Holy Family University
Institutional Review Board

Proposal #
IRB use only

Submission Checklist

Please use the checklist provided below to ensure your submission is complete. Complete and submit this checklist with your application.

All submissions that may require a FULL REVIEW must be submitted no later than two weeks prior to the next scheduled IRB meeting. Please contact the IRB Chair prior to submission if you are unsure if your research would necessitate a full review. The IRB Chair will determine whether the proposed research qualifies as an EXEMPT, EXPEDITED, or FULL REVIEW proposal.

All applications/proposals must be scanned and submitted electronically via the IRB Canvas page. All documents relevant to your proposed study (e.g., proposal, consent form, CV, Ethics Certificate, etc.) must be submitted electronically, including signature pages.

Please note that the signature of your Dean or his/her designee is required with all proposals. If you are not a member of Holy Family University's faculty, staff, or student body, please contact the IRB Chair for instructions on whose signature is required for your IRB submission.

1) IRB Application & Proposal Checklist from IRB School Representative (see next page) □

2) Application for IRB Approval (see page 3 below) □

3) Research Proposal □

4) Informed Consent Form or Research Policy Statement (use template) □

5) Recruitment Materials □

6) Protection of Human Research Participants Certification (required for all researchers involved in study) □

7) Conflict of Interest Form (required for all researchers) □

8) Curriculum Vitae (required for all researchers involved in the study) □

9) Signature/Date: _____ □
(Dean or Designee)

IRB Application and Proposal Checklist

(This page should be completed by the IRB School Representative prior to submission to the Dean)

Title of Proposal: _____

Name(s) of Investigators: _____

Does the IRB application include:

- A *completed* IRB Submission Checklist? ☐ Yes ☐ No
- A *completed* Application for IRB Approval? ☐ Yes ☐ No
- A *current* Ethics Certificate?* (valid w/in the past 3 years) ☐ Yes ☐ No
  - A *signed* Verification Statement?* ☐ Yes ☐ No
- A *completed* Conflict of Interest Form?* ☐ Yes ☐ No
- A current CV?* ☐ Yes ☐ No
- All interview/survey questions? (if applicable) ☐ Yes ☐ No ☐ n/a
- A proposal ☐ Yes ☐ No
- Consent Form, Research Policy Statement, or Info Letter ☐ Yes ☐ No ☐ n/a
- All necessary signatures/dates of researchers ☐ Yes ☐ No
  - [*] **Required for each researcher**

Does the proposal describe:

- The participants? ☐ Yes ☐ No ☐ n/a
- Specific procedures (recruitment and/or data collection)? ☐ Yes ☐ No

Does the Consent Form:

- Follow the IRB template? ☐ Yes ☐ No ☐ n/a
- Include correct contact information for IRB Chair? ☐ Yes ☐ No ☐ n/a
  - Stacy McDonald, Ph.D.
  - smcdonald1040@holyfamily.edu **and** 267-341-3549
- If researcher is planning to record participants, (video/audio) does the Consent Form explicitly state this and how the recordings will be protected and stored? ☐ Yes ☐ No ☐ n/a

Recommendations:

☐ Proceed to Dean

☐ Revise/modify application and resubmit for the following reason(s):

_____

_____

_____

Reviewed by: _____ _____

(Signature) (Date)

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Application for IRB Approval

Investigator Information **Co-investigator / Student**

Full Name: _____ Full Name(s) _____

Department: _____Department: _____

Campus: _____Campus: _____

Address: _____Address: _____

Office Phone: _____Office Phone: _____

FAX: _____ FAX: _____

E-mail: _____ e-mail: _____

_____ _____

Signature/Date: Investigator

Signature/Date: Co-Investigator

Send all future correspondence to:

Name: _____

E-mail address: _____

List key words related to this study:

_____

Proposal title:

_____

Expected length of study: _____

Number of subjects involved: _____

Briefly state the purpose of the study:

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Protection of Human Research Participants Certification

Holy Family University requires that any faculty, staff, or students intending to conduct research involving human subjects complete one of the following training requirements prior to submitting a proposal for approval by the Institutional Review Board.

Option #1 Global Health Training Centre Online Tutorial and Certification https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/ (You will be asked to create a FREE account in order to complete this training (14 modules).

or

Option #2 The Collaborative Institutional Training Initiative (CITI Program) and Certification https://about.citiprogram.org/en/series/animal-care-and-use-acu/ (You will be asked to register to create a FREE account in order to complete this training (9 modules).

or

Option #3 If you have completed a protection of human research subjects certification program required and/or approved by another institution, please submit the name of the program, the organization that developed the program, documentation verifying the content of the program, and documentation verifying that you successfully completed the program.

