

Researcher/Investigator Responsibilities

Introduction

The principal/responsible investigator is ultimately responsible for the conduct of the study, for assuring compliance with IRB policies and procedures and federal regulations and for protecting human subjects. Even though a principal investigator may delegate specific tasks to other members of the research team or if the study is primarily student driven, he or she cannot delegate the responsibility for ensuring that those tasks are completed according to institutional and federal regulations. The responsibilities included in this policy may include responsibilities that may not apply to all principal investigators.

Definitions

Research: As defined by DHHS, any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject: As defined by DHHS: a human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains either data through intervention or interaction with the individual, or identifiable private information. As defined by FDA: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A subject is also an individual on whose specimen a medical device is used.

Intervention: Includes both physical procedures by which data are gathered (e.g., fMRI, attaching leads, etc.) and manipulations of the subjects' environment that are performed for research purposes.

Interaction: Includes communication or interpersonal contact between an Investigator or his/her research staff and the research participant.

Private information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, an educational record).

Individually identifiable: means that the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Responsible or Principal Investigator: The person responsible for the conduct of a human research study at one or more sites, whether on- or off-campus. If the human research study is conducted by a team of individuals, the responsible/principal investigator is the responsible leader of the team. The responsible/principal investigator is held accountable for ensuring that

the team complies with all rules and regulations and engages with human subjects properly and ethically.

Co-Investigator: An individual involved with the principal investigator in the scientific development or execution of a project. A co-investigator typically devotes a specified percentage of time to the project.

Key Personnel: Other individuals who contribute to the scientific development or execution of a research project in a substantive way.

Policy

The primary responsibility of the principal investigator is to acknowledge and accept the responsibility and ethical obligations for protecting the rights and welfare of human research participants in compliance with current federal regulations and IRB requirements governing human subject research.

To serve as the principal investigator on an IRB protocol, he or she must also meet all of the following criteria:

- CREC-certified
- CWRU Faculty member
 - Faculty has to be classified as such by the University's Human Resources Department as reflected in the Faculty Senate Handbook.
 - At the discretion of the IO, he or she may determine whether a researcher, not defined as a faculty member, is able to serve as the principal investigator on a case by case basis.

Note: Even if a study is student-driven, students cannot act as principal investigators, they can only be listed as a co-investigator or research staff/assistant. This applies to all levels of students, undergraduate and graduate.

If the principal investigator is not CREC-certified, another CWRU faculty member who is CREC-certified must be identified as the new principal investigator. It is the responsible investigator's responsibility to ensure that student co-investigators as well as research staff working with identifiable data are properly trained and CREC-certified. The responsibilities of the all primary/responsible investigators, when conducting human subject research, include compliance with:

- DHHS regulations governing human subject protections as outlined in the CWRU Federalwide Assurance (FWA) with OHRP. As part of this agreement with the federal government, CWRU commits to following the Terms of Assurance ([45 CFR 46](#)). The Terms of Assurance are contained in a document on the CWRU website.
- CWRU IRB policies and procedures
- State and Local laws and regulations

Investigator Responsibilities

The principal investigator is the ultimate protector of the research participant's rights and safety. He or she is obligated to:

1) Ensure that all Human Subjects' Research Receives IRB Approval in Writing or a Determination of Exemption before the Research Starts

Investigators may not initiate research involving human subjects without prior IRB review and approval. If data are collected for non-research purposes and an investigator later finds that the data could contribute to generalizable knowledge, the investigator must submit a proposal to the IRB for review and approval prior to research analysis, publication or presentation of the data (e.g., thesis, dissertation, journal article, poster session, public speech or presentation, or project report). It is in the investigator's best interest to consider carefully the likelihood that he or she will want to use data for research purposes in the future, and to seek IRB approval prior to commencing the work.

The implications of engaging in activities that qualify as "human subject research" review without obtaining prior IRB review and approval are significant. Results from such studies may not be published or presented unless IRB approval had been obtained prior to collecting the data. To do so is in violation of CWRU IRB Policy and the investigator would be classified as non-compliant. It is also against CWRU IRB policy to use inappropriately collected human subject research data to satisfy thesis or dissertation requirements. Investigators should seek HRPP or IRB assistance when in doubt about whether proposed research requires IRB review.

Investigators must comply with all IRB decisions, conditions, and requirements and ensure that protocols receive timely continuing IRB review and approval.

2) Ensure that All Information Provided to the IRB is Accurate and Complete so that the IRB may Fulfill its Responsibilities to Review the Research and Make the Required Determinations.

Investigators should incorporate into the research plan a plan to ensure the just, fair, and equitable recruitment and selection of subjects. When some or all of the subjects are likely to be special or vulnerable populations, such as children, prisoners, pregnant women, students, mentally disabled persons, or economically or educationally disadvantaged persons, the study plan should include additional safeguards in the study to protect the rights and welfare of these subjects. The investigator should ensure that the language in the consent form is consistent with that in the protocol/study plan.

