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| IRB Policy #: | 120 |
| Policy Title: | <i>Protocol Transfer to New Principal Investigator</i> |
| Date Approved: | August 12, 2022 |
| Date Reviewed: | |

Purpose: The purpose of this document is to describe available options and next steps for transferring the duties and responsibilities of the approved Principal Investigator (PI) duties to a new PI or terminating the investigation.

Definitions:

Investigator: The HHS regulations at 45 CFR part 46 use the term “investigator” to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB¹.

Principal Investigator (PI): One investigator is designated the “principal investigator” with overall responsibilities for the study².

Policy:

When a PI on a Southern Illinois University Carbondale approved IRB protocol relinquishes affiliation with the university the PI no longer has this institution’s approval to continue their study and must either identify a new PI who will accept responsibility for the study in its entirety, including those actions taken before assuming the role of the PI, or close the study rather than transfer it to a new PI.

When a PI on a Southern Illinois University Carbondale approved IRB protocol either wishes to or is required to relinquish principal responsibility for an approved IRB protocol, the current PI must either identify a new PI who will accept responsibility for the study in its entirety, including those actions taken before assuming the role of the PI, or close the study rather than transfer it to a new PI.

When transferring PI responsibility to a new PI, the following is required:

- A written statement of transfer from the current PI and statement of acceptance from the new PI.
 - The new PI must meet eligibility requirements as defined under IRB policy #110 (Who can serve as a PI).
 - The new PI must have access to all current and previous regulatory and participant documentation, as applicable.
- Revisions to the current study documents to update PI name and contact information.
- A modification submission to change the PI.

The study may also be closed rather than transferred to a new PI. Please see the IRB website and file the Protocol Close-Out Form (a fillable pdf).

Additional considerations may apply for grant funded projects. Questions regarding how the transfer of an IRB protocol might impact a grant should be directed to the Office of Sponsored Projects.

I. References

1. U.S. Department of Health and Human Services, <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html>
2. Ibid.