Verification Statement

I, _____ have completed Option ___ as required prior to submitting a proposal for Institutional Review Board approval. For Options #1 and #2, I have attached a copy of the certificate that I printed out upon completion of the training. For Option #3 I have attached all required documentation as stated above.

_____ _____
Signature Date

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Conflict of Interest Declaration

This form must be filled out for all researchers involved with this project.

Answer ALL questions; you MUST explain any questions answered YES

Do you have a proprietary or financial interest in the test product such as a patent, trademark, copyright, or licensing agreement?

YES ____ NO ____

Have you entered into or expect to enter into any financial arrangement with study sponsor whereby compensation for conducting the study could be influenced by the outcome of the study? (This includes, for example, an equity interest in the sponsor or compensation tied to sales of the product, such as a royalty interest.)

YES ____ NO ____

Do you have a significant equity interest in the sponsor of the study? (This would include, for example, any ownership, stock options, or other financial interest whose value cannot be easily determined through reference to public prices. It also includes an equity interest in a publicly traded company exceeding $50,000 during the period of the study and 1 year thereafter).

YES ____ NO ____

Have you received or expect to receive significant payment of other sorts from the sponsor? [This does not include the cost of conducting clinical studies. This would include, for example, payments made to the investigator or the institution to support activities that have an aggregate monetary value greater than $25,000 (i.e. a grant to fund ongoing research, compensation in the form of equipment, retainers for ongoing consultation or honoraria.)]

YES ____ NO ____

Will you be financially rewarded, directly or indirectly, for the enrollment or participation of subjects?

YES ____ NO ____

_____

Will you or your department be paid or compensated for subjects enrolled?

YES ____ NO ____

_____

Is the funding level contingent upon the number of subjects enrolled?

YES ____ NO ____

_____

Will enrollment of subjects generate medical fees, which will directly or indirectly benefit you or your department?

YES ____ NO ____

_____

Proposal Title: _____

Investigator Name and Title:

_____

By signing below, you certify that the above information is complete and accurate, and you agree to promptly update the above information if any relevant changes occur to your answers.

Signature & Date:

_____

CONSENT FORM TEMPLATE
Instructions are in Bold in parentheses. Use School letterhead

TITLE OF RESEARCH STUDY
Participant Informed Consent

Introduction and Background Information
You are invited to participate in a research study. The study is being conducted by Dr. **(principal investigator/faculty member)** and **(student's name)**. The study is sponsored by **(list if the study is sponsored by an outside source)** and Holy Family University, School of **(give school name)**. The study will take place at **(name of sites where study will be conducted)**. Approximately **(give number)** subjects will be invited to participate. Your participation in this study will last for **(give time in days, months, years, or hours).**

Purpose
The purpose of this research study is to (include a brief description of the scientific purpose of the study. This description should be in lay terms, written so subjects reading at the 5th grade level could understand the terms. Include total study length and session length).

Procedures
In this study, you will be asked to **(Include an explanation of any questionnaires, surveys or other instruments the participant will be asked to complete and explain their purpose. Include information in this paragraph about how long it should take the participant to complete the questionnaires or other procedures).**

Potential Risks and Benefits
The potential of risk to the participants in this study is no greater than that ordinarily encountered during their (select one of the following: **normal daily routine OR performance of their professional responsibilities OR general research studies)**. This may include minimal psychological risks such as concerns about (**insert appropriate concerns**) typically associated with (**insert topic, such as an educational setting**). It is projected that the results will help the researcher better understand (**insert research topic**). The risk to benefit ratio is such that the limited identified risks to the participants and investigators of this study are outweighed by the potential benefit to the participants and larger community. The possible benefits of this study include (**list any possible benefits for the subject or for humankind**). The information collected may not benefit you directly. The information learned in this study may be helpful to others.

Confidentiality
Although absolute confidentiality cannot be guaranteed, confidentiality will be protected to the extent permitted by law. The study sponsor, the Institutional Review Board, or other appropriate agencies may inspect your research records. If the data collected in this research study are published, your identity will not be revealed.

Voluntary Participation
Your participation in this research study is voluntary. You are free to withdraw your consent at any time without penalty or loss of benefit to which you are otherwise entitled.

