# Guidance: Requirements when a Researcher Leaves Geisinger but Will Continue Working on a Study

## Definitions

**Exempt Research** – human subject research that presents no greater than minimal risk to subjects and fits into one or more exempt categories at 45 CFR Part 46.104

**GIRB** – Geisinger Institutional Review Board

**Human Subject** – means a living individual about whom an investigator conducting research:

i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

**Human Subjects Research (HSR)** – Research that involves human subjects

**iRIS** – The online, electronic system used by GIRB to receive research application and protocol submissions, review and provide determinations and approvals, and provide continued oversight for human subjects research

**Key Study Personnel (KSP)** – Research personnel who are responsible for the conduct of human subjects research

**Reliance Agreement** – An agreement between two or more institutions that are engaged in human subjects research, which economizes the IRB review and approval process by limiting the IRB review to only one institution's IRB. The agreement documents the respective authorities, roles, responsibilities, and communication between the institution/organization providing the IRB review and the relying participating sites

**Research** – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

**Reviewing IRB** – The IRB that is responsible for the regulatory review, approval, and continuing oversight of human subjects research at a particular site

**Single IRB** – The IRB that has been selected to carry out the IRB review requirements for participating sites involved in multi-site research. For multi-site research, the sIRB is the reviewing IRB.

## Introduction

Frequently, Geisinger investigators engaged in human subjects research leave Geisinger for other institutions but want to continue working collaboratively on a study with the remaining Geisinger researchers after their departure. This common occurrence can be challenging to navigate without specific guidance on the necessary steps that need to be taken in order to formalize this new working relationship. The purpose of this guidance is to help researchers navigate this scenario and to outline the steps that need to be taken.

One of the keys to properly manage this situation is to ensure that the individual leaving Geisinger engages the appropriate people at his/her new institution and satisfies all requirements of their new institution. When investigators leave Geisinger, it is their responsibility to ensure they are following the applicable processes of their new institution, such as obtaining IRB approvals or exempt determinations, research determinations, and ceding determinations.

## Scenarios

There are two scenarios that determine the steps that need to be followed when a Geisinger researcher leaves the institution but will continue working on a study:

1) Individual leaving will be engaged in human subjects research at their new institution
2) Individual leaving will not be engaged in human subjects research at their new institution

The necessary processes for each are outlined below.

### 1) Researcher leaving will remain engaged in human subjects research at his/her new institution

When the researcher leaving Geisinger will remain engaged in human subjects research at his/her new institution, there are two pathways that can be followed, which are outlined below.

Note that the decision on the appropriate pathway should be based upon input from the study principal investigator, representatives from the external site's Institutional Review Board (IRB) and/or Human Research Protection Program (HRPP) and Geisinger IRB (GIRB).

### A. The researcher's new institution enters into an IRB reliance agreement with Geisinger and GIRB becomes the single IRB (sIRB)

Most IRBs, including GIRB, assess reliance requests on a case-by-case basis to ensure that they are appropriate and acceptable, and in some cases, to ensure that relying on anther IRB is the most effective and efficient way for a multi-site study to move forward.

If the researcher is only engaged in exempt human subject research at his/her new institution and the new institution prefers to cover the research activities under an exempt determination, the IRB of record for the new institution will need to make an exempt determination. GIRB will not make exempt determinations for (or extend current exempt determinations to) other institutions since single IRB requirements take longer to fulfill and require more time and effort than simply requiring the new institution make its own exempt determination.

If the overall study is non-exempt, but the researcher's new institution is only engaged in exempt human subjects research, upon request, GIRB will consider reviewing and approving the researcher's new institution as a site for the research. Such review will occur under GIRB's single IRB process in accordance with GIRB's single IRB requirements and will be considered part of the approval for non-exempt human subjects research.

If it is determined to be appropriate for GIRB to cover IRB review and approval for the researcher's new institution, the researcher's new institution must enter into an IRB reliance agreement with Geisinger to designate GIRB as the sIRB and the IRB of record for the study. This route requires all steps and requirements for GIRB's sIRB process to be followed and met (including coverage of sIRB fees for costs associated with sIRB review). External study personnel should be included on the Geisinger study application in accordance with GIRB's sIRB requirements. In addition to all IRB requirements, Security Compliance and Privacy (SCP) review and all other necessary agreements, such as data use agreements and material transfer agreements need to be executed prior to sharing any data or samples.

### B. The IRB for the researcher's new institution conducts IRB review and provides approval to cover the human subject research activities for which the researcher is engaged at his/her new institution

Under this scenario, the IRB of record for the new institution will need to review and approve the human subjects research activities occurring at the researcher's new institution. The researcher leaving Geisinger must be removed as Key Study Personnel (KSP) from section 3.0 of GIRB's iRIS study application. The study protocol and the section of the study application that addresses data disclosure should be updated as

applicable. If data or samples are being shared, the name of the external individual who will receive the data and the institution he or she is affiliated with needs to be added to the application. In addition to all IRB requirements, Security Compliance and Privacy (SCP) review and all other necessary agreements, such as data use agreements and material transfer agreements need to be executed prior to sharing any data or samples.

### 2) Researcher leaving will not be engaged in human subjects research at his/her new institution

It is the responsibility of the researcher leaving Geisinger to make sure that he/she complies with all requirements of the new institution. Determinations around engagement in research should generally not be made by GIRB or the Geisinger investigator. They should be made through the appropriate pathways (if any) established at the individual's new institution.

When a Geisinger researcher working on a study leaves Geisinger but will continue working on the study at his/her new institution and the continued work on the study does not engage the new institution in human subjects research, an amendment is required to remove the individual form Section 3.0 of the Geisinger study application so that he or she is no longer listed as key study personnel. When data or specimens are being sent to this individual, the section of the study application that collects information about data disclosure as well as the study protocol (when applicable) should be updated to include the name of the non-Geisinger individual who will receive the data and/or specimens and the name of the institution the individual is affiliated with. Documentation of SCP review is required, in addition to the execution of any required agreements prior to sharing any data or specimens.

## Conclusion

GIRB iRIS study applications are specifically intended for GIRB to ensure human subjects research is compliant with federal research regulations, state, and local laws, as well as institutional policies. When GIRB is not the reviewing IRB for a non-Geisinger institution, GIRB has no responsibility to monitor or evaluate training, conflict of interest reporting or study personnel qualifications for non-Geisinger personnel engaging another institution in research. Likewise, when non-Geisinger researchers are not engaging their institution in human subjects research, GIRB has no oversight authority or responsibilities related to non-Geisinger researchers. Removing researchers from study applications when they leave Geisinger helps ensure that appropriate regulatory requirements and processes are being followed both at Geisinger and other institutions.

## Flow Chart

Requirements when a researcher leaves Geisinger and will continue to work on a study