**Relying Site Application**

**INSTRUCTIONS:**

This Relying Site Application should be provided to the point of contact (POC) for each relying site by the lead investigator/research team. This application must be completed and/or reviewed by a member of the relying site IRB and/or HRPP Office as well as the relying site principal investigator or other member of the relying site research team who is familiar with how the study will be conducted at the relying site.

The Relying Site Application contains both local context information specific to the study protocol, as well as research regulatory information that pertains specifically to the conduct of the research at the relying site. This document is intended to contain most of the pertinent information about the conduct of the research at the relying site that is needed for Geisinger IRB (GIRB) to ensure conduct of the research at the relying site is done in accordance with relevant regulations and meets criteria for IRB approval.

As the study is modified over time, this form will need to be revised and submitted to GIRB as part of any amendment that impacts the content of the Relying Site Application. These revisions to the application do not need to be reviewed by a member of the relying site IRB and/or HRPP Office. Should any questions or concerns arise during amendments, GIRB will request additional information.

**Data-Only Sites**- Note: If the relying site is a data-only site, Parts E, G and J do not need to be completed. Parts A, B, C, D, F, H, I, and K do need to be completed. A data-only site is a site where the engagement in research is limited to providing, receiving and/or working with data. Institutions engaged in interacting with participants are not considered data only sites and must complete the entire application.

**Part A – Relying Site Basic Information**

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

**A1.** Geisinger IRB Number:

**A2.** Protocol Title:

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

**A3.** Relying Site:

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

**A4.** Relying Site PI Name:

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

**A4.a.** Relying Site PI Phone Number:

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

**A4.b.** Relying Site PI Email:

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

**A5.** Relying Site Research Team POC (if different than the PI):

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

**A5.a.** Relying Site POC Phone Number:

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

**A5.b.** Relying Site POC Email:

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

**A6.** Where will the study be conducted? (List all locations affiliated with the relying site)

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

**A7.** Relying Site Federal Wide Assurance (FWA) Number (required for all federally funded studies).

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

**A7.a.** Has the relying site’s FWA been extended to non-federally funded research?

[ ]  Yes

[ ]  No

**A7.b.** If all sites listed in **A6.** above are not covered under this FWA, please identify those sites with separate FWAs, the corresponding FWA number and whether it has been extended to non-federally funded research.

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

**A8.** Does the Relying Site have its own IRB?

[ ]  Yes

[ ]  No

**A9.** Have there been any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past 3 years that would be relevant to the conduct of new human subjects research?

[ ]  Yes

[ ]  No

**A9.a.** If yes, please provide details.

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

**A10.** Does the relying site have a post approval monitoring program or other regulatory oversight for ongoing research?

[ ]  Yes

[ ]  No

**A10.a.** If yes, does the post approval monitoring program or other regulatory oversight monitor studies that have been deferred to an external IRB?

[ ]  Yes

[ ]  No

**A10.b.** If the relying site has a post approval monitoring program/regulatory information please provide a URL link or paste details here.

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

**Part B – Relying Site Local Context Information**

**B1.** Are there any state laws that GIRB will need to consider when reviewing this study?

[ ]  Yes

[ ]  No

**B1.a.** If yes, please provide details about any relevant state laws and include links to any key documents, such as institutional policy for applying state law or link to the statute.

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

**B2.** Are there any community or cultural differences for the local population of subjects that require consideration?

[ ]  Yes

[ ]  No

**B2.a.** If yes, please provide details.

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

**B3.** Is 18 the Age of majority for the state in which the relying site is located?

[ ]  Yes

[ ]  No

**B3.a.** If no, please identify the age of majority.

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

**B4.** Does the relying site have a posted policy for the following (check all that apply)?\* Please provide a URL link of the policy or provide details in the text box immediately below each selection below.

[ ]  Age of Assent – please provide a URL link to the policy, or provide details

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

[ ]  Consent Process for those with Impaired Decision Making Capacity

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

[ ]  Use of short forms for non-English speaking individuals

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

[ ]  Translation of consent forms for non-English speaking individuals

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

\* Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.

**Part C – Relying Site Research Team Qualifications**

**C1.** Required Education – All investigators are required to be trained in Human Subjects Research. If the relying site does not have its own training requirements, investigators from the site will need to follow the training requirements of Geisinger or follow an acceptable alternate strategy.

