IRB The IRB Application Packet

The Institutional Review Board (IRB) is responsible for all human research subjects, in accordance with the Department of Health and Human Services (DHHS). All research conducted at the university must be in accordance with the Code of Federal Regulations Title 21 and IRB standards and all Subparts of 45 CFR 46—without exception. This IRB is registered with OHRP under the IORG number and holds Federal Wide Assurances (FWA) registration.

The mission of the IRB is to protect the rights, dignity, welfare, and privacy of the human subjects in all research conducted on behalf of the university. The IRB process adheres to the principles outlined in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report and the regulations of the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), and other applicable agencies. We are committed to advancing the ethical treatment of research participants, promoting the responsible conduct of research, and ensuring and protecting the rights of every human research volunteer. Further, we are committed to the following goals:

- Ensuring that all research involving human subjects receives required approvals before research activities are initiated.
- Creating an environment at the university of respect for, and understanding of, the rights and welfare of research participants.
- Educating the university community about federal, state, and university research regulations, policies, and practices pertaining to the protection of human subjects.

Three basic principles of the Belmont Report are central to the ethics of research involving human subjects and guide the IRBs in ensuring that the rights and welfare of research participants are protected. These are:

- Respect for persons–applied by obtaining informed consent and considering privacy, confidentiality, and additional protections for vulnerable populations.
- Beneficence–applied such that the potential benefits of research are maximized and possible risks are minimized to the persons involved.
- Justice–evidenced in the equitable selection of research participants.

The IRB will enforce the requirements of Code of Federal Regulations Title 21, decision charts, and IRB standards/SOPs to ensure the highest standards in ethical research, investigator conduct, and education regarding ethical research while supporting successful degree completion.

Process Outcomes and Additional Information

Upon completion of the review, a letter is sent to the primary investigator (PI), either authorizing the initiation of the project or containing stipulations that must be met before approval is granted. The involvement of human subjects may begin after stipulations have been satisfactorily addressed and approved.

An investigator who makes a minor modification to an ongoing project must receive approval before involving human subjects in the revised protocol. All modifications to approved protocols must be submitted with a revised application form outlining the changes being made. Minor modifications include minor wording changes in a consent form or minor changes in compensation, time of participation, or subject recruitment, or the use of a new site that is not materially different from a previously approved site. They may also include changes to other parameters, whereby the investigator provides the subjects with more accurate information as a result of additional experience with the protocol. Approval of a minor modification does not change the approval expiration date for a protocol. These cases are given an expedited review in the IRB Office, and the results are communicated to the investigator. Approved cases are listed on the staff

report of the next IRB meeting; further, IRB members may ask for discussion of these cases during any meeting.

The IRB Office will provide written notice to each principal investigator following the review of their protocol. If the protocol is approved, the letter will include the IRB Approval Number and expiration date of the approval. The letter will also include the requirements for reporting any problems involving human subjects, the requirement for prior review of changes in procedures, and any other special terms and conditions. If the Board stipulates changes, or if it disapproves of the protocol, the written notification will state the basis for this decision. The IRB Office may approve the investigator's response to stipulations unless the IRB directs that the response shall be returned to the IRB for review. The Board may also designate one or more Board members to join the IRB Office in reviewing a response to stipulations. For any necessary monitoring of the research or the consent process, the Board will determine the nature and extent of the monitoring activities.

The IRB is responsible for the continuing review system and may perform forum visits/audits, interviews, or other activities to monitor the research and consent processes. Research activities that present no more than minimal risk to human subjects and that involve only procedures listed in one or more of the federally specified categories (as described by federal regulations) may be given a continuing review through the expedited review procedure.

(The application and rubric begin on the next page.)

IRB Application

IRB Application Type	**APPLICATION AND RUBRIC**
Title of the Study	
Investigator	
Email Address of Investigator	
Phone Number of Investigator	
Name of Mentor	
Date of IRB Application	

Purpose of the Study. Summarize the proposed research using non-technical language that someone outside the discipline could readily understand. Briefly explain the research design, procedures to be used, risks, anticipated benefits, and the importance of the knowledge that may reasonably be expected to result. Use complete sentences (limit 300 words).

Supporting Literature. Summarize existing knowledge and previous work supporting the expectation of obtaining valuable results without undue risk to human subjects. Use complete sentences (limit 300 words).

Locations of Research. List the locations of the research (limit 100 words). This includes organizations, their locations, etc., along with locations where face-to-face interviews may take place.

