HOLY FAMILY UNIVERSITY
INSTITUTIONAL REVIEW BOARD

INTRODUCTION

The Role of the Institutional Review Board (IRB)
The IRB informs the University community-at-large concerning the responsibilities of faculty, students, or staff researchers whose projects involve human subjects, in order to insure the procedures are followed to safeguard the rights and welfare of research subjects and are in conformance with federal regulations and University policies.

The function of the IRB is to review research proposals to ensure that risks to subjects are minimized; risks to subjects are reasonable in relationship to anticipated benefits; selection of subjects is equitable; informed consent is obtained and properly documented; data collected is monitored to ensure safety of subjects; and the privacy of subjects and confidentiality of data are maintained. In addition to approving research, the IRB committee also has the authority to require modifications (in securing approval), disapprove research, conduct continuing reviews, observe/verify changes, and suspend or terminate approval of research. These IRB functions are intended to assist researchers by minimizing hazards or misunderstandings, which might lead to litigation or compromised reputations.

What research must be approved by the IRB?
Holy Family University requires that all research involving human subjects conducted by faculty, students, or staff affiliated with the University, be reviewed and approved by the IRB prior to initiation, regardless of the source of funding, and regardless of its federal status as an exempt, an expedited, or a full review project. Research is defined by federal guidelines as a systematic investigation designed to develop or contribute to generalizable knowledge and should be distinguished from potentially similar activities such as employing innovative teaching techniques and administrative data collection.

The IRB Committee Members
The overall composition of the IRB is consistent with federal guideline for Protection of Human Subjects (45 CFR 46). These federal guidelines emphasize the need for board diversity in terms of professional background and perspective, including at least one individual whose primary concern is 'nonscientific' and one person who has no other affiliation with the university. The IRB must be comprised of a minimum of seven (7) members. No member of the IRB shall be involved in the initial or continuing review of an activity in which they have a vested interest, except to provide information requested by the IRB (Appendix I). The IRB, at any time, may invite individuals with competence beyond, or in addition to, that available on the board. Invited participants have no voting privileges. The IRB also assures that consent forms as required by the Health Insurance Portability and Accountability Act (HIPAA) are properly maintained. Holy Family's IRB meets the above guidelines. Each school is required to have at least one faculty member to serve on this board. The IRB reports to the President with the Vice President for Academic Affairs (VPAA) as an ex officio member.

Current IRB Members (2018-2019):
Chairperson: Dr. Stacy McDonald – School of Arts & Sciences
Members:

Dr. Jan Buzydlowski – School of Business Administration
Dr. Daniel Bramer – School of Arts & Sciences and Ethicist
Wendi Smith, MSN –School of Nursing & Allied Health Professions
Dr. Brian Berry – School of Education
Dr. Karen Galardi –Professional Staff
Dr. Faye Schilling – Community Liaison
Dr. Michael Markowitz – Vice President, Academic Affairs

Review Process

Scheduled meetings of the IRB are published on Holy Family's IRB website at the beginning of each academic year. Dates may also be published on the Academic Calendar.

When working on a fixed deadline grant proposal that will require IRB approval, please contact the IRB committee chair EARLY in the grant preparation process to alert the board to the proposal and to discuss submission deadlines.

Submission Deadlines

- Applications may be submitted to the IRB Chair, Dr. Stacy McDonald, **via the IRB Canvas page** at any time.

- Applications that require full review by the IRB must be submitted to the IRB Chair, Dr. Stacy McDonald, **via the IRB Canvas page** at least two (2) 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.

Review process for applications:

- Completed applications and proposals should be submitted to the appropriate IRB School Representative first (with the exception of proposals from the School of Business Administration). If the application is not complete, it will be returned to the primary investigator with a request for more information.

- Once it is approved by the IRB School Representative, it may be submitted to the School Dean for his/her signature. Upon approval by the Dean, it may be uploaded to the IRB Canvas site.

- The chair of the IRB will review the application confirm the correct federally defined review category (EXEMPT, EXPEDITED, FULL REVIEW).

- Exempt and Expedited category applications will be reviewed by either the Chair or a designated IRB member. The chair or board members will make recommendations for 'approval as proposed', 'approval with recommendations', or 'not approved.' The full IRB will review any proposal that is 'not approved' by the exempt or expedited review process.

