

Responsibilities of the Principal Investigator for Research in Progress

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Policy Statement

The Principal Investigator of a human research protocol is the individual with ultimate responsibility for the conduct of the study and for protecting the rights and welfare of research subjects. The Principle Investigator must agree to comply with all UIW policies and procedures concerning the protection of human subjects in research.

Description and Procedures

A. Principle Investigator Responsibilities

The final letter of approval sent to the principal investigator outlines the continuing responsibilities that the investigator has to the IRB while the research is being conducted.

These responsibilities include

1. conducting the study only according to the protocol approved by the IRB;
2. submitting any change(s) to the protocol and/or consent document(s) to the IRB for review and approval prior to the implementation of the change(s);
3. ensuring that only persons formally approved by the IRB enroll subjects;
4. reporting immediately to the IRB any unanticipated problems involving risks and protocol deviations;
5. reporting immediately to the IRB the death of a subject, regardless of cause;
6. reporting promptly to the IRB any significant findings that become known in the course of the research that might affect the willingness of subjects to participate in the study or, once enrolled, to continue to take part;
7. timely submission of an annual status report;
8. completion and maintenance of an active (non-expired) CITI human subjects training certificate; and
9. timely notification of a project's completion.

B. Terminating Faculty or Staff

If a principal investigator leaves a project or leaves the University and the project is an institutional project, the IRB must be informed of the new principal investigator or termination of the research.

For those studies being discontinued when the principal investigator leaves, a formal, written final report must be filed with the IRB. If available, the original PI should submit this document. If not

available, co-investigators will need to do this. If no one is available, the College/School IRB Representative or chair will submit.

Effective Date

August 24, 2020

Revision History

References

Review of Amendments

Required Reporting of Unanticipated Problems and Protocol Deviations

Continuing Review