

Georgetown University Clinical Research Unit

Standard Operating Procedure: ADM-SEPCOM-0425

Effective Date: 4/3/2025

Title: SEPCOM Application Completion Procedure

Supersedes: None

AUTHOR

Name: Angie Patricia Wilkins

Title: Program Manager

Department: Clinical Research Unit

Signature and Date:

DocuSigned by:
Angie Wilkins
A9F26A49494A4C0...

4/3/2025

APPROVED BY

DEPARTMENT HEAD

QUALITY ASSURANCE

Name: Jacqueline Jonklaas, MD, PhD

Terry (Marie Therese) Jeffs, BSN, RN

Title: Program Director

Nurse Manager

Department: Clinical Research Unit

Clinical Research Unit

Signature and Date:

Signed by:
Jacqueline Jonklaas 4/3/2025
0639B8C0A0974A2...

DocuSigned by:
Marie Therese (Terry) Jeffs 2/25/25
7188F39419A2424...

REVISIONS

No.	Section	Pages	Initials/Date

I. PURPOSE

To provide Principal Investigators and Study Coordinators with a Standard Operating Procedure for correctly completing SEPCOM applications.

II. SCOPE

This standard operating procedure will apply to all Principal Investigators and Study Coordinators submitting SEPCOM applications to utilize the Clinical Research Unit's infrastructure, resources and services.

Clinical Research Unit

ADM-SEPCOM-0425

Effective Date: 4/3/2025

III. DEFINITIONS

- A. IRB (Institutional Review Board) is a committee that reviews research involving human subjects to ensure the safety, rights, and well-being of participants, adhering to ethical principles and regulations.
- B. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to help researchers collect and manage data for research studies, offering features like online surveys, databases, and data entry validation.
- C. SEPCOM is the Scientific Evaluation & Prioritization COMMITTEE of the Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS) whose primary focus is to provide comprehensive review for clinical research projects, including review of scientific merit, statistical suitability, patient safety and ethics, and nursing and administrative needs.
- D. CTSA is the Clinical and Translational Science Award that supports the Clinical Research Unit.
- E. CRU is the Clinical Research Unit.

IV. PROCEDURES**A. SEPCOM Application General Information**

- 1. Study teams need to complete and submit an application via REDCap using the link below in order to utilize CRU resources:
https://redcap.georgetown.edu/redcap/surveys/?s=DTMJ4D9EKD#_ga=2.223358296.2106431786.1743423174-161588071.1726776808.
- 2. One of the required documents is the initial IRB application (generally to the GHUCCTS IRB) in which an IRB number is assigned to the study. You do not need to wait for IRB approval prior to submitting a SEPCOM application, however you **MUST** submit an IRB application prior to submitting a SEPCOM application. Review by the two committees is independent but sequential.

Workflow: IRB application → SEPCOM application → SEPCOM review → SEPCOM approval → IRB review → IRB approval (see Attachment E: Summary of Review Process for GHUCCTS Protocols)

- 3. A SEPCOM application will not be forwarded for review until it is both accurate and complete. The SEPCOM administration will reach out to the primary contact to address any discrepancies in the application.
- 4. The SEPCOM Administration will determine the type of review (administrative or full review) based on the type of protocol and its previous level of scientific review.
- 5. SEPCOM applications requiring a full review that were submitted with all the required documentation by the deadline will be evaluated at the next SEPCOM meeting on the 1st Thursday of the month. Please refer to Attachment A: 2025 SEPCOM Schedule & Submission Deadline. Administrative reviews are performed within 5 business days from the day of the complete submission.

Clinical Research Unit

ADM-SEPCOM-0425

Effective Date: 4/3/2025

6. The SEPCOM Administration will notify the IRB and the Principal Investigator of the committee's determination via email.
7. GHUCCTS IRB Committee E meetings are regularly scheduled for the second Thursday of each month from 3:00-5:00 PM. Please refer to Attachment C: IRB Meeting Deadlines and Dates.
8. Contact the SEPCOM/CRU Administration at ghucctscradmin@georgetown.edu for any questions about the application.
9. The CRU Guide for Study Teams (Attachment B) is a great resource for new study coordinators.

