FAU

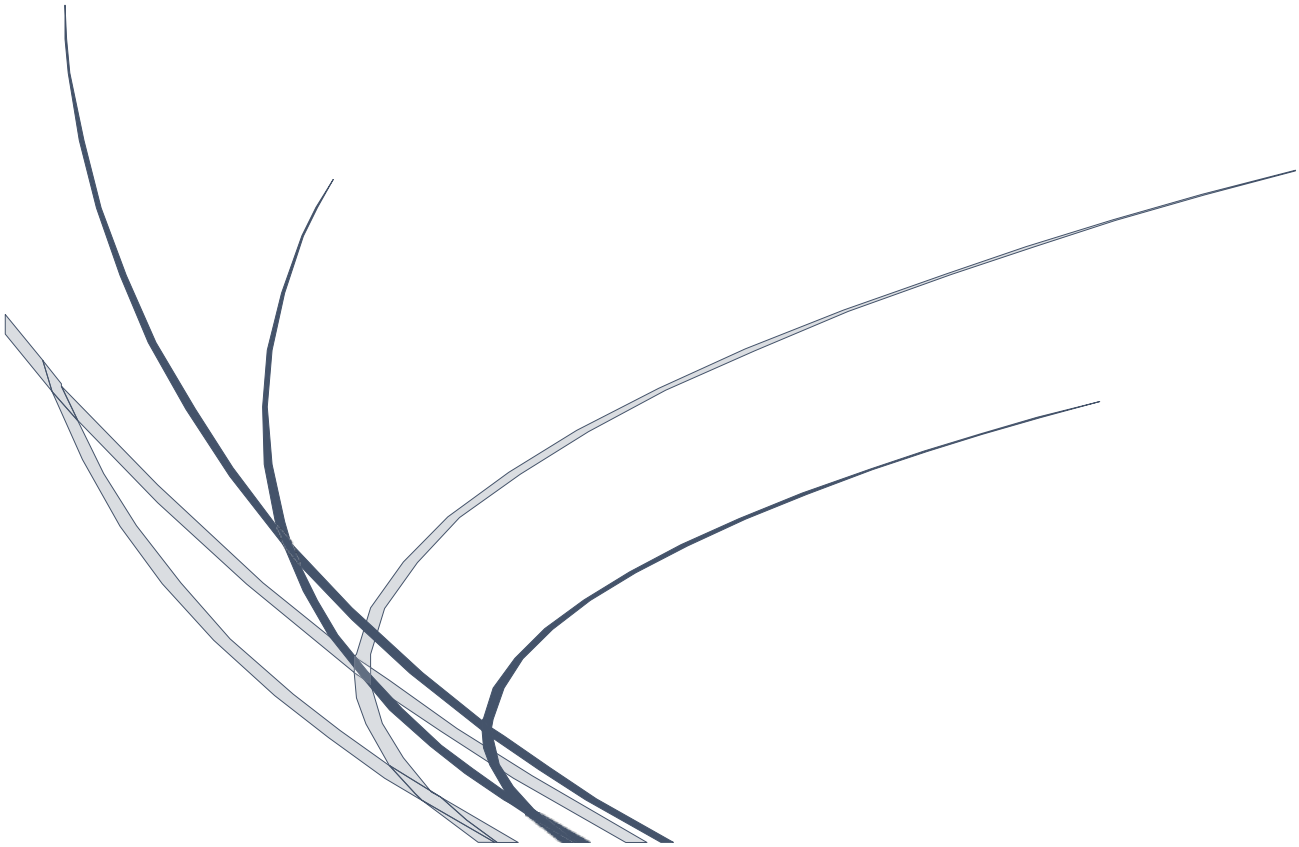
CLINICAL RESEARCH UNIT

Division of Research

Florida Atlantic University

CLINICAL RESEARCH UNIT
INVESTIGATOR MANUAL
VERSION 6.0

December 19, 2023



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Welcome

Welcome Researchers!

Thank you for choosing to carry out your research project at the FAU Division of Research Clinical Research Unit (CRU). The mission of the CRU is to provide dedicated research clinical facilities and experts to foster partnerships between academic leadership and medical investigators. The Clinical Research Unit can provide the tools, training, and guidance to properly conduct clinical research. We have a dedicated staff of professionals who are skilled in several aspects of clinical research, including study startup, project coordination, and regulatory oversight.

