**Supplement Form S**

**Collaborative Research**

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| **PI Name:** | **Date:** |
| Title: | |

Complete this form if the Local Investigator is the Lead Investigator on a Multi-Center Study or if the local site is serving as the Coordinating Center for a Multi-Center Study.

1. **Collaborating Sites**

List all other sites where study activities (e.g., recruitment, enrollment, study procedures, analysis of identifiable data, etc.) will take place.

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| --- | --- | --- | --- | --- |
| **Institution** | **Name of Site Investigator or Responsible Party** | **Name of IRB** | **FWA #** | **Research Activities** |
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1. **Site Approval**

Have all sites undergone IRB review?

Yes. Please include a copy of the IRB approval letter with this submission.

No.\*

\*If no, please clarify:

The site does operate under an IRB and approval is pending

The site does operate under an IRB but review by the IRB is not required because the site’s research activities do not include human subject activities or the site is not considered engaged in the research (include documentation to support this with your submission)

The site does operate under an IRB but is requesting to cede review to [Organization] IRB. Contact information for IRB office:

Other, please explain

1. **Site Coordination**

Describe any plans for initial and ongoing training on important aspects of the protocol.

Describe the plan to manage communication of information that is relevant to the conduct of the research and the protection of human subjects, such as reporting of unexpected problems, protocol modifications, and interim results. **Note**: *For FDA-regulated clinical trials, the plan must include the plan for reporting serious adverse events or serious adverse device effects, significant new risk information, and any other reports mandated by regulation or policy.*

Describe the plan for oversight of research activities at other sites including verification of IRB approvals (initial, continuing, modifications, etc.), safety monitoring, and ensuring data quality and integrity.

**Note**: *For FDA-regulated clinical trials the plan must include the use of trained and qualified monitors to oversee the progress of the research.*