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Ethics Training. All investigators and mentors must file current CITI certificates with the Dissertation Department.

Please note that the university *will not approve* a research project lacking certification.

	Yes	No
Investigator submitted all CITI certificates.	☐	☐

Funding. Indicate whether the research is externally or internally funded or unfunded.

- ☐ External Funding
- ☐ Internal Funding
- ☐ Unfunded

General Exclusions from Exempt Status. Check "Yes" or "No". Checking "Yes" for any of the following implies the research is *not exempt*.

Please note that the university *will not approve* research requiring FDA approval, registration with ClinicalTrials.gov, or HIPAA-protected information.

	Yes	No
The research is FDA regulated.	☐	☐
The research involves prisoners.	☐	☐
The research requires HIPAA-protected information.	☐	☐

Risk Assessment for Adults. Check the appropriate selections.

Definition of Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort (physical, psychological, social, or economic) anticipated in the proposed 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.

Please note that the university *will not approve* research involving minors, prisoners, or adults lacking the capacity to consent.

- ☐ The research involves no more than *minimal risk* to adult participants.
- ☐ The research involves greater than *minimal risk* to adult participants.
- ☐ The research does not involve Human Subjects (e.g., Meta-analysis, Literature Review, etc.).

Describe all reasonably expected risks, harms, and discomforts that may apply to the research. Discuss the severity and likelihood of occurrence.

IRB Application

Criteria for Approval of Research with Human Subjects. Check "Yes" or "No".

Please note that the university *will not approve* research lacking a consent process and consent form.

	Yes	No
The research involves no more than *minimal risk* to participants.	☐	☐
The sampling method ensures that the sample accurately reflects the population of interest.	☐	☐
There is no recorded identifiable information. (If checked *no*, the following must be checked:)	☐	☐
If the study uses identifiable information, there are proper measures to ensure the confidentiality of the data.	☐	☐
There are interactions with participants. *Including: surveys, interviews, and similar interactions.*	☐	☐
The research clearly explains the consent process and consent form.	☐	☐
The consent form discloses the activities involved in the research.	☐	☐
The consent form discloses the procedures to be performed.	☐	☐
The consent form discloses that participation is voluntary.	☐	☐
The consent form discloses the name and contact information of the investigator.	☐	☐
The investigator explains how they will take adequate steps in maintaining the privacy of participants.	☐	☐

Maximum Number of Participants. State an exact maximum number of participants who will be enrolled during the duration of the study.

Enrolment must not exceed the above value without IRB approval.

Categorization of Research. Check "Yes" or "No". At least one of the following must be selected as "Yes".

	Yes	No
Research involving survey procedures, interview procedures, or observation of public behavior.	☐	☐
Research involving the collection or study of existing data, documents, records that cannot be identified, directly or through identifiers linked to the participant.	☐	☐

Target Population(s). Check the target populations of the study.

Population	Excluded	Included	Notes
Minors	☐	☐	Inclusion implies denial of IRB application.
Prisoners	☐	☐	Inclusion implies denial of IRB application.
Pregnant Women	☐	☐	Explain in the risk section of the protocol form whether there are any additional risks to pregnant women and/or fetuses.
Adults with diminished/reduced capacities	☐	☐	Inclusion implies denial of IRB application.
university students or employees	☐	☐	Inclusion might imply denial of IRB application.
Non-English speakers	☐	☐	Protocol form must include the qualifications of the translator(s) and study members if obtaining consent in a language other than English. All written information to be seen by subjects must be translated and submitted with this application.
Tribal populations	☐	☐	Inclusion usually implies special review or denial of IRB application. Contact https://www.ihs.gov/dper/research/hsrp/ for assistance.

Characteristics. Describe the characteristics of the proposed participants and explain how the nature of the research requires/justifies their inclusion.

Exclusions. Will any participants be excluded based on age, gender, race/ethnicity, pregnancy status, language, education, or financial status?

- ☐ Yes
- ☐ No

If *Yes*, then explain the criteria and reasons for each exclusion.

Recruiting. Describe how you will be able to recruit the necessary number of participants to complete the study.

Recruiting and privacy. Explain how the recruiting process respects potential participants' privacy.

Compensation. Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study? (Please note that the university disallows compensation or incentives for participation in research.)

