Principal Investigator (PI) Responsibilities

Part I: IRB Review & Record Keeping

A. **Retention of Communications with LRB & IRB:** The PI must maintain a file of all documents relevant to IRB review for at least three years after closing the project with the IRB. The principal investigator's records should be a mirror image of the IRB's records, meaning that all documents submitted by the researcher to the LRB or IRB and all correspondence between the LRB and the researcher and the IRB and the researcher should be kept on file. More specifically, the researcher's LRB/IRB file should include:

- all materials submitted to the LRB (e.g., protocol, consents, recruitment materials, measures);
- all correspondence between the research team and the LRB;
- all materials initially submitted to the IRB, unless the LRB submits the materials for you;
- all correspondence between the research team and the IRB;
- all materials submitted in response to the IRB review (e.g., revised consents, revised protocol);
- the IRB approval memo & the stamped consent/assent forms that have been approved for use with participants;
- a copy of the "Certification of Approval" sent by the IRB to funding agencies, if appropriate;
- all materials in association with renewals and amendment and all written communications between the IRB and research in association with renewals and amendments;
- copies of any inspection or audit reports.

NOTE: for exempt projects, the researcher is responsible for retaining the only copy of important documents, including:

- recruitment materials;
- letters of collaboration from other institutions (when required by the collaborators' policies); and
- documents certifying that the researcher has met school district requirements when conducting research in educational settings (e.g., a letter of collaboration from the school principal, documentation from the school board).

B. **Amendments to Approved Projects**: Before implementing changes to IRB-approved study materials and procedures, the changes must be reviewed and approved by the IRB. PIs may initiate the review process by completing and submitting an amendment application (available under *Forms & Templates*), along with any revised materials.

C. **Renewals (Continuing Review)**: All research that has been approved by the IRB via **expedited** or **full Board review** must undergo continuing review at least annually or more frequently as determined by the Board when any of the following is true:

- Data collection is ongoing; or
- There will be additional contact with participants; or
- Analysis of research data continues, and the data are identifiable (i.e., associated with identifiers or codes that can be linked to identifiers).

It is the PI's responsibility to submit the continuing review application at least three weeks prior to the expiration of IRB approval on each project. Researchers are informed of expiration dates in their IRB approval memos. Because the timing of renewals is fixed based on the prior year's review, extensions cannot be granted.

When submitting the continuing review application, the PI must include all requested information, along with the current informed consent/assent documents. If changes to the protocol are proposed, a protocol incorporating the changes must be submitted with the other materials.

D. **Unanticipated or Adverse Event Reports and Participant Complaints**: PIs must report all unanticipated risks, adverse events, and participant complaints must be reported in writing to the Director of Research Protections within **72 hours**. ***When an adverse event is severe, all research activities must be suspended immediately, pending IRB review.***

PIs should have a mechanism for tracking unanticipated risks, adverse events, and participant complaints and should include a summary of all such instances each year when submitting renewal materials.

E. **Study Termination/File Closure**

Investigators must notify the IRB when research that has been approved by the IRB is no longer active, so that the IRB protocol can be closed. Closure of a project's IRB file is appropriate where:

- data collection has been completed; and

- there will be no additional contact with participants; and
- analysis of research data continues, but the data are completely deidentified.

F. **Leaving the Institution**
When a researcher with active protocols leaves the institution, s/he must notify the DePaul IRB promptly, so that arrangements can be made to close the protocol file.

Part II: Conduct of Research

A. **Research Procedures**: It is the PI's responsibility to ensure that all aspects of the research are conducted in strict accordance with the most recently approved protocol, including recruitment, data collection, and data analysis. The PI is responsible for the actions of all the co-investigators and students involved in the research study.

B. **Recruiting & Enrolling Participants**: The research team **may not recruit** participants or collect data prior to the full approval by the IRB or after IRB approval has expired. It is the PI's responsibility to be certain that participants are recruited at appropriate times and that they are given ample time to consider their research participation. If recruitment letters, announcements, or other recruitment materials are used, only those materials approved by the IRB for that project may be used. Recruitment or informational materials developed after the IRB approval of a project must be submitted to the Board as a revision for review and approval prior to being incorporated into a project.

C. **Informed Consent/Assent Forms/Process**: Investigators are responsible for obtaining and documenting informed consent/assent in accordance with the most recently approved informed consent/assent or HIPAA authorization form, unless the IRB has granted a waiver or alteration. Investigators should keep the original, signed copies of consent/assent forms in secured research files for at least three (3) years. A standard informed consent/assent process has the following steps:

- The investigator(s) provides the consent/assent form and explains orally to the potential participant the purpose, procedures, risks, and benefits of the research and alternatives to participation.
- The investigator ensures understanding by allowing ample opportunity to answer questions the potential participant may have and by providing sufficient time to the potential participant to consider all options.
- In order to assess understanding of the study during the consent process, the person soliciting consent/assent must ask questions about information provided in the consent form, including:
    i. What is the purpose of the research?
    ii. What are the benefits associated with being in the study?
    iii. What are the risks associated with being in the study?

  Potential participants' answers to these questions should indicate whether they have understood the consent/assent form. If a participant cannot correctly answer a question, then informed consent has not been achieved regardless of whether the individual has signed the consent form.
- After the oral exchange of all pertinent and relevant information, the investigator should ask the potential participant to make a decision regarding his/her participation in the research by signing or not signing the consent/assent form.
- The investigator must give a copy of the form to the participant and keep the signed form. (The copy given to participants may be an unsigned copy. Researchers are advised to have extra copies of consent/assent forms on hand during the consent process, so that a copy can immediately be given to participants to keep.)

D. **Research Records and Data Storage**: The PI should take precautions to avoid any collection or recording of identifiable information that is unnecessary to the study and to guard against release of identifiable information, unless release is mandated by law or the participant has consented to the release. Identifiable study data must be stored securely at all times, whether it is kept in electronic format or in hard copy, so that only trained individuals who are listed on the IRB protocol have access.

In addition, the principal investigator is responsible for ensuring that identifiable study data are permanently deidentified or destroyed at the conclusion of a project, in accordance with the IRB-approved protocol. Researchers who wish to retain individually identifiable data after the conclusion of a study may do so for up to three (3) years, but a written justification must be submitted to the IRB for each subsequent three-year period. In rare cases, it will be appropriate for the researcher or a third party to retain identifiable data indefinitely, because the participants have given their informed consent for such retention.