

**A Principal Investigator's Guide to Responsibilities, Qualifications,
Records and Documentation of Human Subjects Research**
University of Kentucky

I. Compliance with UK IRB and Applicable Federal Requirements

- A. Investigators are responsible for ensuring that research is conducted according to sound research design, the terms of the grant, contract and/or signed agreement and applicable laws and regulations for protecting the rights, safety, and welfare of subjects.
- B. Investigators are responsible for ensuring that research involving humans conforms to generally accepted scientific principles, and that it is based on a thorough knowledge of the scientific literature and other relevant sources of information. The methods to be used should be appropriate to the objectives of the research and the field of study.
- C. Investigators are responsible for providing the IRB with sufficient information and materials to facilitate required determinations.
 - 1. Before initiating research, the investigator is responsible for obtaining written and dated approval from the IRB for the research protocol, written consent form (if documentation of consent is waived, the script of the orally presented consent material), subject recruitment procedures and materials (e.g., advertisements, scripts of orally presented materials), and any other written information to be provided to subjects.
 - 2. During the course of the research, investigators are responsible for maintaining IRB approval, and keeping the IRB informed about the research.
- D. Investigators are responsible for conducting research in compliance with the investigative plan (protocol) as approved by the IRB.
 - 1. Investigators are responsible for complying with the eligibility criteria as specified in the approved protocol.
 - 2. Investigators are responsible for adhering to the procedures as specified in the approved protocol, including randomization procedures, if any.
 - 3. Investigators may not make any changes in the research without prior IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
 - 4. Investigators conducting research involving use of an investigational device must adhere to the plans as approved by the IRB for control, storage, and accountability of the device.
 - 5. Investigators are responsible for promptly reporting to the IRB any deviation from, or a change of the protocol, which was made to eliminate immediate hazards to subjects without prior IRB approval. The report should include a description of the deviation or change and the reasons for implementation. If appropriate, a proposed amendment to the research should be submitted:
 - (i) to the IRB for review and approval, and
 - (ii) to the funding agency.

6. If the research is blinded, the investigators are responsible for only breaking the code in accordance with the protocol and promptly document and explain to the IRB any unblinding due to unanticipated problems involving risks to a subject.
 7. Investigators are responsible for obtaining prior IRB approval for all payments, reimbursements and medical services to be provided to research subjects.
- E. Investigators are required to submit written continuation/final review reports to the IRB at least annually, or more frequently, if requested by the IRB.
 - F. Investigators are responsible for complying with the applicable UK IRB and the federal regulatory requirements related to the reporting of unanticipated problems/adverse events.
 - G. Upon completion of the research, investigators are responsible for providing the IRB with a summary of the outcome, and the funding and regulatory agencies with any required reports.
 - H. If the investigators close out a study, investigators are responsible for promptly informing the IRB.

II. Informed Consent/Assent Process and Documentation

- A. Investigators are responsible for ensuring that informed consent/assent/HIPAA authorization, if applicable, is obtained and when applicable, documented, unless a waiver of the requirement has been approved by the IRB, prior to a prospective subject's participation in a research study. The process includes providing subjects with sufficient information so they can make informed choices on beginning and continuing participation and this dialog should be documented throughout the study. When vulnerable populations are involved in research, investigators must comply with the additional safeguards as required for IRB approval.
 1. Prior to involvement of subjects, investigators are responsible for obtaining written IRB approval of the recruitment and informed consent/assent process including, if applicable, the written consent/assent or form (if documentation of consent is waived, the script of the orally presented consent material) and other oral or written information to be provided to subjects.
 2. If individuals other than the principal investigator are to obtain consent/assent/authorization, the investigators are responsible for designating only qualified individuals. Investigators must identify the individuals in the IRB application and specify whether they are authorized to obtain informed consent/assent/authorization. Individuals designated to act on behalf of the investigators must be approved by the IRB prior to involvement in the consent/assent/authorization process.
 3. Investigators are expected to use only written information approved by the IRB, and/or consent documents containing the "IRB Approval" stamp.
 4. Neither the investigators, nor others involved in the research, should coerce or unduly influence a subject to participate or to continue to participate. The investigators should be cognizant of any potential environmental or situation influence and distinguish between clinical research and standard treatments to avoid therapeutic misconception.

5. When subjects are to be paid or otherwise rewarded for inconvenience and time spent, the investigators are responsible for proposing a payment for IRB approval that is not so large as to unduly influence prospective subjects to consent to participate in the research.
6. The investigators, or a person(s) designated by the investigators, are responsible for informing the subject or the subject's legally authorized representative, of all pertinent aspects of the research.
7. Investigators are responsible for ensuring that the language used in the oral and written information about the research, including the consent form, is in non -technical and practical language that is understandable to the subject or the subject's legally authorized representative.
8. The investigators, or a person(s) designated by the investigators, are responsible for providing accurate information about the research, including the written information and that all questions about the research should be answered to the satisfaction of the subject or the subject's legally authorized representative. An investigator must provide a potential subject with sufficient opportunity and ample time to decide whether or not to participate in the research study during the consent process.
9. Investigators are responsible for ensuring appropriate signatures on the consent document(s) are obtained. Only the investigator should sign on the line provided for "Investigator." Only individuals authorized by the investigators to obtain informed consent should participate in the consent process and/or sign on the line provided for "Name of [authorized] person obtaining informed consent".
10. Investigators are responsible for ensuring that each person or legally authorized representative (LAR) signing a consent or assent form is given a copy of the signed form or, if applicable, the signed authorization form.
11. Investigators are responsible for informing the subject or the subject's legally authorized representative (and/or documenting the communication) in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation. The communication of this information may include re-consent/assent of active subjects and should always be documented.