3) Develop a Research Plan that is Scientifically Sound and Minimizes Risk to the Subjects.

Investigators should ensure that the research plan includes adequate provisions for the monitoring of subjects and data to ensure the safety of subjects and that there are adequate provisions to protect the privacy interests of subjects. The study plan should contain adequate provisions to protect the confidentiality interests of subjects, including an information security plan that considers the collection, storage, maintenance, analysis, and transmission of data and other identifiable information. The investigator should have a procedure to receive questions, complaints, or requests for additional information from

subjects and a process to respond appropriately. All unanticipated problems, deviations, complaints, non-compliance, suspensions, terminations, and any other events must be reported to the IRB per CWRU policies especially if information becomes available that suggests a change to the potential risks or benefits of the research.

- 4) **Have Sufficient Resources Necessary to Protect Human Subjects, Including:**
 - a. Access to a population that would allow recruitment of the required number of subjects;
 - b. Sufficient time to conduct and complete the research;
 - c. Adequate numbers of qualified staff;
 - d. Adequate facilities;
 - e. Necessary equipment;
 - f. A plan to ensure proper supervision of the research including a plan for periods of absence or decreased availability;
 - g. Availability of medical, psychological, or other support that subjects might require during or as a consequence of their participation in the research.

- 5) **Complete Financial and Contractual Requirements and Required Institutional Approvals Before the Research Begins**

Investigators may not initiate research without executing all federal and state requirements, as well as all agreements and prerequisites set forth in a grant or contract that is to be completed prior to the conduct of research. Investigators must ensure that all research involving human subjects is reviewed by other experts (scientific review) and CWRU components and committees as applicable to the research. This includes filing an annual outside interests certification disclosure for the investigator and all study staff.

- 6) **Conduct Study In Accordance with the Ethical Principles in *The Belmont Report* and the Approved Protocol and Consent**

The principal investigator must not institute any changes to the IRB-approved protocol and/or consent form document without first obtaining IRB approval for such changes (i.e., research instruments/questionnaires, recruitment materials etc.). If the principal investigator is conducting sponsored research, the study sponsor must also be notified of an investigator's intent to modify the protocol or consent form. **In rare instances, an investigator may deviate from the protocol without first notifying the IRB in order to eliminate immediate hazard to a study participant. Any such protocol deviations must be promptly reported to the IRB via a protocol deviation form via the iRIS electronic system.** Failure to comply with this requirement can result in an allegation of non-compliance. Documentation surrounding the event should also be placed in the research record and the medical record if applicable.

- 7) **Personally Conduct or Supervise the Study**

Principal/Responsible Investigators may delegate research responsibility; however, they must maintain oversight and they retain ultimate responsibility for the conduct of those to

whom they delegate responsibility. It is the responsibility of the principal investigator to inform all study staff including co-investigators, research nurses, coordinators, etc. about the protocol and consent form. The principal investigator is ultimately responsible for the conduct of the study. It is the responsibility of each investigator to assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified under the laws of Ohio and the policies of CWRU to perform them.

Every member of the research team is responsible for protecting participants in research. Co-investigators, study coordinators, research assistants, and all other research staff have a strict obligation to comply with all IRB determinations and procedures, to adhere rigorously to all protocol requirements, to inform investigators of all serious and unexpected adverse reactions or unanticipated problems involving risk to participants or others, to oversee the adequacy of the informed consent process, and to take whatever measures are necessary to protect the safety, rights and welfare of participants. Regardless of involvement in research, each member of the research team is responsible for notifying the IRB promptly of any serious or continuing noncompliance with applicable regulatory requirements or determinations of the designated IRB of which they become aware, whether or not they are directly involved in the research.

The principal investigator should assure that all study personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based and assure that all persons assisting with the research are adequately trained and informed about the protocol and their specific duties and functions. When delegating authority, the investigator should provide all co-investigators, and research staff with a copy of the current research protocol and consent form and fully inform them of:

- Study procedures (including modifications to the protocol).
- Informed consent/assent requirements and process.
- Potential risks associated with study participation and the steps to be taken to prevent or minimize these potential risks.
- Data and safety monitoring plan
- Adverse event reporting requirements.
- Data and record-keeping requirements.
- Current IRB approval status of the study.

In addition to assuring that the site and facility are trained and prepared to initiate and implement the research, documentation of such training must be obtained and maintained. The principal investigator must also ensure that, if the protocol lists collaborating investigators at another institution, appropriate IRB approval for the study has been obtained at the other institution. It is also the responsibility of the principal investigator to be aware of any conflicts of interest for any members of the study team.

8) Recruit Subjects in an Ethical Manner

The recruitment of subjects must respect the research subject's right to privacy and data confidentiality. An investigator should not contact his or her own patients, clients or

students unless the investigator has obtained the proper IRB approval and if the investigator has provided the IRB with a clear and thorough plan to prevent coercion and undue influence, for example, by having a department assistant recruit and consent the investigator's students (investigator is not in the classroom), and then retain the consent forms until after final grades have been completed.