Enclosed you will find the steps needed to engage CRU services, the application steps and necessary forms, and information regarding investigator responsibilities. Please read the information provided in this packet carefully. If you have any questions, please contact the CRU staff. We look forward to working with you on your project!

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Clinical Research Unit (CRU)
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CRUDOR@health.fau.edu

Procedures for Clinical Research Unit Use

1. Pre-Submission Consultation

All researchers who wish to use the Clinical Research Unit (CRU) space, personnel, or equipment for conducting studies with human participants must submit the Request for Clinical Research Unit Consultation Meeting form (Appendix A). Investigators should submit the form as early as possible, preferably when the project is being prepared for submission to the funding agency, but no later than 30 days before submission to the Institutional Review Board (IRB). Investigators are encouraged to engage with the CRU at the time of study development to minimize delays in study approval and execution. Along with the form, investigators should submit the current protocol, schedule of events, consent form, lab manual, drug or device brochure, and any other documents that would be relevant or helpful to CRU staff. Once the application is received, CRU staff will review the documents to ensure that the unit can effectively meet the needs of the study and will set up a meeting with the investigator's team to discuss the project's needs and how the CRU can meet them. After the meeting, the CRU will confirm the feasibility of the study and prepare a letter of agreement for CRU services, which will include – for funded studies - costs for the use of CRU services. This document will be forwarded to the investigator for review, approval, and signature.

The investigator will return a copy of the signed agreement via email to CRUDOR@health.fau.edu. The approval process is expected to take less than 30 days.

Due to the nature of the CRU as a core unit, the signed agreement will serve as documentation for the IRB and IBC submissions of the CRU as performance site. This document will avoid listing each individual personnel from the CRU in the compliance applications if allowed. All CRU standard procedures and personnel training have been approved by the compliance committees and listing the CRU as a core will eliminate - on a case-by-case basis- repeated submission of SOPs and certifications from the CRU.

2. Principal Investigator Eligibility

The CRU supports all levels of clinical research investigators including those in training working under the oversight of an FAU eligible Principal Investigator (PI).

Following FAU policy 10.2.8, individuals employed by Florida Atlantic University that hold one of the following positions may serve as PI and Co-Principal Investigator (Co-PI).

Principal Investigator:

- Faculty - Tenure-Track (Full, Associate and Assistant Professors)
- Research Faculty - NON-Tenure-Track (Full, Associate and Assistant Professors)
- Clinical Research Faculty – NON-Tenure-Track (Full, Associate and Assistant Professors)
- Executive Directors, Directors, Associate and Assistant Directors within Pillars/Institutes and other FAU units
- Instructors holding a regular, full-time (1FTE) appointment at FAU
- Librarians holding faculty status equivalent to or greater than Assistant Professor
- Vice Presidents, Senior/Executive Associate VP, Associate VP and Assistant VP serving in these positions at FAU in any of the service areas (Research, Student Affairs, etc.)
- Principals, Assistant Principals, Directors (Associate and Assistant) and Professors (Associate and Assistant) for A.D. Henderson University School and FAU High School.
- Senior Research Fellows – senior position given to a postdoctoral fellow.

Co-Principal Investigator/Co-Investigator Positions List:

- Adjunct Faculty
- Affiliate Faculty
- Post-Doctoral Fellows
- Visiting Faculty

External users who hold a formal appointment of *Clinical Research Assistant Professor, Clinical Research Associate Professor* or *Clinical Research Professor* in one of the Pillar Institutes, a college or as a cross-appointment between a Pillar and a college can serve as PI in projects using the CRU for clinical research.
Other external investigators (i.e.: clinical affiliates) MUST identify and collaborate with eligible FAU PI to be able to conduct their research at FAU.

For more information, please visit the website below, and click Policy 10.2.8 Principal Investigator Eligibility Policy:
https://www.fau.edu/research-admin/sponsored-programs/policies/

3. Application for Clinical Research Unit Services

When the investigator receives notification that the project is funded or, for non-funded projects, when the investigator is ready to submit to the compliance committees, the Application for Clinical Research Unit Services (Appendix B) must be completed and submitted via email to CRUDOR@health.fau.edu. This application is the official request to use CRU services and may be submitted concurrently with IRB and other committee submissions (Institutional Biosafety Committee, Imaging Committee, other committees as applicable). The CRU must be listed on the IRB application as a performance site. Applications are reviewed on a rolling basis as soon as all the required documents are received.