- The IRB chair will inform the applicant of the IRB's decision and provide guidance related to any modifications requested if the application is 'approved with recommendations.' All proposals 'approved with recommendations' will be re-submitted to the Chair for final approval once revisions are completed.

IRB Considerations in Review of Proposal

The IRB will pay special attention to the following:

1. **Identification and Assessment of Risks**: These may be of a physical, psychological, social or economic nature. In behavioral, social, and some biomedical research, the methods for gathering information may pose the added risk of invasion of privacy and possible violations of confidentiality.

2. **Determination that Risks are Minimized:** Precautions, safeguards, and alternatives should be incorporated into the research design where warranted to reduce the probability of harm.

3. **Assessment of Anticipated Benefits:** Benefits may be to subjects and to society. The IRB will look for a clear statement of benefits to subject, as well as identification of the knowledge researchers expect to gain.

4. **Determination that Risks are Reasonable in Relation to Anticipated Benefits:**. Evaluation of the risk/benefit ratio is the major ethical judgment IRBs must make. In reaching this judgment the IRB will take into account the subject population (e.g., children, pregnant women, terminally ill). In research where no direct benefits to the subject are anticipated, the IRB must evaluate whether the risks presented by procedures performed solely to obtain generalizable knowledge are ethically acceptable.

5. **Informed Consent:** Because of the centrality of informed consent to research with human subjects, a separate section above lists the basic elements of the consent document and process. The IRB will evaluate the information to be presented to subjects in light of the risks and benefits of the proposed research procedures.

6. **Privacy and Confidentiality:** Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. For example, in recruiting subjects through a clinic, institution, or doctor, it is important that potential subjects have an opportunity to refuse participation before their identity or means of contacting them is revealed to a researcher. Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in

ways that are inconsistent with the understanding of the original disclosure without permission.

The IRB will seek to determine whether an invasion of privacy is involved. It will also examine the research design to assure that information linked to individuals is adequately protected from breaches of confidentiality. There are specialized security measures developed for this purpose. These include the use of codes, storage of data under lock and key, and certificates of confidentiality.

Report of IRB Decisions

For exempt proposals, the Chair of the IRB will forward the decision in 30 days or less via e-mailed letter to the primary investigator. At the completion of Expedited or Full reviews, the IRB chair will send an e-mailed letter to the primary investigator. The letter will indicate one of the following:

- The proposal is approved as submitted.

- The proposal is approved with specific revision(s). The investigator is required to resubmit the proposal to the IRB Chair to confirm that the revisions were made. A letter of approval is then forwarded to the primary investigator.

- The proposal is not approved. The proposed research cannot be conducted at Holy Family University

- The proposal was tabled. Discussion of the proposal has been postponed pending further information.

Any revisions to the human subjects proposal requested by the IRB should be incorporated into the written proposal, with revision dates on each revised page and on the proposal itself, so that the operative approved one is clearly marked.

Informed Consent Approval
When the Informed Consent document has been approved by the IRB, the primary researcher should print the approved document on Holy Family University letterhead and it should be given to participants, signed, and returned to the primary investigator for safekeeping. The investigator must retain signed consent forms for at least three years past completion of the research activity and should inform the IRB, in writing, where the forms are kept. IRB approval of the research together with the informed consent document expires one year from the date of initial approval. It is the responsibility of the researcher to provide timely application for continuing IRB review and approval as necessary. Please contact the Chair of the IRB if you have any questions regarding informed consent.

IRB Requirements for Approved Projects
Periodic Review (Taken from Section 46.109e of OPRR Reports: protection of Human Subjects. Title 45, Code of Federal Regulations, Part 46)

"The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year." The frequency, with which reports must be submitted to the committee, will be determined by the board and communicated to the researcher in the project approval letter.

- ***Adverse Effects or Significant Reactions***
  Principal investigators are responsible for immediately reporting to the IRB, in writing, any unanticipated injuries or other problems involving risks to subjects and others.
- ***Amendments/Changes***
  Modifications to the approved research proposal that affect the treatment of human subjects must be communicated in writing, reviewed, and approved by the IRB chair or designee prior to their implementation. Proposed changes should not be initiated without IRB review and approval.

