



Institutional Review Board (IRB)

Handbook of

Guidelines and Processes

**For the Protection of Human Subjects in
Research at Franklin University**

2016

Table of Contents

INTRODUCTION	1
DEFINITIONS	1
GENERAL GUIDELINES	1
IRB STRUCTURE	2
IRB RECORDS	2
TRAINING REQUIREMENTS	3
THE REVIEW PROCESS	3
A. IRB APPLICATION.....	3
B. IRB RECEIPT OF THE APPLICATION.....	4
C. IRB REVIEW.....	4
TYPES OF IRB REVIEW	4
A. EXEMPT	4
B. EXPEDITED REVIEW	5
C. FULL BOARD REVIEW.....	5
ADDITIONAL INFORMATION ON IRB REVIEWS	6
A. MODIFICATIONS.....	6
B. STUDENT APPLICATIONS.....	6
C. CONDITIONS UNDER WHICH BLANKET IRB APPROVAL MAY BE SUBMITTED	6
D. EXTERNAL APPLICATIONS.....	6
THE INFORMED CONSENT PROCESS	6
A. INFORMED CONSENT	6
B. RETAINING AND STORING SIGNED INFORMED CONSENT DOCUMENTS	7
APPENDIX A. CHECKLIST FOR DETERMINING WHETHER AN ACTIVITY REQUIRES IRB REVIEW .	8
APPENDIX B. TEMPLATE OF CONSENT FORM	9
APPENDIX C. IRB APPLICATION EVALUATION CRITERIA	11

INTRODUCTION

Human subjects are often used in medical and clinical research as well as social and behavioral research. Franklin University is committed to assuring that research activities conducted under its auspices do not violate the rights and welfare of human participants.

To help assure the protection of human subjects, Franklin University has established the Institutional Review Board for Human Subjects Research (IRB). The IRB is a committee that consists of University's faculty and staff and is responsible for overseeing research projects involving human subjects. To help determine whether an activity requires IRB review and approval, a checklist is provided in Appendix A.

Franklin University has developed guidelines and procedures for human subjects research, which are adapted from the U.S. Department of Health and Human Services [Code of Federal Regulations](#) (CFR Title 45, Part 46, 2009).

DEFINITIONS

Franklin University adopts the following definitions of terms as adapted from the [Code of Federal Regulations](#) (CFR Title 45, Part 46, 2009).

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject refers to a living individual about whom an investigator/researcher (professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

IRB is the Institutional Review Board for Human Subjects Research. This board is appointed to review research involving human subjects for compliance with applicable federal, state, and local regulations and protection of human rights and welfare. The IRB membership includes Franklin University faculty and staff.

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Risk refers to the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study (*See also: Minimal Risk*).

Principal Investigator (PI) is the lead researcher for a research project.

GENERAL GUIDELINES

For reviewing and approving research, Franklin University's IRB abides by the following general guidelines as adapted from the [Code of Federal Regulations](#) (CFR Title 45, part 46, 2009):

1. **Risks to subjects are minimized** by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. **Risks to subjects are reasonable** in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of interventions subjects would receive even if not participating in research).
3. **Selection of subjects is equitable.** In making this assessment the IRB shall take into account the purposes of the research and the setting in which the research will be conducted.
4. **Unless waived by the IRB, informed consent will be sought from each prospective subject or the subject's legally authorized representative,** in accordance with, and to the extent required by *CFR Title 45, 46.116*.
5. **Unless waived by the IRB, informed consent will be appropriately documented,** in accordance with, and to the extent required by *CFR Title 45, 46.117*.
6. **Where appropriate, the safety of subjects will be ensured** through appropriate data monitoring methods provided in the research plan.
7. **Vulnerable populations may require special considerations.** Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards will be included in the study to protect the rights, welfare and privacy of these subjects.

IRB STRUCTURE

The IRB shall have representatives from different areas of the University. There is one member from each academic unit (Colleges and International Institute for Innovative Instruction). There is also at least one representative from the non-academic areas of the University.

IRB meetings shall be scheduled on a monthly basis, but will only be called as need requires. The Chair will call the committee together and preside.

Research proposals shall be made available to members for review prior to scheduled meetings.

No members of the IRB shall participate in the IRB's review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

IRB RECORDS

The IRB shall maintain adequate documentation of IRB activities, including the following:

1. Research applications reviewed, approved sample consent documents, and progress reports submitted by investigators;
2. Records of continuing review activities;
3. Copies of all correspondence between the IRB and the investigators;

4. A list of IRB members.

All records required by this policy shall be retained for at least three (3) years, and records relating to research which is conducted shall be retained for at least three (3) years after completion of the research. The Office of Assessment will house and maintain IRB records.

TRAINING REQUIREMENTS

Prior to submitting a research proposal to the IRB, all faculty, staff, and students are required to complete a training program for protecting human research participants. The National Institute of Health (NIH) provides an online training course entitled Protecting Human Research Participants (PHRP), which is free of charge. PHRP is designed to prepare researchers to understand their obligations to protect the rights and welfare of human subjects in research. PHRP includes six modules and can be completed using multiple login sessions. Total completion time is approximately two to three hours.