Once compliance approvals are obtained, please communicate with the CRU to order supplies needed for the study. If specialized supplies are needed, longer times should be planned to order and receive supplies in the period between compliance approvals and study in-service meeting.

Required Training

CRU staff members have completed required CITI, Environmental Health & Safety, and Institutional Biosafety Committee training, as well as other training relevant to their job functions. Investigators wishing to use the CRU for their research studies and their research staff also need to complete research-specific training, as applicable. Training requirements are as follows:

- CRU Standard Operating Procedures
- HIPPA Privacy Essentials Course – it has been replaced with CITI Information Privacy & Security (IPS) training
- CITI training required by Research Integrity: https://www.fau.edu/research-admin/research-integrity/responsible-conduct-of-research/
- Environmental Health & Safety training http://www.fau.edu/ehs/training/
- Institutional Biosafety Committee training https://www.fau.edu/research-admin/research-integrity/institutional-biosafety-committee/ibc-training-requirements/

Additional training may be required based on the nature of the study being conducted. CRU staff

have completed CITI, IATA, and Environmental Health & Safety training; documentation of training is available upon request.

4. Protocol Initiation/In-service Meeting and Study Initiation in the CRU

The investigator's study staff must draft and submit study procedure orders and data collection flowsheets to the CRU for review and approval; CRU staff can assist with this process if needed. The investigator will schedule a protocol initiation/in-service meeting once the following have been completed:

- All compliance approvals have been received
- Training for all staff who will be working on the study has been completed
- The investigator's team is ready to begin the study in the CRU

The in-service should occur approximately four (4) weeks before the first participant is scheduled. A sample agenda for this meeting can be found in Appendix C. At this meeting, study procedures to be completed on the CRU, visit scheduling procedures, study order sheets, data collection, and other topics important for the study to be carried out in the CRU will be discussed. Attendees at this meeting should include the study investigators, study staff who will be accessing the CRU during the conduct of the study, and CRU staff members who will be working on the study.

Once the investigator and all staff who will be involved in the study have completed all start-up requirements, the investigator will receive notification that the study may commence in the CRU. The checklist below may be used to assist with confirming that all requirements have been completed.

Complete	N/A	
□	□	Institutional Review Board approval: letter submitted to CRU
□	□	Institutional Biosafety Committee approval, if applicable: letter submitted to CRU
□	□	Imaging Committee approval, if applicable: letter submitted to CRU. Imaging Committee will not approve the study without all staff involved in imaging completing training on the applicable imaging modality(-ies).
□	□	CV and medical license of principal investigator and investigator providing medical oversight: submitted to CRU, if applicable
□	□	CITI training required by Research Integrity completed by all study staff who will be accessing the unit. Clearance letter for all staff members submitted to CRU.
□	□	Training required by FAU Environmental Health & Safety completed by all study staff who will be accessing the unit. Clearance letter for all staff members submitted to CRU.
□	□	Training required by FAU Institutional Biosafety Committee. Clearance letter for all staff members submitted to CRU.
□	□	CRU Standard Operating Procedure training
□	□	Other training, as applicable
□	□	Research procedure orders in place
□	□	Data collection forms in place
□	□	Protocol Initiation/In-service Meeting
□	□	Letter approving start of study in CRU received

If there are study-provided lab kits, supplies, or equipment to be used for the study, these items should be discussed at the initiation/in-service meeting. Any equipment brought into the CRU must be tested for electrical safety and calibrated, if applicable, by biomedical engineering.

5. ClinicalTrails.gov Requirement

The PIs are required by law to submit registration for certain clinical trials of drug products (including biological products) and device products to ClinicalTrails.gov, in accordance with the Final Rule for Clinical Trials Registration and Results Information Submission (42CFR Part 11) and Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801). Please, see the Final Rule Information page by clinking the link below:

https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission

In accordance with 42 CFR Part 11, there must be one responsible party for the purposes of submitting information about applicable clinical trial. The sponsor of an applicable clinical trial is considered to be a responsible party unless the sponsor designates a qualifies PI as the responsible party. The responsible party must register an applicable clinical trial no later than 21 calendar days after enrolling the first human subject.

In addition to registering clinical trials, the sponsor or the PI is responsible for providing timely updates, submitting summary results, and making information publicly available in order to fulfill a number of purposes and stay compliant with multiple laws.