9) Ensure That the Requirements for Obtaining Informed Consent Are Met

The principal investigator for an IRB-approved study is ultimately responsible for the conduct of the study including the entire informed consent process and the instruction and oversight of individuals who may be involved in this process. It is the principal investigator's responsibility to oversee the informed consent process, making sure that each potential subject fully understands the purpose of the research, the research procedures, the potential risks of study participation, and his or her rights as a research study volunteer. No human subject may be involved in research prior to obtaining their consent or, if approved by the IRB, obtaining consent/permission from their legally authorized representative, unless a waiver of the requirement has been approved by the IRB. The principal investigator is also required to include appropriate additional safeguards in the study to protect research subjects who are likely to be vulnerable to coercion or undue influence. It is the principal investigator's responsibility to assure that potential subjects have the cognitive ability to give consent. If the responsible investigator cannot determine cognitive abilities, he or she is responsible to find someone with the appropriate qualifications to make that determination.

The principal investigator does not have to obtain consent personally. The principal investigator may delegate this authority to a study team member. The requirements for consent designees include:

- They must be listed in the IRB protocol and approved as a person who may obtain consent.
- They must be CREC-certified.
- These individuals must be knowledgeable about the study and capable of answering study-related questions posed by the potential participant.

The principal investigator must ensure that each of these requirements are met and documented prior to the designee obtaining consent. If this responsibility is designated to a co-investigator, this should be clearly described in the protocol and IRB application.

10) Maintain a Protocol File of Human Research Project Documents

The principal investigator must maintain documentation of research regulatory documents and other essential document of the human subject's research project. At minimum, the regulatory file must include the following items:

- A copy of all IRB approvals and acknowledgements including, new protocol approvals, amendments, continuing reviews, protocol deviations, and adverse events.
- A copy of the federal grant application (if applicable).

- A copy of the consent form with the IRB stamp and expiration date. A copy of all correspondence with the IRB, or others. Other essential documents include the following items:
 - A copy of all data derived from the study (case report forms, computer data, adverse event reports, etc.)
 - All pages of the original consent, assent, and HIPAA Authorization form signed by each participant enrolled in the research (if applicable).
 - For studies involving procedure completed while the participant who is a patient or program client, the investigator is responsible for ensuring that a copy of the consent form is in the patient's record.

11) Comply with Federal and Institutional Time periods for Record Retention

The principal investigator is required to retain records associated with a human subject's research project depending on contractual agreements, funding source requirements or regulations. The data stored must be kept in a secure, protected manner. If electronically stored, the investigator is to take all precautions such as using passwords to access a non-integrated server, an iron key, or external hard drive.

12) Respond To Subjects Who Have an Adverse Event

The principal investigator must ensure that subjects who have suffered an adverse event associated with research participation be directed to receive adequate care as reflected in the informed consent document to alleviate the consequences of the adverse event.

13) Keep Subjects Fully Informed of any New Information

The principal investigator must ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the study

14) Provide Timely Reports to the IRB as required

Any protocol deviation must be reported via iRIS immediately upon learning of the deviation. The principal investigator must respond promptly to all requests for information or materials solicited by the IRB, including the timely submission of the research study for IRB continuing review.

15) Make Records Available for Inspection

Investigators are required to make research records available for audit by the CWRU IRB and any other CWRU office as required by IRB and institutional policies, the CWRU Institutional Compliance office and any other CWRU Department as required by the IRB and institutional policies, the OHRP, and any other accrediting bodies (e.g., AAHRPP).

16) Protect Subject Privacy and Maintain Data Confidentiality

It is the responsibility of the principal investigator to provide a subject privacy and data confidentiality plan in the research protocol for IRB review and approval. The plan must describe how the principal investigator and study team will ensure respect for subject privacy during research interactions and how confidential information will be protected from improper use and disclosure. Discussion of maintenance of subject identifiers or a

plan to destroy identifiers at the earliest opportunity consistent with the appropriate conduct of the research must be included. Assurances must be provided that confidential (private) information is necessary for the conduct of the research and that this information will not be re-used or disclosed to any other person or entity without written authorization by the subject.

17) Participant Complaints/Concerns

The principal investigator is responsible for providing contact information in the consent form to allow participants an opportunity to express complaints or concerns about study procedures or participation. Contact information for the study staff and for the CWRU IRB must be included in the consent form. Complaints received by the IRB, the Office of Research Administration, and/or the University Compliance Office will be investigated by the CWRU IRB staff and the result reported to the IRB and the Associate Vice President of the Office of Research Administration.

The principal investigator is required to retain documentation in the protocol file of any complaints or concerns and their resolution. Serious complaints involving subject rights or welfare or integrity of the research study should be brought to the attention of the IRB when they occur, and all other complaints should be reported at the time of continuing review.

References and/or Regulatory Citations

45 CFR 46 PROTECTION OF HUMAN SUBJECTS (DHHS) -
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>