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| **Date:** | [Insert date] |

1. **PURPOSE:**

This Standard Operating Procedure (SOP) describes the standards for assessing the feasibility of implementing a research protocol at Emory University (EU).

The purpose of the SOP is to describe the procedure of clinical trial feasibility undertaken at Emory University and to ensure:

* Assessment of the feasibility of conducting a specific protocol at EU
  + - Before agreeing to participate in a clinical research study, the Investigator and EU must agree to scientific, clinical and ethical merits of the study, the financial impact to the institution, compliance with regulations, and the operational feasibility of conducting the study at EU
* All relevant departments (internal and external) are consulted and can support the project
* The proposed trials are a strategic fit and aligned with EU
* Research projects have the best possible outcome in terms of recruitment, patient safety, budget and time frames

1. **SCOPE**:

This SOP applies to all the clinical studies being considered for conduct in the [insert department/division] at EU.

This SOP provides instruction and sets minimum standards regarding the process for reviewing the feasibility of implementing a research protocol throughout EU with emphasis on recruitment, site logistics, and financial resources for implementation and completion of the study.

Departments must utilize and complete the protocol feasibility assessment process prior to grant, IRB (initial and annual review), or FDA submissions.

1. **RESPONSIBLE INDIVIDUALS:**

This SOP applies to all Investigators who would like to implement a research study that prospectively enrolls human subjects. Research projects including sponsored research, clinical trials, and FDA regulated studies (including investigator initiated) are subject to this policy. Retrospective chart review, biorepositories, tissue and blood sample banking, exempt research, questionnaire studies, and behavioral research are all exempt from this requirement. If research design includes elements that span both exempt (chart review) and non-exempt (FDA regulated), then this SOP would apply to that research protocol.

The Investigator is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow SOP. The clinical research team may include but is not limited to the following members: Investigator, Sub-Investigator, Clinical Research Coordinator (CRC), Clinical Research Nurse (CRN) other research staff as appropriate, Administrative/Support staff.

**4. Definitions:**

**Feasibility Assessment:** To evaluate the possibility of conducting a clinical trial in a proposed location based on a list of questions. The answers will allow the qualified Investigator to make an informed decision regarding the feasibility of the study at his/her site.

1. **Procedure:**

The Feasibility Assessment is an ongoing two-part process that captures information needed by EU. This process should be completed by the department prior to both the initial review and each subsequent continuing review of the Institutional Review Board (IRB).

***5.1: Part 1*** focuses on assessing the number of eligible participants available for recruitment within EU.

To obtain the number of potentially eligible participants for the study, *a query of the electronic medical record (EMR) may be conducted through:*

* *TriNetX software based upon information provided in part 1 by the Requester*
* *Emory* [*I2B2*](https://it.emory.edu/catalog/data-and-reporting/i2b2.html) *query of Emory Healthcare electronic health record data*
* *EeMR until EPIC implementation (planned October 2022)*

***5.2 Part 2***focuses on the study start-up and captures information regarding key inclusion and exclusion criteria, site logistics, contractual/financial and additional EU resources and ancillary services needed after the study start-up process to conduct the study. This is necessary to continue reviewing feasibility within the department/division, and capture important information required to conduct a trial at EU.

**If using TriNetX:**

The Requester should populate the necessary information into the TriNetX system.

A member of the [department/division designee] will enter information into the TriNetX system to obtain the number of eligible participants within EU for the research trial.

TriNetX query results are provided to the Requester and study team within [insert # business days]; results include a query screenshot detailing outcomes from the EU database. For a study to qualify as feasible, there must be 5 times the number of required participants available in the EU systems (5 x Anticipated Accrual at Local Site).

Email notifications from [department/division designee] alerts Requesters regarding the outcome of review within [# business days].

* **Feasible** (query returns >5 times Anticipated Accrual at Local Site) for implementation which should prompt completion of *Part 2.*
* **Not feasible** (query returns < 5 times Anticipated Accrual at Local Site) due to low number of eligible participants in the EU database.
* **Exempt** (query returns < 5 times Anticipated Accrual at Local Site) due to special considerations including rare disease or specific patient population that cannot be queried. Protocol exemptions will be reviewed by the [insert role – should be based upon scientific expertise] and exemption notice will be sent when applicable.

Studies deemed Feasible or exempt in Part 1 should proceed to Part 2: Study Start-up Process in parallel with their IRB submissions.

Studies deemed not feasible may NOT proceed with IRB submission or the Study Start-up Process.

**Part 2: Clinical Operations Considerations**

Purpose: *Part 2* captures all information required by Research Administration Services (RAS), Pre-Award, and ancillary cores such as Investigational Drug Services, Radiology, Emory Medical Laboratory, etc.

Information required in this section pertains to site logistics to conduct protocol.

***5.3 Feasibility Outcome***

The [insert role – should be based upon scientific expertise] reviews and signs-off on all Clinical Trial Feasibility Review Forms and will return the signed document to the Investigator and [department/division designee] listed on the form. This signed document should be retained by the study team and attached for reference to the corresponding IRB submission.

1. **APPENDIX**
2. Clinical Trial Feasibility Review Form
3. Clinical Trial Feasibility Assessment Form