**Relying Site Continuing Review Form**

**INSTRUCTIONS**

The lead site Principal Investigator\* (or designee) is responsible for compiling all necessary information from each relying site and submitting it to GIRB on a Continuing Review Form in iRIS. The Relying Site Continuing Review Form gives the GIRB specific details about the research activity at each relying site and helps the lead investigator collect and organize the information necessary for submitting the continuing review**.** The Relying Site Continuing Review Form should be completed by each relying site lead investigator (or designee) and submitted by the lead site Principal Investigator as an attachment to the Continuing Review Form in iRIS. The information compiled on this form should be specific to the relying site, not cumulative between all sites. Each site requires its own form.

See the “Continuing Review Section” of the *Geisinger IRB Investigator’s Guide for Geisinger Serving as the Single IRB* for specific instructions on completing the main Continuing Review Form in iRIS.

When the first Continuing Review Form is submitted, each Relying Site Continuing Review Form should be uploaded as a new study document in iRIS. It is recommended to clearly title the document when uploading to iRIS (e.g., 2022 Continuing Review Form for [site name]). For each subsequent continuing review, Relying Site Continuing Review Forms must be checked-in using the check-in/checkout function in iRIS, to make use of the document library and keep the files organized. All continuing reviews should be submitted in iRIS no later than 30 days prior to the study’s expiration date. GIRB recommends submitting continuing review forms at least 60 days prior to the study’s expiration date.

If you need assistance completing this form, please contact the Geisinger IRB Office at irbreliance@geisinger.edu.

\* In most cases, the lead site Principal Investigator is the Geisinger Principal Investigator. Some exceptions may include when GIRB is the sIRB but Geisinger is not the lead site or is not a participating site in the research.

Part A – Basic Information

|  |
| --- |
| 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. |

A5. Name of individual completing this form:

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

Part B – Recruitment and Enrollment Details

**B1**. Please provide a summary of the study activity at the relying site over the past approval period. If there hasn’t been any activity, please indicate why.

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

**B2.** Is the study closed to enrollment at the relying site?

[ ]  Yes

[ ]  No

**B3.** Please provide the applicable number of subjects from the start of the study at the relying site. Please pay close attention to the definitions below in **Part D**.

**B3.a.** Number of individuals contacted for the research

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

**B3.b**. Number of participants **screened** for the research at the relying site:

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

**B3.c.** Number of participants who were **screen failures** at the relying site:

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

**B3.d.** Number of participants **enrolled** at the relying site:

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

**B3.e**. Number of participants **withdrawn** at the relying site:

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

 **B3.e.1.** Please provide an explanation for each participant withdrawn:

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

**B3.f.** Number of participants deceased at the relying site. Only provide for studies that involve participant interaction:

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

**B2.h.** Number of participants that have completed all study related activities at the relying site:

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

Part C – Additional Information

**C1.** Over the past review period, were there any participant complaints received at the relying site?

[ ]  Yes

[ ]  No

 **C1.a.** If yes, please provide details and the outcome of all complaints

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

**C2.** Summarize any unanticipated problems that occurred at the relying site since the last continuing review

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

C3. Have there been any protocol deviations over the past review period?

[ ]  Yes

[ ]  No

**C1.a.** If yes, please provide an overview or submit a spreadsheet detailing the deviations

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

**Part D** – Definitions

**Screened**

* For research without participant interaction (such as chart review studies or studies conducted under a waiver of consent), individuals whose identifiable information and/or biospecimens are used to determine who may potentially be eligible to be included in a study.
* For research studies with participant interaction, individuals who have given informed consent and participated in screening procedures to determine eligibility. Note that informed consent is required before any screening procedures are conducted. If the research does not involve screening procedures based on this definition, enter “0”.

**Screen failures**

 Individuals who gave informed consent and participated only in screening procedures to determine eligibility, but who also were determined to be ineligible to take part in the study. Screen failures are not considered to have enrolled in the study and should only be reported for studies with participant integration.

**Enrolled:**

* For research without participant interaction, individuals whose identifiable information and/or biospecimens are eligible for inclusion and have been used in the study evaluation.
* For research studies with participant interaction, individuals who are eligible for participation, have given informed consent (if applicable) completed the procedures that determine eligibility (if applicable) and participated in some or all of the study procedures. This includes:
	+ Participants who stopped active study treatment but continue to allow study-defined procedures such as study visits, lab tests, x-rays questionnaires and data collection
	+ Participants who stopped all active participation but allow ongoing follow-up such as data collection from standard of care visits, tests, procedures follow-up to access survival status.

**Withdrawn**

* For research without participant interaction, individuals who were considered enrolled whose information was withdrawn from use in the study evaluation for some reason.
* For research studies with participant interaction, individuals who have given informed consent and participated in some study procedures, but who withdrew or were withdrawn from the study. No further data is collected about the individual. There are two main types of withdrawals:
	+ Active withdraw with no continued follow-up: participant or investigator initiates a formal complete withdraw from study (e.g., participant indicates they wish to withdraw themselves or investigator removes participant due to a reason.
	+ Passive withdraw: informal withdrawal where an enrolled participant does not continue participating in study activities but does not communicate this to the study team (e.g. lost to follow-up)