III. Monitoring and Oversight of Research

- A. Investigators are required to permit and facilitate monitoring and auditing by the IRB, applicable funding agencies and, at reasonable times, inspection by federal and state regulatory agencies as appropriate.
- B. For research that collects data through intervention or interaction with individuals, the investigator is responsible for ensuring that each subject is appropriately monitored and that the research itself is monitored for subject safety and scientific considerations. Investigators must develop procedures for promptly reporting to the IRB, appropriate institutional officials, and/or funding agency representative, of any unanticipated problems involving risks to subjects or others.
 1. For all research involving intervention or interaction with individuals, investigators are responsible for having a thorough understanding of the intervention including potential risks,

interactions and precautions and are responsible for monitoring each subject's experience and take steps to, safeguard their individual rights and welfare.

2. For investigator-initiated research involving subject-administration of drugs, devices or biologics, investigators are responsible for complying with all Food and Drug Administration (FDA) sponsor requirements.
 3. For research requiring subject-administration of drugs or devices, the investigators, or a person designated by the investigators are responsible for explaining the correct use of the product(s) to each subject and should check at appropriate intervals that each subject is following the instructions properly.
 4. For research that is greater than minimal risk, clinical research or NIH or FDA regulated clinical trial, investigators are responsible for establishing a data and safety monitoring plan (DSMP) and for implementing the plan as approved by the IRB.
 - a. If the DSMP includes a data and safety monitoring board (DSMB), the PI is responsible for submitting documentation regarding DSMB activities (i.e., summary report, meeting minutes) to the IRB as provided to the PI by the sponsor or as prepared by the PI. It is the PI's responsibility to acquire documentation that DSMB activities have occurred if not provided by the sponsor.
 - b. At the time of continuation review of the study, the PI is responsible for submitting documentation representing DSMP or DSMB activities not previously submitted to the IRB.
- C. Qualified investigators are responsible for personally conducting or supervising the research.
1. Investigators are responsible for clearly describing, in the investigational plan, involvement of others in the conduct of research.
 2. Investigators are responsible for maintaining a list of appropriately qualified persons to whom he/she has delegated significant research-related duties.
 3. Investigators are responsible for ensuring that all associates, colleagues, and employees assisting in the conduct of the research are informed about their obligations in meeting the investigators' obligations and commitments.

IV. Qualifications of Investigators

- A. Investigators must be qualified by education, training and experience to assume responsibility for the proper conduct of human subject research.
1. Investigators are responsible for being able to provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the IRB, funding agencies, and/or the regulatory agencies.
 2. Investigators are responsible for being thoroughly familiar with the appropriate use of proposed investigational procedures, techniques and products, as described in the current literature, in product information, investigator's brochure and in other available information sources.

3. Investigators are responsible for reviewing, and complying with professional practice standards, ethical codes, applicable regulatory requirements, IRB guidance documents and Office of Research Integrity/IRB standard operating procedures.
4. Investigators are responsible for disclosing, eliminating or appropriately managing, to the satisfaction of the University, any conflicts of interest that might bias or appear to bias the research and the reporting of results in accord with University policy.
5. A qualified physicians (or dentists, when appropriate), who are an investigators or a sub investigators, are responsible for all research-related medical (or dental) decisions.
6. Investigators who are also serving as FDA-regulated sponsors are responsible for being knowledgeable about the additional regulatory requirements of sponsors and for ensuring that the requirements are followed by all study personnel.

V. Resources

- A. As part of their qualification to conduct research, investigators are responsible for ensuring adequate resources are available.
 1. Investigators are responsible for being able to demonstrate (e.g., based on retrospective data) potential for recruiting the required number of eligible subjects.
 2. Investigators are responsible for having sufficient time committed to properly conduct and complete the research project within the proposed time period
 3. Investigators are responsible for having available an adequate number of qualified staff and adequate facilities for the foreseen duration of the research to conduct the research properly and safely.

VI. Investigator Records and Documentation

- A. The investigators are responsible for the accuracy, completeness, legibility, and timeliness of the data recorded and reported in research and in publications about the research.
- B. As appropriate to the research and as specified by applicable regulations, investigators are responsible for maintaining documents, which individually and collectively permit evaluation of the conduct of the research and the quality of the data produced. At a minimum, these documents include the following:
 1. the investigational plan (protocol) and amendments, as approved by the IRB;
 2. the grant, contract and/or signed agreement between the investigator and the funding agency;
 3. form(s) used to obtain and document consent/assent;
 - (i) current IRB approved form(s);
 - (ii) documentation of consent/assent for each subject, if applicable;
 4. any written recruitment materials and other written information given to subjects;

5. data collection form(s) including source documents and case report forms;
 6. accountability records of investigational products;
 7. correspondence from the IRB including approval letter(s);
 8. any reports from monitoring and auditing bodies;
 9. reports of unanticipated problems/serious adverse events;
 10. approvals from regulatory authorities, if applicable.
- C. Investigators are responsible for maintaining records for six years after completion of study and should take measures to prevent accidental or premature destruction of these documents. Investigators are responsible for storing data in a secured fashion to prevent breaches of confidentiality.
- D. For research which falls under FDA authority, investigators are responsible for retaining the signed documents and IRB research records for the period specified in the applicable FDA regulations if the requirements are longer than six years after completion of the study.

Guidance adapted by University of Kentucky Office of Research Integrity from "Statement Regarding Investigator Responsibility" by Gary L. Chadwick, Pharm.D., MPH, CIP

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