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Externally Conducted Research Studies

OVERVIEW OF INVESTIGATOR RESPONSIBILITIES AND INFORMATION REQUIRED TO SUBMIT A STUDY CONCEPT OR FULL PROPOSAL

Please read this section to understand the expectations placed on individuals proposing to serve as "investigators" who wish to submit an External Research Grant request. Please note that a member of Emergent's Medical Affairs department is available to provide information on the submission and review process,

Overview of Responsibilities of Investigator

Qualifications

The investigator shall have the appropriate qualifications, education, and experience to conduct the study. Where the proposed study involves the medical management of patients, the investigator must be a licensed healthcare professional (e.g., MD, DO, PharmD, NP, PA, RN, etc.) and able to medically manage the enrolled subjects and serve as the Legal Sponsor of the study.

Procedures

The investigator (or their affiliated institution) must have current procedures and infrastructure in place for carrying out clinical trials safely, effectively, and in accordance with all applicable FDA regulations and industry standards of practice.

Responsibilities

The investigator must act as both sponsor and investigator as defined in the applicable regulations where the study will be conducted. The below list is a representative list of typical responsibilities of the investigator:

1. Comply with all applicable regulations and industry standards of practice applicable to each role
2. Ensure the appropriate institutional and regulatory approvals, including IRB approval
3. Design the clinical trial protocol
4. Initiate, conduct, and monitor all aspects of the study, ensuring appropriate medical safeguards and reporting of adverse events
5. Register the trial on the applicable government registration site (e.g. in US FDA's clinicaltrials.gov website in EU the EU Clinical Trials Register) and post study results at trial completion
6. Provide study status updates as stipulated by the Research Agreement
7. Collect, analyze, and interpret study results
8. Publish or present study results, regardless of outcome

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Overview of Information Required to submit a research Concept or Full Proposal for consideration by Emergent's External Research Grant Review Committee

Documentation Required for review of **Concept**:
A investigator is strongly encouraged to submit a concept initially to assess Emergent's interest. However, please understand that a *full proposal* must be submitted before Emergent's External Research Grant Review Committee makes a final determination on any submission. To submit a concept please provide:

1. Study synopsis
2. Investigator's curriculum vitae and contact information
3. Contact information for the affiliated institution (e.g., university, hospital, health center, etc.)
4. Overall support requested (estimated amount of study drug product, estimated funding, or both)

Documentation Required for review of **Full Proposal**:

- Detailed study protocol
- Research site information:
    - Number of sites (if multiple, please specify the primary site)
    - Address, city, state, and country of each site
- Detailed type of Emergent support requested (study product, funding, or both)
- Name(s) of any Emergent and/or Emergent study products to be used in the study
- Study title
- Synopsis
- Background
- Objectives
- Study design, including
    - Primary endpoints and any secondary endpoints
    - Number of subjects
    - Dosing regimen
    - Duration
- Description of safety reporting processes
- For animal studies, facility and welfare (OLAW) registration # is required
- Statistical analysis plan, including sample size justification and power calculation
- Publication/presentation plan
- Description of any third-party services required
- Specific product supply requirements (if requested), including: Total amount of each Emergent licensed product requested, need by dates(if applicable) and any special needs need to be communicated to the product leads (e.g., placebo)
- Study timeline, including first patient first visit, last patient last visit, and expected publication date.

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- Detailed budget (if funding is requested) specifying the total monetary request and the expected costs at fair market value related to the following:
  - Overhead
  - Direct study fees
  - Indirect study fees
  - Subject-related study fees
  - Study-related personnel
  - Laboratory fees
  - Data management fees
  - Publication fees
  - Institutional review board fees
  - Diagnostic services
  - Equipment and supplies
  - Third-party services fees (if any)
- Supporting taxpayer identification documentation (e.g. in US IRS W-9)