For more information, please visit the website below:

https://clinicaltrials.gov/ct2/manage-recs/background

6. Study Conduct

Appointments may be scheduled in the CRU during the hours of operation, Monday-Friday 8:00AM – 5:00PM. All study appointments will be coordinated by CRU staff and should be scheduled before 4:00PM. Anyone needing study appointments after 4:00PM must receive written authorization from the CRU Director or CRU Assistant Director.

Appointments are requested using the Appointment Scheduling Form (Appendix D), which should be sent via email to CRUDOR@health.fau.edu. Research procedure orders (Appendix E) signed by the investigator must be received at least 72 hours prior to the appointment. Once the appointment time is approved, a calendar invite will be sent to the investigator, study staff, physician providing medical oversight (if applicable), and CRU staff. When required, it is the investigator's responsibility to ensure that appointments are scheduled when a physician is available for medical oversight. Appointments should be scheduled as soon as possible before the visit, but at least 72 hours prior; CRU staff will do their best to accommodate last-minute appointment requests, but accommodation cannot be guaranteed.

Unless the participant is consented for the study in the CRU, study staff must bring copies of the signed consent and HIPAA forms (if applicable) with them to the participant's first visit. These documents will be filed in the CRU's study files. When participants are reconsented during the course of the study, those documents should also be submitted to the CRU for filing.

When the investigator receives a continuing renewal letter (annually) from the IRB, a copy of the letter must be provided to the CRU as proof of ongoing study approval. The CRU must also be notified when the investigator closes the study.

It is the investigator's responsibility to report adverse events, serious adverse events, protocol deviations, and other issues that affect the rights or safety of study participants to the funding agency and/or IRB within the proscribed time frames.

Investigators must notify the CRU Director or CRU Assistant Director in writing as soon as possible when a study monitor, sponsor, or regulatory agency has requested to visit the CRU.

7. Changes in Research Services

Any changes to the research conducted in the CRU must be submitted on a Request for Change in Research Services form (Appendix F) and submitted to the CRU for review and approval before changes in research procedures can be made. This approval is over and contingent to any approvals needed from the IRB or ancillary committees.

Appendix A: Request for Clinical Research Unit Consult Meeting

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Clinical Research Unit
Division of Research

Form 1 - Request for Clinical Research Unit Consult Meeting

Please submit this form and applicable documents to CRUDOR@health.fau.edu.

Today's Date (DD/MMM/YYYY): / /

Principal Investigator Information

Name: Department/College:

Phone: ( ) - Email:

Other Contact: Title:

Phone: Email:

Study Information

Project Title:

IRB #: Sponsor/Other #:

ICD-10 Diagnosis Codes/Research Indication:

Brief Project Description:

Funding Source

Funding Source: ☐ NIH/Federal ☐ Foundation ☐ Private
☐ Industry ☐ Department ☐ State/Local
☐ Not Funded ☐ Other

Sponsor Name:

Estimated # Participants:

Planned Start Date (DD/MMM/YYYY): / /

Planned End Date (DD/MMM/YYYY): / /

Description of CRU Services Needed

Are there any special days/times that your visits need to be scheduled?

☐ No ☐ Yes Explain:

Will you be providing any study-specific supplies, forms, or equipment (lab kits, machines, flow sheets, orders, etc.)?

☐ No ☐ Yes Explain:

Is there any other information about your project that you feel it is important for the CRU to consider?

☐ No ☐ Yes Explain:

Are the following documents attached?

Protocol/Grant Application	Version:	☐ Yes	☐ No	☐ N/A
Informed Consent	Version:	☐ Yes	☐ No	☐ N/A
Lab Manual	Version:	☐ Yes	☐ No	☐ N/A
Schedule of Events	Version:	☐ Yes	☐ No	☐ N/A
For Clinical Trials: CV/Biosketch and Medical License of Investigator Providing Medical Oversight	Version:	☐ Yes	☐ No	☐ N/A
Additional Document(s)				

Appendix B: Application for Clinical Research Unit Services

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Clinical Research Unit
Division of Research

Form 2 - Application for Clinical Research Unit Services

Please submit this application and applicable documents to CRUDOR@health.fau.edu.