B. SEPCOM Application Section A: Protocol Information

1. Section A.1 - provide the Principal Investigator's Name, Email, Phone, Title, Department, Division, Institution and Area of Expertise.
2. Section A.2 - provide the Co-Investigators' Name, Email, Phone, Title, Department, Division, Institution and Area of Expertise.
3. Section A.3 - provide the Name, Email, Phone and Role of the person submitting the SEPCOM application. Add additional study coordinators (personnel) if needed.
4. Section A.4 - select if the person submitting the SEPCOM application is also the Billing Point of Contact (BPC). If not, add the Primary BPC Name, Email and Phone.
5. Section A.5 - provide the full study title and the short title as it appears on the protocol. An estimated end of enrollment date is needed in this section.
6. Section A.6 - provide as much funding information as possible. The funding source is a required field (e.g. NIH, Biogen).
7. Section A.7 - select the IRB of record and provide the assigned IRB number. If there is an external IRB, select "Other" and specify the IRB that will oversee the study.
8. Section A.8 - select the sites in which the study will be implemented.
9. Section A.9 - select all the study categories that apply. Qualifying studies are eligible for a discounted rate. Industry-sponsored studies are often multi-site (implemented at multiple sites other than GU/GUMC).
10. Section A.10 - select the type of study. Select the phase if the study is a clinical trial. Participants under 18 are considered pediatric.

C. SEPCOM Application Section B: Inclusion of Diverse Populations

1. Check all the priority GHUCCTS populations that the study is making special effort to recruit, if applicable.
2. Make a selection for special efforts made to include people with limited English proficiency. This is a required field.
3. Indicate all the topic areas of interest for GHUCCTS consultation services. The SEPCOM Administration will connect the study team with the appropriate GHUCCTS personnel based on the selections.

D. SEPCOM Application Section C: Projected Enrollment & Use of CRU Services

Clinical Research Unit

ADM-SEPCOM-0425

Effective Date: 4/3/2025

1. The total estimated enrollment at GHUCCTS site must be the same as the local number of subjects listed on the IRB Site Supplement Document and Informed Consent Form.
2. Section C.1 - The most common type of visit requested is outpatient but if the study requires inpatient, off-site visits or lab processing check all that apply for which CRU support is needed.
 - a. Inpatient
 - a.1. List the total number of inpatient visits per patient for which CRU support is needed
 - a.2. List the inpatient visits for which CRU support is requested using the visit names as they appear in the protocol and Schedule of Assessment (e.g. Baseline/Day 1)
 - a.3. Provide an estimate of the duration of each inpatient visit (e.g. Baseline/Day 1: 28 hrs)
 - b. Outpatient
 - b.1. List the total number of outpatient visits per patient for which CRU support is needed
 - b.2. List the outpatient visits for which CRU support is requested using the visit names as they appear in the protocol and Schedule of Assessment (e.g. Screening, Baseline, Month 1)
 - b.3. Provide an estimate of the duration of each visit (e.g. Screening: 3hrs, Baseline: 5hrs)
 - c. Off-site Visit (not on the CRU)
 - c.1. Provide the specific location (e.g. unit in the hospital or community site) where the CRU Nurses need to scatter to perform the services requested.
 - c.2. List the total number of off-site visits per patient for which CRU support is needed
 - c.3. List the off-site visits for which CRU support is requested using the visit names as they appear in the protocol and Schedule of Assessment (e.g. Screening, Baseline, Month 1)
 - c.4. Provide an estimate of the duration of each off-site visit (e.g. Screening: 3hrs, Baseline: 5hrs)
 - d. Lab Processing Only
 - d.1. This selection means that participants will not come to the CRU and no other procedures other than specimen processing and shipping will be needed.
 - d.2. The study personnel are responsible for bringing the samples and all supplies to the CRU for processing and shipping.
 - d.3. The study personnel are responsible for submitting an appointment request and signing in at the front desk when dropping off the samples at the CRU and must connect with lab personnel directly.

Clinical Research Unit

ADM-SEPCOM-0425

Effective Date: 4/3/2025

3. Make a selection for sample shipment based on the protocol and any research labs that need to be collected and sent to a central lab.
4. Make a selection for sample storage depending on the need to store samples at the CRU for more than a week. The CRU does not offer long-term storage and any samples stored for longer than a week will be charged a monthly fee.
5. Section C.2 - Check all the reasons your study requires or needs CTSA/CRU support and add comments if any.

