This application is specific to the coordinating center research activities. It does not include the local site research activities which should be submitted as a separate application in PittPRO. Each site must obtain approval from their respective local IRB. This application must be uploaded into PittPRO under the Basic Information page, question #8.

Has the Coordinating Center PI assumed the responsibility for the following:

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Yes or No** | **Additional Information** |
| Design and development of the protocol and/or consent template |       | If Yes, attach the protocol and/or consent template on the Basic Information page, question #8 |
| Design and development of case report forms/data collection tools |       | Case report forms are not required to be submitted to the IRB. Data collection tools must be uploaded in PittPRO under Research Activities, question #2 |
| Randomization, registration, and/or tracking subject enrollment |       | If Yes, describe the process:       |
| Tracking, reporting, and maintaining serious adverse events, and unanticipated problems involving risks to subjects or others, and dissemination of information to all sites |       | If Yes, address the mechanism to be employed:      If No, indicate who (by role) will be responsible for this activity:       |
| Providing periodic updates to all sites on subject enrollment, study progress, amendments, and relevant scientific advances |       | If Yes, address the mechanism to be employed:      If No, indicate who (by role) will be responsible for this activity:       |
| Monitoring/auditing each site to assess study progress, protocol adherence, consenting processes, and accuracy of research records |       | If Yes, address the mechanism to be employed:      If No, indicate who (by role) will be responsible for this activity:       |
| Ensuring that the affiliated sites are using the correct version of the IRB protocol and consent documents, and maintaining IRB approval throughout the conduct of the study |       | If Yes, address the mechanism to be employed:      If No, indicate who (by role) will be responsible for this activity:       |
| Data management, including transmission, storage, and analysis |       | Address in PittPRO, Electronic Data Management section |
| Distributing or storing drugs and/or devices |       | If Yes, address the process for distribution:       If No, indicate who (by role) is responsible:       |
| Long-term storage (banking) of biological specimens |       | Address this in PittPRO by choosing “Specimens” under Study Scope and responding to the questions in the Data and Specimens section |
| Indicate other responsibilities not listed above |       |
| Describe the steps that will be taken to ensure that each external site is fully informed of study procedures and requirements prior to its initiation of research procedures. Also describe what steps will be taken to ensure regulatory compliance |       |