Research Subject's Rights and Contact Persons
You acknowledge that all your present questions have been answered in language you can understand and all future questions will be treated in the same manner. If you have any questions about the study, please contact **(Name and phone number of the researcher)** If you have any questions about your rights as a research participant, you may contact Dr. Stacy McDonald at 267-341-3549 or smcdonald1040@holyfamily.edu. At that time, you will have the opportunity to discuss in confidence any questions about your rights as a research participant. The IRB, composed of members of the University community as well as lay members of the community who are not connected with the University, has reviewed this study.

Consent
You have discussed the above information and hereby consent to voluntarily participate in this study. You have been given a copy of the consent.

_____ _____
Signature of Subject Date Signed

_____ _____
Signature of Investigator Date Signed

Proposal Guidelines

Please include the following in your proposal:

- A brief literature review, statement of the objectives (research questions), rationale (need) for the proposed project, and the proposed site(s) for data collection.

- A detailed description of the subjects:

    - Who will be the subjects? How and from where will they be obtained? If you plan to advertise for the subjects, include a copy of the recruitment ad.
    - What are the inclusion criteria for subjects? Exclusion criteria? Justify the inclusion and exclusion criteria you have established.
    - How will you assure the subjects meet these inclusion and exclusion criteria? Include a copy of any questionnaire or similar instrument that the investigator or subject completes to identify inclusion or exclusion (if applicable).

- A description of the Procedures (What precisely will be done to the subjects):
    - Explain your methods and procedures in terms of what will be done to the subjects as they participate in the research project.
    - If you are using a questionnaire or handout, please include a copy.
    - If you are not the author of the data collection instrument, please include written documentation from the author granting you permission to use the instrument.
    - If you are using specialized equipment, please include a detailed description of the equipment and how it will be used as well as the potential effect on subjects.

- A description of the potential risks to the subjects.
    - If no expected risks, or minimal risk, please state this and explain why it is minimal risk.
    - What potential benefits will accrue to justify these risks?
    - How will data be monitored to ensure the safety and privacy of the subjects?

- Informed Consent (use Holy Family templates)
    - State how the subjects' informed consent will be obtained (i.e., in person, via the first page of an online survey, etc.).
    - Provide a copy of the Informed Consent Form, Research Policy Statement, or Informational Letter that will be provided to subjects.
    - The Informed Consent Form must include or address the following (each item is taken directly, or paraphrased, from the Code of Federal Regulations, Office of the Protection of Human Subjects (OPHS) reports: "Protection of Human Subjects, Title 45, Code 46):

        1. All of the significant material bearing on the risks and benefits attendant to the research. Federal regulation requires that each subject be given a copy of the consent statement.
        2. Be written in a manner understandable by the subjects or their representatives.
        3. Clearly state that the study involves research and explain the purpose(s) of the research.

4. Describe the procedures to be followed and identify any which are experimental. Include a statement of the duration and frequency of each subject's participation.
5. Describe any foreseeable risks or discomforts to the subjects.
6. Explain how the risks will be minimized.
7. Describe any benefits to the subject or to others, which may reasonably be expected from the research.
8. Disclose appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
9. Provide each subject with the name and telephone number of the person to contact for answers to questions regarding the research and research subjects' rights, and the name and telephone number of the person to contact in the event of a research-related injury to the subject.
10. State that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
11. Describe the extent, if any, to which the confidentiality of the records identifying the subjects will be maintained.
12. For research involving more than minimal risk, an explanation as to whether any compensation is available and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information can be obtained.
13. Conclude with a statement to the effect that "I understand the above statements and I hereby consent to participate in the research as it has been explained to me."
14. Follow the consent statement with lines for the signature of the subject, parent(s) or guardian, as appropriate, a witness to the signature(s), the signature of the investigator, and the date.
15. Consent forms must be retained for at least three years following the conclusion of a research project.

- **In addition to the above, the following need to be addressed as appropriate:**
  - If vulnerable populations are involved, additional safeguards are generally required. In the case of children, in addition to the required parental/guardian consent, an "assent" document should be prepared, written in language the child will understand.
  - If the subjects are non-English-speaking, the document should be translated.
  - Where the potential need to report illegal activity to the authorities exists (e.g., child abuse, drug and alcohol abuse by minors), the subjects should be so informed before agreeing to participate.
  - Where there is reason for special concern (e.g., regarding pressure on potential subjects), the IRB may require monitoring (such as a third-party observer).