Here are the steps for accessing the training:

- 1) Follow the link to go to the NIH training course [Protecting Human Research Participants \(PHRP\)](#).
- 2) Register for the course.
- 3) At the end of the course, make sure you save an electronic copy of the COMPLETION CERTIFICATE before you log off. This certificate serves as evidence that you have completed the training.

A PHRP completion Certificate remains current for three years. All IRB applications must be accompanied by current and valid certificates for all researchers listed in the application. All certificates must be kept current for the entire duration of a research project.

For those needing to renew their NIH PHRP Completion Certificate, please follow the steps below to insure that the new certificate has the current completion date:

- 1) Log in to the site.
- 2) Select “Edit User Info” from the menu on the right side of the Main Menu, to go to the “Edit Profile” page.
- 3) Scroll to the bottom of the page and select “Retake Course,” which will ensure that the new certificate has the current completion date.

Additionally, training is also available, at a cost, from the Collaborative Institutional Training Initiative (CITI) at the University of Miami. Franklin University’s IRB accepts training completion certificates from CITI as valid certificates.

THE REVIEW PROCESS

A. IRB Application

1. The principal investigator prepares the [IRB application](#) which must contain:
 - 1) Completed IRB application form;
 - 2) Informed consent documentation (see Appendix C for a sample);
 - 3) A copy of the actual survey instrument, questionnaire or data record form to be used in the project;

- 4) A current **IRB** training completion certificate for each listed investigator, which should be less than or equal to three years old, for each of the researcher(s). All certificates must be kept current for the entire duration of a research project. Training certificates are acceptable from the NIH in Protecting Human Research Participants or the CITI program at the University of Miami.
2. All employee applications will be first sent to the supervisor of the Principal Investigator for review. All student applications will be first sent to his/her faculty supervisor for review.
3. Applications approved by (faculty) supervisors will then be sent to the IRB for review. This round of reviews may take up to four weeks.

B. IRB Receipt of the Application

Upon the submission of an IRB application, applicants will receive a confirmation email, which contains an Application ID#. The Application ID# is a unique identification number for each submitted IRB application. Investigators are recommended to keep a record of their Application ID# for future references.

C. IRB Review

The IRB uses a list of evaluation criteria to conduct reviews of IRB applications. Appendix C provides the evaluation criteria.

TYPES OF IRB REVIEW

Depending on the risk to participants, research may fall into one of three categories: **Exempt**, **Expedited Review**, or **Full Board Review**. The IRB Chair or one or more IRB members designated by the Chair may determine what type of IRB review a research project needs.

In case of **Exempt** or **Expedited Review**, the Chair or one or more IRB members designated by the Chair may review and approve the project.

In case of **Full Board Review**, a minimum of five members of the IRB must review the research.

A. Exempt

If the project falls into the **Exempt** category, the principal investigator need not resubmit the project for continuing IRB review as long as there are no modifications in the exempted procedures.

The following categories are considered **Exempt** from further review:

1. Research conducted in established educational settings, involving normal educational practices, such as:
 - a) research on regular and special educational instructional strategies, or
 - b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **UNLESS**:
 - a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

- b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
4. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

The approval period of exempted research projects is usually an indefinite time period. Re-review is not required unless or until the investigator proposes modifications to the project.

B. Expedited Review

Research activities involving no more than “minimal risk” to subjects and in which the only involvement of human subjects will be in one or more of the following categories may fall into the category of Expedited Review:

1. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
2. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigation does not manipulate subject’s behavior and the research will not involve stress to subjects.
3. Recording of data from adults using non-invasive procedures, such as moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
4. Voice recordings made for research purposes such as investigations of speech defects.
5. Moderate exercise by healthy volunteers.

The approval period for expedited review is usually one year (exceptions may apply). Three months prior to the approval expiration date, the IRB will issue a reminder notice listing procedures for submitting an application for continuing review. Subject recruitment and data collection without continuing IRB approval are not permitted beyond the expiration date assigned by the IRB.

C. Full Board Review

Any research involving the use of human subjects which does not fall into the “Exempt” or the “Expedited Review” categories must be submitted to the IRB for a full board review. Examples may include research that involves the use of any of following:

1. Minors, prisoners, pregnant women, impaired adults, or other vulnerable population
2. Illegal activities such as drug use
3. Private activities such as sexual behavior

4. FDA approved drugs and devices presenting more than minimal risk
5. Non-FDA approved drugs and devices
6. Deception

The approval period for full board review is usually one year (exceptions may apply). Three months prior to the approval expiration date, the IRB will issue a reminder notice listing procedures for submitting an application for continuing review. Subject recruitment and data collection without continuing IRB approval are not permitted beyond the expiration date assigned by the IRB.

ADDITIONAL INFORMATION ON IRB REVIEWS

A. Modifications

Researchers wishing to modify an approved research, such as a change in the approved number or type of participants, adding or dropping measures, should submit a modification request: [Modifications of IRB Approved Human Subject Research](#).

B. Student Applications

Students cannot serve as Principal Investigators. Their applications must reflect faculty sponsorship from their faculty supervisors or dissertation chairs. The responsibility for complying with the IRB Guidelines and Processes is shared by the faculty sponsor and the student.