- ☐ Yes
- ☐ No

Consent processes. Explain the informed consent process and submit a copy of the informed consent form along with this application. All studies at the university must include an informed consent form and consent process. Explain when and where consent will be obtained and how subjects and their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation.

Privacy. Describe the provisions to protect the privacy interests of the participants. Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records. Further, indicate what will happen to identifiable data at the end of the study. (Primary research data should be retained for a minimum of three years after the final project closeout.)

Research assistants. Research assistants are all persons who contribute to the implementation of the study, including interaction with subjects and/or access to data, but do not participate in the design and development of the study protocol. The IRB needs to be made aware of anyone who will be interacting with participants and their qualifications to do so to ensure that the rights and safety of the participants will be adequately protected. As such, the use of research assistants has to be communicated to the IRB, and documentation on their having completed ethics training, as well as any study-specific training needed to adequately protect participants, must be provided. When possible, information about research assistant recruitment and status should be provided.

Research assistants also include statisticians, subject matter experts, and individuals charged with assisting with the shaping, handling, processing, and interpretation of data.

Please describe the utilization of research assistants, if applicable.

Instrumentation. If the research involves any of the following, check the appropriate box.

Instrument	Involved	Notes
Audio or video recordings	☐	The consent form must indicate whether recording is optional or required for the study. If optional, provide an opt-in/opt-out section within the consent form.
Data, private or proprietary	☐	Inclusion implies denial of IRB application.
Data, publicly accessible	☐	None.
Deception	☐	Inclusion implies denial of IRB application.
Focus groups, interviews, or surveys	☐	Include surveys, interview guides, and focus group manuals.
Translated documents	☐	Include material in English and its translated equivalent.
Waiver of documentation (signature) of informed consent.	☐	Inclusion implies denial of IRB application.
Waiver of parental consent/permissions.	☐	Inclusion implies denial of IRB application.

State the sources of publicly accessible data utilized by the study.

Potential Conflict of Interest. One or more of the following categories must be selected.

It is the responsibility of the IRB and its members to represent the interests of human subject participants and to ensure that the subjects are completely informed about the research in which they will participate, that participation is voluntary, and that the risks of participation are accurately evaluated and do not outweigh the potential benefit to the subjects or society.

A conflict of interest occurs when an IRB member is in a position to advance the IRB member's interest or that of the IRB member's family or others to the potential detriment of any human subject involved in the research under review. This conflict of interest can take many forms, including financial conflict of interest if the IRB member or institution stands to benefit financially from the research.

A conflict of interest can also exist during the review process if a member of the IRB has a relationship with the investigator(s) conducting the trial, including as a research collaborator, member of the family, or in a student or mentor relationship, etc. Most potential conflicts of interest can be managed or eliminated via recusal of the conflicted person from IRB deliberations on the project where the conflict exists. It is the IRB member's responsibility to inform the Chair of the IRB of any potential conflict of interest that they might have with any human subject research under review by the Board.

Investigators conducting human subject research can also have conflicts of interest, including financial conflicts of interest, if they or their family stand to benefit as a result of their human subject research. Investigators with a financial interest in the entity sponsoring their research should inform the Board of this and potentially also inform the subjects.

Do any of the members of the study, or any of their family members, have a financial or other business interest in the source(s) of funding, materials, or equipment related to this study?

- ☐ Yes
- ☐ No

IRB Application

Principal Investigator Assurance Statement

I understand the IRB's policies and attest:

- ☐ that the information in this application is complete and accurate;
- ☐ that research efforts (and data collection) will not commence before IRB approval;
- ☐ to the scientific merit and importance of the study;
- ☐ to my competency as an investigator as to conduct the research project;
- ☐ that all instruments and equipment are adequate to conduct the research project.

I agree to:

- ☐ comply with IRB requirements and decisions;
- ☐ accept responsibility for all aspects of the research project;
- ☐ obtain prior approval from the IRB before amending or altering the study or its documents;
- ☐ report to the IRB in the event of adverse event(s) or unanticipated problems;
- ☐ complete and submit all required IRB forms;
- ☐ notify the IRB immediately upon the discovery of a potential conflict of interest not disclosed in this application.

Electronic Signature/Agreement

Investigator

Date of IRB Application

STOP HERE: APPLICATIONS MAY ONLY BE SUBMITTED BY THE DISSERTAION CHAIR OF THE INVESTIGATOR

SUBMIT COMPLETED APPLICATIONS AND RELEVANT DOCUMENTS