Principal Investigator Information

Name: Department/College:
Academic Rank: Specialty:
Phone: ( ) - Email:
Other Contact: Title:
Phone: Email:

Medical Oversight Physician Information *(if applicable)*

Name: Department/College:
Rank: Specialty:
Phone: - Email:

Co-/Sub-Investigators

Name: Department/College:
Name: Department/College:
Name: Department/College:
Name: Department/College:
Name: Department/College:

Study Information

Project Title:
IRB #: Sponsor/Grant/Other #:
IRB of Record:
IRB Submission Date (DD/MMM/YYYY): / / ☐ Approved ☐ Pending
If Approved, IRB Expiration Date (DD/MMM/YYYY): / /
Funding Source: ☐ NIH/Federal ☐ Foundation Private
☐ Industry ☐ Department ☐ State/Local
☐ Not Funded ☐ Other
Investigational: ☐ IND ☐ IDE ☐ BLA ☐ NDA ☐ ANDA ☐ N/A
Number(s): Name:
Study Phase: ☐ I ☐ I-II ☐ II ☐ II-III ☐ III ☐ III-IV ☐ IV ☐ N/A
☐ Pilot

Investigator-Initiated? ☐ Yes ☐ No

Participant Information

Participants: Planned Start Date (DD/MMM/YYYY): / /

Target Population:

ICD-10 Diagnosis Code(s): ☐ N/A

Participant Age Range: Planned End Date (DD/MMM/YYYY): / /

Visits/Participant: Estimated Length of Visits: (15 min increments):

Medical risks (cardiac, vascular, pulmonary, etc.)?	☐ Yes	☐ No
Behavioral risks (agitation, aggression, psychosis, paranoia, etc.)?	☐ Yes	☐ No
Cognitive risks (memory, attention, confusion, etc.)?	☐ Yes	☐ No
Fall precautions?	☐ Yes	☐ No
Seizure precautions?	☐ Yes	☐ No
Infection control requirements?	☐ Yes	☐ No
Nursing assistance required?	☐ Yes	☐ No

If any of the above questions were answered "yes", please explain how risks to research participants will be mitigated.

Has a Data Safety Committee been established? ☐ Yes ☐ No

CRU Services Requested (select all that apply)

☐ Phlebotomy†	☐ Specimen Storage†	☐ Informed Consent	☐ Vital Signs
☐ Single Draw	☐ -80 freezer	☐ Physical Exam	☐ Weight
☐ Multiple Draws	☐ -20 freezer	☐ Cognitive Testing	☐ Height
☐ Urine Sample†	☐ Refrigerator	☐ Infusion Pump Use	☐ ECG
☐ Oral/Buccal Swab†	☐ Urinalysis†	☐ Fecal Sample†	☐ Exam Room
☐ Specimen Processing†	☐ Specimen Shipment†	☐ ECG Machine Use	☐ Ultrasound
☐ Monitoring/Observation	☐ Exam Room Use	☐ Study Coordinator	☐ Nursing
☐ Pharmacy Services	☐ Infusion Bay Use	☐ DXA Scans‡	☐ Regulatory
☐ Glucose Finger Stick†	☐ Urine HCG Testing	☐ Anthropometrics	☐ Data Entry
☐ Administer Medication	☐ Functional Testing	☐ Gait Lab Use	☐ OCT
☐ Auditory Testing	☐ Visual Testing	☐ Spirometry	☐ Audiometry
☐ Ankle-brachial Index	☐ Body Composition	☐ Pulse Oximetry	☐ Hand Grip
☐ Waist Circumference	☐ Strength Testing	☐ Hand Dexterity	☐ Screening
☐ Balance Assessment	☐ Gait Testing	☐ Interview Room	☐ Nasal Swab†
☐ Other:			

† Protocols involving collection of samples must receive approval from the FAU Institutional Biosafety Committee. ‡ Protocols involving imaging must receive approval from the FAU Human & Animal Imaging Committee.

Supplies to Be Provided by Investigator

Supplies to Be Provided by CRU

Financial Information:

Billing Phone: -

Contact:

Tag #:

Award #: Award Amount: $

Dates of Grant Support (DD/MMM/YYYY): / / to / /

Voucher Support Requested?

