Principal Investigator:

IRB Protocol Number:

**Saint Louis University Institutional Review Board**

Supplemental Application for Coordinating Center (CC) Activities

*Use this form only if Saint Louis University will function as a Coordinating Center for a multi-center trial, or when the SLU PI is the direct recipient of a federal grant and the research will be conducted at other sites. When complete, upload as an attachment to the eIRB Application.*

1. **List all non-SLU Performance Sites that are “engaged” in research** (insert rows if needed).

*An institution or performance site is “engaged in research” when its employees or agents obtain participant consent, intervene or interact with living individuals for research purposes, or obtain individually identifiable private information for research purposes. See the* [*OHRP Guidance on Engagement*](http://www.hhs.gov/ohrp/policy/engage08.html)*.*

Each site will require a letter of IRB approval and a FWA number if federally funded. If interested in determining whether SLU IRB can serve as the IRB for all/other sites, call 977-7744. **If no non-SLU sites are engaged, you do not need to complete this application.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of Performance Site and PI**  **(list all participating sites below)** | **Site FWA # (required if federally funded)** | **Current IRB Status** | **IRB Protocol Number** | **IRB of Record** | **Non-SLU IRB Approval** |
|  |  | Approved  Pending |  | SLU  Other | Attached  Pending |
|  |  | Approved  Pending |  | SLU  Other | Attached  Pending |
|  |  | Approved  Pending |  | SLU  Other | Attached  Pending |
|  |  | Approved  Pending |  | SLU  Other | Attached  Pending |
|  |  | Approved  Pending |  | SLU  Other | Attached  Pending |

1. **How long will you function as Coordinating Center (or primary awardee)?**

**Anticipated End Date (Month/Year):**

1. **Has the Saint Louis University Coordinating Center/PI assumed responsibility for the following?**

|  |  |  |
| --- | --- | --- |
| **Protocol and/or case report form development and/or distribution**  (Will SLU be developing/providing the research protocol and/or data collection forms/instruments/CRFs to performance sites?) | | Yes  No  N/A |
| **Sample consent form development and/or distribution** | | Yes  No  N/A |
|  | If “Yes,” describe the coordinating center/PI’s role in reviewing modifications made by each collaborating institution to assure changes are appropriate. A copy of the sample consent form must be submitted with this Application. | |
| **Critical documents management** | | Yes  No  N/A |
|  | If “Yes,” describe the types of documents the coordinating center/PI is responsible for managing (e.g., tracking IRB approvals at each participating site and assuring IRB approval is granted prior to enrollment of participants at each site). | |
| **Site selection and training in study procedures** | | Yes  No  N/A |
|  | If “Yes,” briefly describe site selection, qualifications, and how training will be provided. Please include how sites are selected, including factors such as: PI and key study personnel qualifications, experience, adequate resources and facilities. If “No,” please explain who will be responsible for site selection and site training. | |
| **Assuring informed consent is obtained from each participant enrolled at the participating sites** | | Yes  No  N/A |
|  | If “Yes,” describe the mechanisms tobe employed. If “N/A” or “No,” explain who is responsible for assuring informed consent is obtained at performance sites. | |
| **Tracking of serious adverse events and unanticipated problems involving risk to participants or others, reporting to participating sites and regulatory reporting** | | Yes  No  N/A |
|  | If “Yes,” describe who will be responsible for receiving and reviewing serious adverse events and unanticipated problems involving risk to participants or others reported by the participating sites. How will reports be disseminated to other participating sites, IRBs, sponsors, data safety monitoring boards and applicable regulatory agencies? If “No,” explain who will be responsible for all of the above. | |
| **Data & Safety Monitoring** | | Yes  No  N/A |
|  | Describe how the coordinating center will minimize risks to participants in relation to coordinating center responsibilities (e.g., overall monitoring and reporting, site visits, designated data safety monitor/board/committee, sharing interim safety results). | |
| **Data/Specimen Storage** | | Yes  No  N/A |
|  | If “Yes,” describe the process and tools that will be utilized in the storage of research information, including data (hard copies and electronic databases, specimens, audio/videotapes, etc.). Indicate who will have access to the research information, how participant confidentiality will be assured and describe the final disposition of the research information when the study is concluded *(e.g., will information/specimens be destroyed, transferred to the sponsor, or will the coordinating center PI maintain the information/specimens?)* Describe how codes will be generated if codes are used to protect identities, and who will have access to such codes. If a certificate of confidentiality will be provided, include the name of the person holding the certificate. If “No,” explain who will be responsible for storage. | |
| **Statistical Analysis** | | Yes  No  N/A |
|  | If “Yes,” describe who will perform the statistical analysis and the qualifications of the individual performing the statistical analysis. In addition, describe whether the analysis will involve identifiable samples/information. | |
| **Publication or Presentation of Study Results** | | Yes  No  N/A |
| **Other Coordinating Responsibilities Not Already Described** | | Yes  No  N/A |
|  | If “Yes,” describe: | |