E. SEPCOM Application Section D: Services Requested - Only specify the services being requested from the CRU

1. Section D.1 - Select all the types of specimen collection and processing requested for the appropriate type(s) of visit (outpatient, inpatient, off-site).
2. Section D.2 - Select all the types of physical examinations requested for the appropriate type(s) of visit (outpatient, inpatient, off-site).
3. Section D.3 - Select the type of participant teaching/training required for the appropriate type(s) of visit (outpatient, inpatient, off-site).
4. Section D.4 - Select the type of monitoring required for the appropriate type(s) of visit (outpatient, inpatient, off-site).
5. Section D.5 - Specify any special testing or procedures if applicable for the appropriate type(s) of visit (outpatient, inpatient, off-site). Also add any comments from other D sections.
6. Section D.6 - Select the type of medication to be administered by CRU Nurses for the appropriate type(s) of visit (outpatient, inpatient, off-site).
7. Section D.7 - Specify if CRU assistance is needed to collect other data (e.g. questionnaires). Select if patients will require a meal which is typically added to the budget for visits expected to take 2 hours or more. Select from the list all the special equipment needed for the study. Select any special rooms needed to complete the required visit procedures. (e.g. separate room for cognitive testing).

F. SEPCOM Application Section E: Supplemental Document Upload

1. The documents listed below are required for GU and MedStar to start the SEPCOM review process. Do not submit the application until you have all of the required documents.
 - Full Protocol
 - IRB application (not approval)
 - IRB Site Supplement Document (required for GU and MedStar)
 - Investigator's CV
 - Informed Consent Form (draft or approved)
 - Summary Statement (if federally-funded) or other evidence of previous scientific review if applicable
2. The following documents are not required to start the SEPCOM review process but are extremely helpful if available:
 - Lab Manual
 - Investigator's Brochure
 - Pharmacy Manual (if investigational product involved)

Clinical Research Unit

ADM-SEPCOM-0425

Effective Date: 4/3/2025

- Case Report Form (CRF)
- Original IRB Approval Memo
- Budget from Funding Source
- Assent Form as Approved or Submitted to the IRB

G. SEPCOM Application Section F: Signatures

1. The pdf version of the SEPCOM Application Signature Page is attached in this section and it can be downloaded for signature.
2. Study personnel assigned regulatory or SEPCOM related duties by the Principal Investigator can also sign the application as Designees.
3. Electronic signatures are acceptable
4. The signed page must be uploaded twice in the sections listed below:
 - Responsibility for Scientific Conduct
 - Responsibility for Medical Conduct
5. Click Submit once all the sections are completed

H. Changes to SEPCOM Application After Submission

1. In order to make changes to the application after it has been submitted, contact the SEPCOM/CRU Administration at ghucctsruadmin@georgetown.edu. A unique code and link will be provided to make changes to the application.

V. References

- A. SEPCOM Schedule & Submission Deadlines
- B. ADM-SEPCOM-07.31.2019
- C. CRU Guide for Study Coordinators
- D. IRB Meeting Deadlines and Dates
- E. Summary of Review Process for GHUCCTS Protocols and SEPCOM Review Flow Diagram

VI. Attachments

- A. SEPCOM Schedule & Submission Deadlines
Link: <https://georgetown.box.com/s/5csiy2p353k948d09bo1h3ra9wc6hpdc>
- B. CRU Guide for Study Coordinators
Link:
<https://docs.google.com/document/d/1Cr5kcOW0x0SAXGIfxy0INUclFKRxxFu4fG6CVrL-dbo/e/dit?usp=sharing>
- C. IRB Meeting Deadlines and Dates
Link: <https://georgetown.app.box.com/s/x4fpbktqz9r4gqcxzx14jxmk8i0321fg>
- D. Summary of Review Process for GHUCCTS Protocols and SEPCOM Review Flow Diagram
Link:
<https://georgetown.app.box.com/file/68394593805?s=zexjlirmwy21d7kujrjw52035tqivw9ns>

Clinical Research Unit

ADM-SEPCOM-0425

Effective Date: 4/3/2025