Are any procedures billable to insurance? ☐ Yes ☐ No

☐ Yes ☐ No

Required Attachments (mandatory in order to receive approval to use the unit):

Final Protocol/Grant Application	☐ Yes	☐ No	☐ Pending	☐ N/A
Schedule of Events	☐ Yes	☐ No	☐ Pending	☐ N/A
IRB-Approved Informed Consent	☐ Yes	☐ No	☐ Pending	☐ N/A
IRB Determination Letter	☐ Yes	☐ No	☐ Pending	
IBC Approval Letter	☐ Yes	☐ No	☐ Pending	☐ N/A
Imaging Committee Approval Letter	☐ Yes	☐ No	☐ Pending	☐ N/A
Final Lab Manual	☐ Yes	☐ No	☐ Pending	☐ N/A
Final Pharmacy Manual	☐ Yes	☐ No	☐ Pending	☐ N/A
Visit Flow Sheets	☐ Yes	☐ No	☐ Pending	☐ N/A
Study Visit Orders	☐ Yes	☐ No	☐ Pending	☐ N/A

Additional Document(s)

Are you planning on collecting any data and/or samples off campus?	☐ Yes	☐ No	
If yes, do you have study personnel to collect your data and/or samples?	☐ Yes	☐ No	☐ N/A
If yes, do you have an FAU designated vehicle to travel off campus and transport your specimens?	☐ Yes	☐ No	☐ N/A
If you need the CRU to process your samples, do you have a plan to deliver/ship those samples to the CRU?	☐ Yes	☐ No	☐ N/A

Application Completed & Submitted By:

Responsibility for Scientific Conduct:

I attest the information provided in this application is current and accurate. In addition, I confirm that:

- I will adhere to the FAU Division of Research Policies and Clinical Research Unit Standard Operating Procedures.
- I will ensure that all personnel from my staff who utilize the Clinical Research Unit complete the required training.
- I will ensure that the study is conducted as approved by the IRB.
- I will provide the Clinical Research Unit with amendments, continuing approvals, and other reports and updated documents in a timely manner.
- I will report adverse events to the Clinical Research Unit and/or the IRB within the required time frames.

Principal Investigator Name (PRINT):

Principal Investigator Signature: _____

Date: _____

Responsibility for Medical Oversight (if applicable):

As oversight physician, I confirm that:

- I will supervise and accept responsibility for medical oversight for this protocol.
- I will accept responsibility for the safety of the human subjects enrolled under this protocol.
- I will ensure that all subjects meet eligibility criteria.
- I will report adverse events to the Clinical Research Unit and/or the IRB of record. Medical Oversight Physician Name (PRINT):

Medical Oversight Physician Signature: _____

Date: _____

Appendix C: Sample Protocol Initiation/In-service Meeting Agenda

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Initiation/In-service Meeting Agenda
[Protocol Name]
[Principal Investigator]
[Date}

Please bring the following documents to the initiation/in-service meeting:

- IRB approval letter
- Final protocol/grant application, consent form, and other study-related documents
- Copies of study flowsheets/data collection forms & study visit orders
- Lab processing instructions/lab manual
- Other documents needed for CRU staff to complete study tasks

The meeting should cover the following items:

1. Project Title
2. Staff Introductions
    a. Principal Investigator
    b. Co-/Sub-Investigator(s)
    c. Other study staff with whom CRU staff may be interacting
3. Project Overview
    a. Brief description of the study
    b. Aims/goals of the study
    c. Anticipated start date
    d. Length of study participation
    e. Number of planned participants
    f. Information about the study intervention (drug, device, procedure, etc.)
4. CRU-Specific Study Details
    a. Number, frequency, & length of study visits
    b. Visit scheduling procedures, including specific timing and scheduling form review
    c. Coordinator and/or nursing tasks
    d. Study participant number/ID assignment
    e. Consent procedures, if applicable
    f. Data collection procedures, including forms
    g. Study orders
    h. Any special training or equipment needed
    i. Expected adverse events and reporting procedures
    j. Procedures to contact investigator and/or other study staff in case of emergency & medical coverage
5. Lab Instructions
    a. Type, number of collection tubes
    b. Supplies provided by study or need to be purchased
    c. Sample collection conditions (ambient, refrigerated)
    d. Centrifugation instructions (temperature, speed, time)
    e. Sample storage conditions (ambient, refrigerated, -20, -80)
    f. Number of aliquots, timing, labeling instructions
    g. Any other study-specific processing procedures
6. Other considerations

Appendix D: Appointment Scheduling Form

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Form 3. - Appointment Scheduling Form

Use one form per participant. Please submit this form to CRUDOR@health.fau.edu.

