A Principal Investigator’s Guide to Responsibilities, Qualifications, Records, and Documentation of Human Research

I. Compliance with 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 complying with the recruitment plan as specified in the approved protocol/application.

3. Investigators are responsible for adhering to the procedures as specified in the approved protocol, including randomization procedures, if any.

4. Investigators may not make any changes in the research without prior IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

5. 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.

6. Investigators are responsible for promptly reporting to the IRB any deviation from, or a change to 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.

7. 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.

8. 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 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 providing the funding and regulatory agencies with any required reports.

H. When a Principal Investigator (PI) leaves Franklin University, he/she must close out his/her protocol(s). If applicable, he/she must close out the protocol to another PI, who will take responsibility for the research.

I. 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 is obtained, if applicable, and documented, when applicable, 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. This dialogue 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. Investigators must ensure the form and process begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

3. If individuals other than the principal investigator are to obtain consent/assent/authorization, 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.

4. Investigators are expected to use only written information approved by the IRB, and/or consent documents containing the “IRB Approval” stamp.

5. Neither investigators nor others involved in the research should coerce or unduly influence a subject to participate or to continue to participate. Investigators should be cognizant of any potential environmental or situational influence.

6. When subjects are to be paid or otherwise rewarded for inconvenience and time spent, 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.

7. 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.

8. 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.

9. Investigators, or a person(s) designated by the investigators, are responsible for providing accurate written and verbal information about the research unless the IRB grants a waiver of the informed consent process. All questions about the research should be answered to the satisfaction of the subject or the subject’s legally authorized representative. Investigators must provide potential subjects sufficient opportunity and ample time to decide whether or not to participate in the research study during the consent process.

10. Investigators are responsible for ensuring appropriate signatures on the consent document(s) are obtained. 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”.

11. 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 and, if applicable, the signed authorization form.

12. Investigators are responsible for informing the subject or the subject's legally authorized representative 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 any noncompliance or unanticipated problems to the IRB, appropriate institutional officials, and/or funding agency representative.

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 taking steps to safeguard their individual rights and welfare.

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.

4. Investigators are responsible for maintaining appropriate oversight of research and research staff, and for delegating research responsibilities, functions, and activities appropriately.

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 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 and 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 IRB Office 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.
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 an adequate number of qualified staff and adequate facilities to conduct the research properly and safely for the duration of the research.

VI. Investigator Records and Documentation

A. 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; and
10. approvals from regulatory authorities, if applicable.

C. Investigators are responsible for maintaining signed documents and IRB records for at least three years after study closure and should take measures to prevent accidental or premature destruction of these documents. Investigators are responsible for storing records consistent with IRB policy and the plan approved by the IRB in a secured fashion to prevent breaches of confidentiality.

D. For research which falls under the authority of a regulatory or funding agency, investigators are responsible for retaining the signed documents and IRB records for the period specified in the applicable regulations if the requirements are longer than three years after completion of the study. For multi-site
studies, investigators consult the study sponsor regarding retention requirements, but must maintain records for a minimum of three years after study closure.

VII. Investigator Responsibilities for Research Reviewed by Non-Franklin University IRB

A. The Franklin investigator is responsible for complying with the reviewing IRB’s policies and procedures as well as the terms of reliance agreements and other Franklin research requirements outside of the IRB review (e.g., HIPAA, Conflict of Interest). These responsibilities include, but are not limited to:

1. complying with the reviewing IRB’s procedures for initial and continuing review, record keeping, reporting requirements, and that all information requested by the reviewing IRB is provided in a timely manner.

2. disclose conflicts of interest and comply with any conflict of interest management plans that may result in coordination with the relying organizations and reviewing IRB.

3. promptly report to the reviewing IRB proposed changes to the research. The Franklin investigator cannot implement changes to the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

4. do not enroll participants in research prior to review, approval, and other applicable requirements by the reviewing IRB.

5. obtain, document, and maintain records of consent for each participant or each participant’s legally authorized representative.

6. promptly report to the reviewing IRB any unanticipated problems according to the requirements specified in the reliance agreement.

7. report non-compliance, subject complaints, protocol deviations, and/or other events in accordance with the requirements specified in the reliance agreement. This may include reporting to both the reviewing IRB and the Franklin University IRB.

9. have appropriate qualifications and expertise to conduct the research, are knowledgeable about laws, regulations, codes, and guidance governing their research, and are knowledgeable about both the reviewing IRB’s and Franklin’s policies and procedures.

10. conduct monitoring in addition to or in cooperation with the reviewing IRB, when appropriate.

Modified from “Statement Regarding Investigator Responsibility” by Gary L. Chadwick, Pharm.D., MPH, CIP, and from the University of Kentucky Office of Research Integrity