**Single IRB Intake Form**

This form is used to collect information required for Geisinger IRB to establish and provide IRB fees associated with single IRB (sIRB) review. Geisinger IRB will consider whether we are willing to serve as the sIRB and will provide a letter of support if it is determined that Geisinger IRB has the expertise and resources to fulfill this role. You are not permitted to indicate that Geisinger IRB is willing to serve as the Single IRB for other participating sites without receiving a letter of support.

**NIH (and other Grant) Funded Research**

For studies that are in the planning stage (e.g., you are preparing a grant submission), these fees generally must be included in the budget for all grant application submissions. Therefore, this form must be completed and submitted at least 4 weeks before your grant submission deadline, but we recommend submitting it as soon as possible.

For NIH grant applications, the NIH sIRB Policy only applies to non-exempt human subjects research. If your application is for multi-site research that is exempt, Geisinger IRB will not serve as the sIRB and will generally not make exempt determinations for the other sites involved in the research. The only exception is for sites that are unable to make their own determination (for instance, if the institution does not have its own IRB).

**All Other Forms of Funding (Industry Sponsor, Investigator Initiated, Non-Profit)**

For all other forms of funding, this form must also be submitted to Geisinger IRB to provide sIRB fees associated with sIRB review. Please skip the “Grant Information” section below if your multi-site study does not require a grant submission.

Please complete the information below and email this form and any available supporting documents (protocol, consent, grant application, etc.) to The GIRB Reliance Team at irbreliance@geisinger.edu.

**Contact Information**

**Geisinger Principal Investigator** **Study Contact**

Click or tap here to enter text. Click or tap here to enter text.

**Principal Investigator Department** **Study Contact E-mail**

Click or tap here to enter text. Click or tap here to enter text.

**Principal Investigator E-mail** **Study Contact Phone Number**

Click or tap here to enter text. Click or tap here to enter text.

**Principal Investigator Phone Number**

Click or tap here to enter text.

**Grant Information**

**Grant Application Title**

Click or tap here to enter text.

**Grant Short Title**

Click or tap here to enter text.

**Sponsor/Funding Agency Name**

Click or tap here to enter text.

**Grant Submission Deadline** **Anticipated Funding Date**

Click or tap to enter a date. Click or tap to enter a date.

**Study/Recruitment Details**

**Study Title**

Click or tap to enter a date.

**Approximate Recruitment Start Date**

Click or tap to enter a date.

**Will Geisinger be the Lead Site\*?**

Click or tap here to enter text.

**Will Geisinger be the Coordinating Center\*\*?**

Click or tap here to enter text.

*\* The lead site is generally the site that receives a grant or contract directly from the NIH or funding agency and then establishes a subaward or subcontract to each participating site. For studies that are not funded through a grant, the lead site is often the site affiliated with the overall study principal investigator.*

*\*\* Generally, the coordinating center is the site that directs and coordinates the activities of other participating or collaborative sites engaged in the research. Often, the coordinating center is also the lead site, but this is not always the case.*

Please provide a brief description of the proposed study and Geisinger’s role in the study. Please be specific about all interventions (e.g., investigational drug or device, behavioral, specimen collection) and participant interactions (e.g., study visits, surveys, interview, focus groups) that occur as part of the research.

Click or tap here to enter text.

**Please indicate the anticipated risk level of the study:**

[ ]  Minimal Risk\*

[ ]  Greater than Minimal Risk

\* Minimal risk means *that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of the general population or during the performance of routine physical or psychological examinations or tests* (45 CFR 46.102).

**Participating Site Information**

**Anticipated number of sites that will rely on Geisinger IRB:**

Click or tap here to enter text.

**Please complete the section below with the details for each site that will rely on Geisinger. Each legal entity must be named separately.**

|  |  |  |
| --- | --- | --- |
| Name of Relying Institution  | State | Enrolling (interacting or intervening with) Participants |
| 1. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 2. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 3. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 4. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 5. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 6. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 7. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 8. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 9. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 10. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 11. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 12. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 13. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 14. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 15. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 16. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 17. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 18. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 19. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |
| 20. Click or tap here to enter text. | Click or tap here to enter text. |  [ ]  Yes [ ]  No |

**Official IRB Use**

**Does GIRB support serving as the sIRB?**

[ ]  Yes

[ ]  No

**If no, provide rationale:**

Click or tap here to enter text.

**Anticipated study risk level** **Anticipate IRB review type**

[ ]  Minimal Risk [ ]  Exempt\*

[ ]  Greater than Minimal Risk [ ]  Expedite

 [ ]  Full Board

**sIRB fee breakdown**

Click or tap here to enter text.

**Total sIRB Cost**

Click or tap here to enter text.

**Completed by**

Click or tap here to enter text.

\*GIRB does not routinely serve as the sIRB for exempt human subjects research. Generally, the only exception is for student-based research where the student’s involvement in the research engages both Geisinger and their academic institution but no other individuals at the academic institution are involved in human subjects research activities.