Study Information	
IRB #	
Requested By:	
Request Date:	
Investigator Information	
Name:	
Phone:	( ) -
Email:	
Study Staff Information	
Name:	
Phone:	( ) -
Email:	
24/7 Contact for Medical Emergencies	
Name:	
Phone:	( ) -

Signed study consents/reconsents MUST be provided to CRU staff before or at the time of first visit for any study visits using CRU staff.

Participant Information	
Participant ID:	
Legal Name (Last, First, MI):	
Date of Birth (DD/MMM/YYYY):	/ /
Phone Number:	
E mail:	
Visit Information (if requesting more than 1 visit, use additional spaces on reverse side of this form)	
Study Visit ID:	
Visit Date (DD/MMM/YYYY):	/ /

Visit Type:	☐ New ☐ Follow-Up ☐ Phlebotomy ☐ Sample Drop-Off
Arrival Time (HH:MM)	:
Anticipated Visit Length:	hours minutes (round to next 15-minute increment)
Staff Requirements:	
Space Requirements:	
Additional Comments:	

Visit Information	
Study Visit ID:	
Visit Date (DD/MMM/YYYY):	/ /
Visit Type:	☐ New ☐ Follow-Up ☐ Phlebotomy ☐ Sample Drop-Off
Arrival Time (HH:MM)	:
Anticipated Visit Length:	hours minutes (round to next 15-minute increment)
Staff Requirements:	
Space Requirements:	
Additional Comments:	

Visit Information	
Study Visit ID:	
Visit Date (DD/MMM/YYYY):	/ /
Visit Type:	☐ New ☐ Follow-Up ☐ Phlebotomy ☐ Sample Drop-Off
Arrival Time (HH:MM)	:
Anticipated Visit Length:	hours minutes (round to next 15-minute increment)
Staff Requirements:	
Space Requirements:	

Additional Comments:	
Visit Information	
Study Visit ID:	
Visit Date (DD/MMM/YYYY):	/ /
Visit Type:	☐ New ☐ Follow-Up ☐ Phlebotomy ☐ Sample Drop-Off
Arrival Time (HH:MM)	:
Anticipated Visit Length:	hours minutes (round to next 15-minute increment)
Staff Requirements:	
Space Requirements:	
Additional Comments:	

Appendix E: Study Visit Orders

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Form 4 - Clinical Research Unit Study Visit Orders

Email to:
CRUDOR@health.fau.edu

Study Visit ID:

Participant ID:

Participant Name:

Date of Birth (DD/MMM/YYYY): / /

Protocol #:

Allergies

Latex ☐ Yes ☐ No
Food ☐ Yes ☐ No

Peanuts ☐

Eggs ☐

Other (specify) ☐

Medications/Drugs ☐ Yes ☐ No

Medication Name	Type of Reaction

Visit Date & Time

Orders

Please describe the procedures requested for this order and include as many details as possible (i.e.: # tubes, butterfly, processing, specific test from cognitive battery, order of testing, etc.)

PI/Designee Signature:

Date:

Appendix F: Request for Change in Research Services

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Clinical Research Unit
Division of Research

Form 5. - Request for Change in Research Services

Please submit this form and applicable documents to CRUDOR@health.fau.edu.

Today's Date (DD/MMM/YYYY): / /

Principal Investigator Name:

Research Team Contact: Name: Phone: -

IRB #:

Project Title:

IRB Submission Date (DD/MMM/YYYY): / / ☐ Approved ☐ Pending

Changes to the Research

Change in Number of Participants	☐ Yes	☐ No
Change in Number of Visits	☐ Yes	☐ No
Change in Study Activities	☐ Yes	☐ No
Protocol	☐ Yes	☐ No
Informed Consent	☐ Yes	☐ No
Lab Manual	☐ Yes	☐ No
Pharmacy Manual	☐ Yes	☐ No
Additional Documents	☐ Yes	☐ No
New Documents	☐ Yes	☐ No

Additional Information/Comments:

Are the following documents attached?

Submit tracked changes version of each document or summary of changes, if available.

Revised Protocol/Amendment	☐ Yes	☐ No	☐ Pending	☐ N/A
Revised Informed Consent	☐ Yes	☐ No	☐ Pending	☐ N/A
IRB Approval Letter	☐ Yes	☐ No	☐ Pending	☐ N/A
Revised Lab Manual	☐ Yes	☐ No	☐ Pending	☐ N/A

Other Revised/New Document(s)

PI/Designee Signature:

Date: