

Application for Human Subjects Research Review by the IRB

Form Last Updated July 6, 2017

Application Instructions:

1. This form and all required attachments must be completed, submitted, and the application approved before research activities involving human subjects are begun. Submit this application with all required attachments to: irb@franklin.edu.
2. For all researchers submitting IRB applications (including faculty, staff, and students), evidence needs to be presented of completed IRB training, which should be less than or equal to three years old. Current IRB training completion certificates are acceptable from either one of the following organizations: (1) The National Institute of Health (NIH) and (2) The Collaborative Institutional Training Initiative (CITI) at the University of Miami. NIH provides a free online training course Protecting Human Research Participants (PHRP), available at <https://phrp.nihtraining.com/users/login.php>, while the CITI training courses are not free. For each researcher involved, you must submit a valid and current training certificate.
3. All IRB applications from Franklin employees must be reviewed and approved by the immediate supervisors of the Principal Investigators (PIs) before they are sent to the IRB for reviews.
4. Students cannot be Principal Investigators and will have to be sponsored by a Faculty Supervisor/Dissertation Chair (for students who conduct dissertation studies). The Faculty Supervisor/Dissertation Chair serve in the role of the Principal Investigator.
5. Please allow four weeks from the date delivered for notice of the IRB's decision on your proposal. The researcher will be notified via e-mail regarding the status of his/her application. If the researcher is a student, the faculty supervisor will receive a copy of the e-mail as well.
6. If you are an External Applicant, your application will have to be sent to the Franklin University Provost Office for pre-approval first. Please contact the Provost Office at 614.947.6199 for further information.

Part I. Identifying Information

A. Project Title	Data Collection Period	
B. Principal Investigator (PI)	Department	Phone/e-mail
Other Investigators	Department	Phone/e-mail

Part II.

Supporting the Franklin Mission

Please check all that apply for each section below:

Educational Philosophy

Please identify how the research contributes to Franklin University’s mission as reflected through the four educational philosophy cornerstones. Please check all that apply below:

- Ensuring academic quality
- Providing access to educational opportunities
- Adapting to the needs of students
- Responding to changes in society, professions, and the business community

Review Category

Please check all that apply below for each section:

Exemption

Note: All research involving children (less than 18 years old) must go through Full Board Review.

- Research conducted in established educational settings, involving normal educational practices
- Research involving educational tests, if participants CANNOT be identified in any way
- Research involving surveys or interviews, if participants CANNOT be identified in any way

- Research involving observation of public behavior, if participants CANNOT be identified in any way
- Research involving the collection of existing data, documents, records, if these sources are publicly available and participants CANNOT be identified in any way
- Research involving surveys or interviews of public officials or candidates for public offices

Expedited Review

Please check all that apply below:

- Study of existing data, documents, records, pathological specimens, or diagnostic specimens
- Non-manipulative and non-stressful research on individual or group behavior or characteristics
- Recording data from subjects 18 years of age or older using non-invasive procedures commonly found in clinical practices
- Voice recording for research purposes
- Moderate exercise by healthy volunteers

Full Board Review

Please check all that apply below:

- Minors, prisoners, pregnant women, impaired adults
- Illegal activities such as drug use
- Private activities such as sexual behavior
- FDA approved drugs and devices presenting more than minimal risk
- Non-FDA approved drugs and devices
- Deception

Part III. Funding and Other Support

Is the research funded or has funding been requested?

- Yes
- No

Is there any support, other than monetary, being provided for the study (i.e. - materials, equipment, etc.)?

Yes

No

Part IV. Outline of Research Project

Type your responses to all of the questions outlined below. Please type your responses in the space underneath each question. Please provide as much detail as possible in your answers.

Background and Rationale

Summarize the justification for the study. Evaluate prior research for relevance to the research question under study. Discuss the anticipated results, potential pitfalls, and the significance of the research including potential benefit for individual subjects or society at large. Discuss how public health and social welfare might be enhanced. Benefits may include direct benefits to the participants (e.g., smokers who take part in a smoking-cessation study may stop smoking), material benefits to the participants (e.g., money, extra credit), benefits to the research community (e.g., adding to the field of knowledge on the research topic), and/or benefits to the researchers (if the researchers are students who are learning how to conduct research studies).