Please check one of the following:

[ ]  My institution has human subjects research training requirements (See details in C1.a., below) and all staff listed on this protocol have completed those requirements.

[ ]  My institution does not have our own human subjects training requirements. The requirements of Geisinger are being followed for staff listed on this study.\*

[ ]  My institution does not have our own human subjects training requirements. An acceptable alternate strategy will be followed (See details in C1.b., below)

**C1.a.** Please describe the relying site’s human subject’s protection training and education requirements for researchers and study staff and include initial and continuing education requirements.

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

Please contact Geisinger’s Office of Research Compliance at orc@geisinger.edu for instructions on Geisinger’s training requirements.

**C1.b.** Please describe the acceptable alternate strategy that will be followed at the relying site.

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

**C2.** Do all individuals at the relying site who are involved in this protocol have the appropriate credentials and/or qualifications, and meet the institution’s standards for eligibility to conduct the research?

[ ]  Yes

[ ]  No

**C3.** Do all investigators who are involved in this protocol at the relying site have adequate resources to protect human subjects?

[ ]  Yes

[ ]  No

**C3.a.** If no, please provide details.

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

**Part D – Relying Site Conflict of Interest**

**D1***.* Does the relying site have a conflict of interest (COI) policy and review process?

[ ]  Yes

[ ]  No, the relying site will rely on Geisinger’s COI review process\*

**D1.a.** If yes, please describe the relying site’s process to address conflicts of interest in the conduct of human subjects research, including how information about potential conflicts are identified, reviewed and processed by the HRPP.

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

\*If the relying institution does not have a COI policy and/or review process, the relying institution may rely on Geisinger’s review process.

**\*\*If the relying Site does not have a COI POLICY OR review process, Please skip to Part E\*\***

**D2.a**. If the relying site has a COI review process, is it compliant with [42 CFR, Subpart F](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F) for Public Health Service funded research?

[ ]  Yes

[ ]  No\*

\*If the research is PHS-funded, and the relying site does not have a compliant review process, the relying site will need to rely on Geisinger’s COI policy and review process.

**\*\*If the relying Site does not have a PHS compliant COI review process and the research is PHS-funded, Please skip to Part E\*\***

**D3.** Did the relying site determine there is a relevant individual or institutional financial COI?

[ ]  No

[ ]  Yes and the COI has been eliminated

[ ]  Yes and a management plan has been developed\*

\*Please submit all management plans with the amendment to add the relying site under GIRB approval.

**D3.a.** If yes, please provide a summary of the conflict and how it has been eliminated and/or the management plan, or attach documentation.

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

**D3.b.** If yes, please provide the name and contact information for the appropriate point of contact for questions related to the determination and/or local management plan.

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

**Part E – Relying Site Ancillary Reviews**

**E1.** Are there any site-specific ancillary reviews that could impact the IRB review and/or approval at your site and need to be addressed by the reviewing IRB?

[ ]  Yes

[ ]  No

**E1.a.** If yes, what is the current overall status of review and approval by the applicable ancillary committee(s)?

[ ]  Pending

[ ]  Complete

**E1.b.** If yes, please provide details (i.e., outcome, anticipated date of review) or attach documentation

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

**Part F – Relying Site Research Engagement**

**F1.** Please identify the research activities occurring at the relying site (select all that apply):

[ ]  Direct recipient of federal funds

[ ]  Recruitment of participants

[ ]  Enrollment of participants

[ ]  Research intervention with participants (only select if the study involves an intervention)

[ ]  Research interactions with participants

[ ]  Data collection\*

[ ]  Receiving Data\*

[ ]  Analysis of data\*

[ ]  Other – Please describe:

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

\*If the participating site is a **data-only sites**, please proceed to and complete Parts I, K and L

**Part G – Relying Site Screening, Recruitment and Consent**

**G1.** Please clearly describe how eligible participants are identified at the relying site.

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

**G2.** Please clearly describe the initial contact and/or recruitment plan of eligible participants at the relying site. Please be specific and describe any institutional requirements as well as who (e.g. research assistants, study coordinators, investigators, etc.) will be involved in participant recruitment.

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

**G3.** How will informed consent be obtained at the relying site?\*

[ ]  Written Informed Consent

[ ]  Waiver of Documentation of Consent

[ ]  Waiver of Consent

[ ]  Alteration of Consent, please describe

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

If multiple selections were made, please explain:

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

\* Note, if different than what GIRB has approved for other sites, additional justifications may need to be provided. Please review the GIRB initial approval letter to see what has been approved.

**G4.** Will informed consent be obtained using a Legally Authorized Representative for any participant populations involved in the research?

[ ]  Yes

[ ]  No

**G4.a.** If yes, please provide details.

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

**G5.** Will non-English speaking participants be enrolled in the research at the relying site?

[ ]  Yes

[ ]  No\*

\*If non-English speaking participants are not being enrolled at the relying site, please skip to **G6.**

**G5.a.** If yes, how will non-English speaking participants be enrolled?

[ ]  Translated Consent Document\*

[ ]  Short Form Consent Process (See details in G5.b., below)

\* All translated consent documents along with translation certificates need to be included in the submission to add the relying site

**G5.b.** Please specify the Short Form Consent Documents to be used:

 [ ]  Existing Geisinger Short Forms (already approved for use)

[ ]  Other\* - Please describe:

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

\* Requires submission to GIRB for review and approval

**G6.** Please provide any institutionally-required consent form language for compensation in the event of research-related injury:

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

**G7.** Please provide any institutionally-required consent form language for pregnancy testing in minors:

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

**G8.** Please provide any institutionally-required consent form language for genetic testing:

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

**G9.** Please provide any other consent form language required by site policy or state law:

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

**G10.** Are participants being compensated for participating in the research at the relying site?

[ ]  Yes

[ ]  No

**G10.a.** If yes, please provide details, including the type of compensation, the amount of compensation and the frequency of compensation.

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

**Part H – Relying Site Protocol Specific Details**

**H1.** Based on the research activities described in the protocol and associated documents, will the relying site be engaged in all described activities?

[ ]  Yes

[ ]  No

**H1.a.** If no, please describe the research activities limited to the relying site.

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

**H2.** Are there any changes required to the study plan related to the available resources at your site?

[ ]  Yes

[ ]  No

**H2.a.** If yes, please provide details.

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

**H3.** Do local requirements or state laws stipulate any other requirements for the implementation and/or conduct of the protocol at your site that differ from those described in the protocol or associated documents?

[ ]  Yes

[ ]  No

**H3.a.** If yes, please provide details.

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

**H4.** Will drug and/or device storage be managed centrally by a pharmacy at the organization?

[ ]  Yes

[ ]  No

[ ]  N/A

**H4.a.** If no, please provide details.

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

**H5.** Given the nature of this particular research study, is there any local context (i.e. any additional factors particular to this study or the community, such as community attitudes, ethnic diversity, language, etc.) that may contribute to the acceptability of this research in your area?

[ ]  Yes

[ ]  No

**H5.a.** If yes, please provide details.

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

**Part I – Relying Site HIPAA Determinations**

**I1.** Is Geisinger making HIPAA determinations on behalf of the relying site?

[ ]  Yes, please continue with completing the remainder of this section

[ ]  No, please skip to **Part J\***

\* Select “No” if study does not involve patients and/or their protected health information

**I2.** Please identify the HIPAA determinations that are required for the research at the relying site.\*

[ ]  Partial Waiver for Screening and Recruitment

[ ]  Alteration of HIPAA to get Verbal Authorization

[ ]  Alteration Other – Please describe:

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

[ ]  Full Waiver of HIPAA Authorization

**I3.** How will HIPAA Authorization be obtained?\*

[ ]  Signed and Dated/Written Authorization

[ ]  Verbal Authorization

[ ]  Authorization is not being obtained

[ ]  Other – Please describe

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

If multiple selections were made, please explain:

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

\* Note, if different than what GIRB has approved for other sites, additional justifications may need to be provided. Please review the GIRB initial approval letter to see what has been approved.

**I4.** What type of HIPAA Authorization Form will be used at the relying site?

[ ]  Standalone HIPAA Authorization Form

[ ]  Combined HIPAA Authorization and Consent Form

[ ]  All of the relying site’s research activities are conducted under a waiver of HIPAA Authorization

**Part J – Relying Site Vulnerable Populations\***

\*Geisinger does not review research enrolling prisoners.

**J1.** Will vulnerable populations be enrolled into the research at the relying site?

[ ]  Yes

[ ]  No\*

\*If vulnerable populations are not being enrolled at the relying site, please skip to **Part K**

**J2.** Please identify the vulnerable populations to be enrolled at the relying site.

[ ]  Minors

[ ]  Pregnant Women/Fetuses

[ ]  Students

[ ]  Employees

[ ]  Decisional Impairment

[ ]  Economically Disadvantaged

[ ]  Educationally Disadvantaged

[ ]  Other – Please describe

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

**J2.** Do local requirements or state laws stipulate requirements for enrolling vulnerable populations at your site that differ from those described in the protocol or associated documents?

[ ]  Yes

[ ]  No

**J2.a.** If yes, please provide details.

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

**J3**.Please describe the additional protections in place to ensure the safety of any vulnerable populations being enrolled at the relying site.

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

**J4**.If adults with decisional impairment will be enrolled, will they have (check all that apply):\*

 [ ]  Temporary Decisional Impairment

 [ ]  Chronic Decisional Impairment

\*Skip to **question J6** below if adults with decisional impairment are not being enrolled at the relying site.

**J5.** Will consent be obtained from a Legally Authorized Representative?

[ ]  Yes

[ ]  No

**I2.a.** If yes, please describe the plan to assess the competency of the subjects.

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

**I2.b.** If no, please provide details.

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

**J6.** How will parental permission be obtained at the relying site?\*

**\*\*If Minors are not being Enrolled at the relying site, please skip to Part K\*\***

[ ]  Written Parental Permission

[ ]  Waiver of Documentation of Parental Permission

[ ]  Waiver of Parental Permission

[ ]  Alteration of Parental Permission, please describe

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

If multiple selections were made, please explain

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

**J7.** How will assent be obtained at the relying site?\*

[ ]  Written Assent

[ ]  Waiver of Documentation of Assent

[ ]  Waiver of Assent

If multiple selections were made, please explain

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

\* Note, if different than what GIRB has approved for other sites, additional justifications may need to be provided. Please review the GIRB initial approval letter to see what has been approved.

**Part K – Relying Site Data Confidentiality**

**K1.** Only IRB approved study personnel will have access to the data at the relying site:

[ ]  Yes

[ ]  No

[ ]  If no, please explain

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

**K2.** Do local requirements or state laws stipulate requirements for how data will be accessed and/or shared at your site that differ from those described in the protocol or associated documents?

[ ]  Yes

[ ]  No

**K2.a.** If yes, please provide details.

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

**K3.** How will the confidentiality of the data be maintained at the relying site? What securities and provisions are in place to limit access to the data?

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

**K4.** Will the relying site receive any data for research purposes, such as for data analysis?

[ ]  Yes

[ ]  No

**K4.a.** If yes, please identify the type of data that the relying site will receive:

[ ]  Fully identifiable data set

[ ]  Limited data set

[ ]  De-identified data set

[ ]  Aggregate data set

If multiple selections were made, please explain

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

**K5.** Will the relying site disclose data outside of the relying institution (including sharing data with the study sponsor or the lead site/coordinating center)?

[ ]  Yes

[ ]  No (Skip to **Part L**)

**K5.a.** If yes, please identify all individuals, groups and entities to which the relying site will disclose data

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

**K5.b.** Please identify the types of data that the relying site will disclose:

[ ]  Fully identifiable data set

[ ]  Limited data set

[ ]  De-identified data set

[ ]  Aggregate data set

If multiple selections were made, please explain

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

**K5.c.** Please describe the secure method that will be used to transmit the data.

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

**Part L – Relying Site Personnel Completing this Relying Site Application**

**L1.** Individual from the relying site IRB/HRPP Office who has completed and/or reviewed the information in the completed application for accuracy.

Name

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

Job Title

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

Email address

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

Phone Number

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

**L2.** Individual from the relying site research team who has completed and/or reviewed the information in the completed application for accuracy.

Name

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

Job Title

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

Email address

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

Phone Number

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| Click or tap here to enter text. |