C. Conditions Under Which Blanket IRB Approval May be Submitted

Courses in which the curriculum consists substantially of independent student research are subject to IRB approval. Faculty members will need to submit an IRB application for this kind of courses.

D. External applications

The IRB focuses on reviewing applications from students and employees (both full-time and part-time) of Franklin University. For external applications, researchers must first contact the Franklin University Provost's Office for initial screening.

THE INFORMED CONSENT PROCESS

A. Informed Consent

Participants' involvement must be *voluntary* and *informed*. Before participation, participants must receive an explanation of the purposes of the research, what they will be asked to do, and any potential risks involved. They must be told that they may refuse to participate and may discontinue participation at any time without penalty.

For **anonymous** questionnaires and surveys, where the only link to the subject would be the signed Consent Form, the written consent can be waived, because the subject is better protected without the existence of a signed document.

In cases of *oral consent*, a witness must be present, and a written copy of the oral summary must be approved by the IRB and given to the participant or to the participants' legal guardian.

In the case of minors, signed permission must be obtained from a parent or legal guardian who has been informed.

Template of Consent Form is provided in Appendix B

B. Retaining and Storing Signed Informed Consent Documents

Signed informed consent forms should be stored in a secured location which is accessible to the University if the forms need to be examined. Access to these documents should be limited to those authorized persons who have a need to know their contents, ordinarily the investigator (and co-investigators), a representative of the IRB. In compliance with federal regulations, consent documents must be retained for a period of three years following the completion of the research. External requests for access to research data and/or document production must be referred to the Office of AIE.

The IRB should be informed of any change in storage locations of signed informed consent forms within the three-year retention period. If consent documents are maintained by a student or a staff member, they must be turned over to the responsible faculty member or supervisor sponsor after data collection is completed.

Appendix A. Checklist for Determining whether an Activity Requires IRB Review

An activity needs to be reviewed by the IRB if it is **research** that involves **human subjects**. The checklist below aims at helping to determine whether an activity requires the IRB review.

Is it research?

A research activity must meet **BOTH** of the following criteria:

- ✓ The activity is a **systematic investigation**, including research development, testing and evaluation.
- ✓ The activity is designed to **develop or contribute to generalizable knowledge**.

Does it involve human subjects?

Human subjects are involved if ANY of the following conditions are true:

- ✓ The activity involves a living individual about whom an investigator (whether professional or student) conducting research obtains data through **intervention** or **interaction** with the individual.
- ✓ The activity involves a living individual about whom an investigator (whether professional or student) conducting research obtains **identifiable private information**.

If an activity is categorized as **research** that involves **human subjects**, the investigator will need to submit the Application for Human Subjects Research Review to the IRB for approval.

Appendix B. Template of Consent Form

Franklin University
Human Subject Consent Form

Title of Research:
Principle Investigator:
Department:

I have been asked to participate in a research study (*Insert general statement about study*). The purpose of this study is (*Insert research purpose in generally understandable language*). I was asked to be a possible participant because (*Insert how subject was identified*). A total of (*Insert number of study subjects*) people have been asked to participate in this study.

If I agree to participate in this study, I will be asked to (*Insert tasks and procedures*). My participation will take (*Insert length of time for participation, frequency of procedures, etc.*). The risks associated with participation of this study are (*Insert risks*). The benefits of participation are (*Insert benefit(s), if no benefits state the fact here*).

I will receive (*Insert reimbursement information, if no monetary compensation, state the fact here*). This study is (*anonymous or confidential cannot be both and explain how this will be accomplished*). I have the right to obtain a summary of the results of this research if I would like to have them.

I understand that my participation is voluntary. If I decide to participate, I have the right to refuse to answer any of the questions that may make me uncomfortable. I also have the right to withdraw from this study at any time with no repercussions.

I understand that this research has been reviewed and approved by the Franklin University Institutional Review Board. For questions regarding participants' rights, I can contact the Institutional Review Board at irb@franklin.edu.

I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study. I have been given a copy of this consent form. By signing this document, I consent to participate in the study.

Name of Participant (printed): _____

Signature of Participant (or legal guardian): _____

If legal guardian, print name: _____

Date: _____

Signature of Principal Investigator: _____

Date: _____

Contact Information of Principal Investigator:

APPENDIX C. IRB APPLICATION EVALUATION CRITERIA

IRB Evaluation Criteria	Yes	No	Not Applicable	Comments
1. All required components are fully addressed in the IRB Application.				
2. The design of the study allows the research question(s) to be answered.				
3. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.				
4. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.				
5. Selection of subjects is equitable, in consideration of the purposes of the research and the setting in which the research will be conducted.				
6. Unless waived by the IRB, informed consent will be sought from each prospective subject or the subject's legally authorized representative.				
7. Unless waived by the IRB, informed consent will be appropriately documented.				
8. When appropriate, the safety of subjects will be ensured through appropriate data monitoring methods provided in the research plan.				
9. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.				

<p>10. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.</p>				
<p>Additional Comments</p>				
<p>Overall Decision</p>				