Provide the background and rationale of the research:

Purpose

Describe the purpose(s) of the research:

Benefit(s)

Describe the benefit(s) of the research:

Research Question(s)

List the research question(s) that will be explored in this research:

Research Design & Procedures

Describe the research design & procedures. Please complete the following sections below (A - F):

A. Project Length

Estimated Start Date:	Estimated End Date:
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B. Research Design

Research Design (type of research, e.g., qualitative/quantitative, survey/ex post facto, etc.) The research design should be identified and should be appropriate to answer the research question(s) under study. Check all that apply:

- Qualitative research
- Quantitative research
- Survey research
- Ex Post Facto research
- Mix-methods research
- Correlational research
- Experimental research
- Quasi experimental research
- Other(s)

C. Research Activities

Check all research activities that apply:

- Audio, video, digital, or image recordings
- Existing data, not publicly available
- Existing data, publicly available
- Focus groups
- Internet or e-mail data collection
- Observation of participants (including field notes)
- Oral history (does not include medical history)
- Record review (which may include Protected Health Information)
- Specimen research (must be existing at time of application)
- Surveys, questionnaires, or interviews (one-on-one)
- Surveys, questionnaires, or interviews (group)
- Taste-testing
- Other

Describe the research design & procedures. Please complete the following sections below (D - F):

D. Research Location(s) & Setting

Please describe the setting and location(s) of the research. Research to be conducted at locations other than approved performance sites may require a letter of support or another institution's approval.

List the specific site(s) at which the research will be conducted (include both domestic and international locations). Please also describe the research setting including physical location(s), host organization(s), organizational liaison and contact information and justify the selection of the research setting.

NOTE: Investigators are responsible for obtaining and maintaining documentation of any additional approvals, letters of support, or other site agreements.

Location Name:

Address (Street, City, & State, or Country):

Describe the research setting including physical location(s), host organization(s), organizational liaison and contact information and justify the selection of the research setting:

E. Participants

Please state how many participants will be recruited, characteristics of the participants including any eligibility requirements (for example, male college students who are 18 years old or older), a description of how participants will be recruited, and whether there will be any incentives for participation (e.g., money, extra credit).

Specify the number of participants in the study:

Describe the characteristics and eligibility requirements of the participants (age, gender, occupation, etc. should be included here):

Describe how the participants will be recruited:

Please indicate whether participants will receive compensation (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement).

Will participants receive compensation or other incentives to participate in the research study?

Yes

No

F. Instrumentation

If the study is QUANTITATIVE, identify and define independent and dependent variables. If the study is QUALITATIVE, identify and define variables of interest. If the study uses MIXED METHODS, identify independent and dependent variables for quantitative data, and identify and define variables of interest for qualitative data.

Identify and define variables:

Provide validity and reliability data for selected measures. Threats to internal / external validity should be considered. Describe measures that have been/will be taken to avoid study bias.

Provide validity and reliability:

Describe instrument design and state sources:

G. Data Collection & Storage

Describe Methods for Data Collection:

State the timeline for subject evaluations and the duration of subject participation in the project:

State how and where will the data will be stored securely:

Risks

Risk 1 - State how this study avoids/minimizes subject risks. Risks may be physical (e.g., increased heart rate, blood pressure) and/or psychological (e.g., stress, embarrassment, anxiety).

State how this study avoids/minimizes subject risks:

Risk 2 - Identify the plans and the proposed safeguards for subject confidentiality (plans for coding data and for securing written and electronic subject records).

Identify the plans and the proposed safeguards:

Physical Activity

If your research involves physical activity (e.g., running in place, riding a bicycle), you must monitor the condition of the participants.

Does the research involves physical activity?

- Yes
- No

Identifiable Data

Indicate what will happen to identifiable data at the end of the study. Primary research data should be retained for a minimum of five years after final project closeout. Other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)

Will identifiable data be collected?

Yes

No

HIPAA Compliance

Any research which involves individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule (<http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/>) requirements must comply with the HIPAA policy.

Is this project required to conform to HIPAA?

Yes

No

H. Data Analysis

Specify the analysis techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analysis approaches.

Specify the analysis techniques/approaches the researcher will use:

Part V. Attach the following to your proposal:

1. Informed Consent.

Note: 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.

2. All materials that will be presented to participants. This includes written materials (e.g., questionnaires, interview protocols, scales) and audiovisual materials (e.g., photographs, CDs, DVDs).

3. **A current Completion Certificate demonstrating completed training in Protecting Human Research Participants for each of the researcher(s). The certificate needs to be less than or equal to three years old.**

Agreement/Acknowledgement

I certify that the research project detailed in this Application is an accurate and complete description of the research I plan to conduct. I understand that the review of this Application and the decision of the Franklin University Institutional Review Board is based on the information in this Application and any attachments and subsequent amendments. I further acknowledge that my research request is not approved until I have written documentation from an IRB official advising me that I may proceed with recruiting participants and collecting data.

I agree to the terms statement as stated above.

Please type your full name (as your e-signature):	Date:
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Please type full names as e-signatures

Principal Investigator's signature: _____ *Date:* _____

Other Investigator's signature: _____ *Date:* _____

Other Investigator's signature: _____ *Date:* _____

Other Investigator's signature: _____ *Date:* _____

I have reviewed the research project detailed in this Application. Upon considering the project's **value, workload, and resource requirements**, I recommend approving it to move forward.

Immediate Supervisor's signature: _____ *Date:* _____