARKING

Parking:
If you are driving to the site, you will park in the University Boulevard Parking Deck at:
1915 University Blvd,
Birmingham, AL 35294

Please see map below with the deck highlighted in lime green being where you will park. Once you have parked in the deck, you will walk up 19th or 20th St. S. and find the Community Health Building. 930 20th St. S, Birmingham, AL, 35205. Once you arrive you will need to call your CRE contact and let them know you are here. They will meet you at either entrance marked by the red arrows to take you to your designated area.



Rideshare:
If you are using rideshare, you will have them drop you off at our office:
20th St. Community Health Services (CH20)
930 20th St. S.
Birmingham, AL 35205

You will need to be dropped off at either of the entrances marked with a red arrow in the map above. Once you arrive you will need to call your CRE contact and let them know you are here. This is a secure building so you will need to wait outside until they come down to get you. Please do not follow anyone into the building.

OUR TEAM

Directors

Cynthia Irwin Joiner, PhD, MPH, RN
Vice Chair Research Operations & Development |Associate Professor
Assistant Dean Clinical Research Operations
Executive Director Clinical Research Enterprise
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Managers

Sarah Houston, MBA, RN, CCRP
Research Nurse Manager
Clinical Research Enterprise
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Role: finance, study start-up, special teams

Susan Ellen Binkley, MS, RN
Clinical Research Nurse Manager
Clinical Research Enterprise
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Role: research coordinator and research assistant oversight, daily clinical operations

Felice Y. Cook, BA
Manager- Clinical Research Regulations
Clinical Research Enterprise
Department of Medicine
fycook@uabmc.edu
Role: regulatory coordinator oversight, daily regulatory operations

Leigh Powell, MSN, RN, CCRC
Manager-Clinical Research Nursing
Clinical Research Enterprise
Department of Medicine
lcpowell@uabmc.edu
Role: grants and pre-awards personnel oversight, daily grants and pre-awards operations

YOUR STAY IN — BIRMINGHAM

Nearby Hotels and Accommodations:

The Hilton, Residence Inn, Hotel Indigo, and Homewood Suites are all within walking distance from the site as they are just one to two blocks away. With good parking options at each locations these hotels are recommended if you are driving or plan to fly in and use a ride share or taxi to get to the site.

The Hilton
808 20th Street South
Birmingham, AL 35233
Tel (205) 933-9000

Residence Inn Marriott
821 20th Street South
Birmingham, AL 35205
Tel (205) 731-9595

Hotel Indigo
1023 20th St. S.
Birmingham, AL 35205
Tel (205) 933-9555

Homewood Suites
1016 20th St. S.
Birmingham, AL 35205
(205) 703- 9920

YOUR STAY IN — BIRMINGHAM

Nearby Dining Optins and Local Attractions:

We sincerely hope you enjoy your stay in the Birmingham area. Below are some of our staff's favorite local spots for food and entertainment!

Saw's Soul Kitchen
sawsbbq.com
215 41st St. S.

University Taco
http://universitytacos.com
2009 University Blvd

The Falafel Cafe
falafelcafe.net
401 19th St. S.

T-Bones
tboneschеesesteaks.com
1017 20th Street South

Hattie B's Hot Chicken
hattieb.com
2808 7th Avenue South

Fish Market
http://thefishmarket.net/
612 22nd Street

Filter Coffee Parlor
https://www.filtercoffeeparlor.com/
1927 11th Ave S.

Bandido Coffee Parlor
1024 20th St. S. Suite #103

Birmingham Museum of Art
http://www.artsbma.org
2000 Rev. Abraham Woods, Jr. Blvd

Vulcan Park
http://www.visitvulcan.com
1701 Valley View Drive

Railroad Park
http://www.railroadpark.org/
1600 1st Avenue South

Civil Rights Institute
http://www.bcri.org/index.html
520 16th Street North

Alabama Sports Hall of Fame
http://ashof.org/
2150 Richard Arrington Jr. Blvd. N.

Botanical Gardens
http://www.bbgardens.org/
2612 Lane Park Road

Birmingham Zoo
http://www.birminghamzoo.com
2630 Cahaba Road