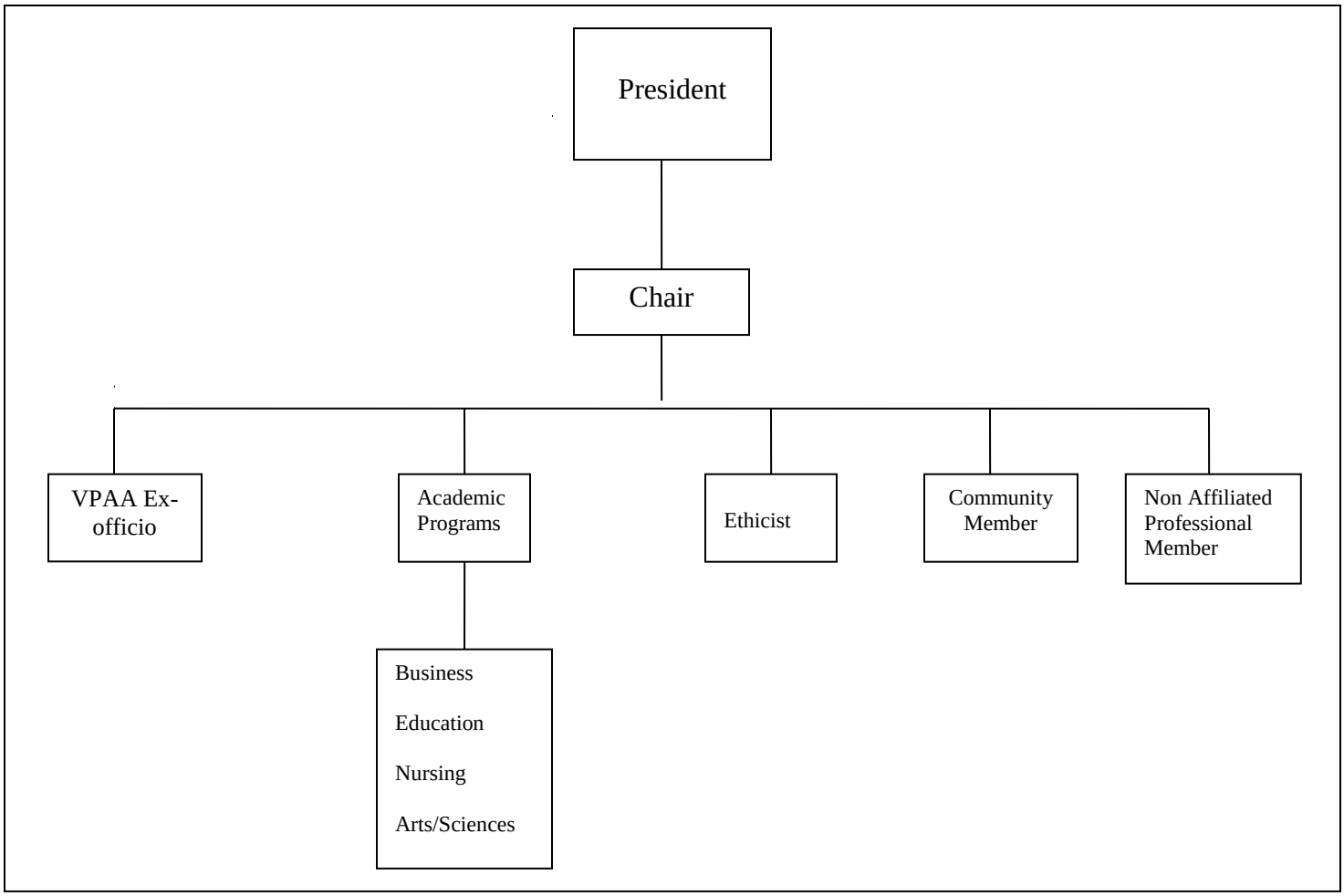
  Report concerning the progress of a research project should be made in writing to the IRB via the Academic Affairs Office. Holy Family University's policy for ongoing research requires a review at least once every twelve months. The IRB may require more frequent review, as appropriate to the degree of risk to participants. This review should be substantive and meaningful, not simply a statement of "no change." The primary investigator should supply an electronic copy to the IRB chair, Dr. Stacy McDonald (smcdonald1040@holyfamily.edu), at least one month before expiration of the specified approval date to allow for sufficient time for review and response.

IRB Authority
The IRB has the authority to suspend or terminate previously approved research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants.

All research that involves human subjects, conducted at Holy Family University, **MUST** have approval of the IRB prior to implementation. The IRB has the authority to sanction any faculty and staff who does not adhere to IRB policies.

APPENDIX I

HOLY FAMILY UNIVESITY IRB ORGANIZATIONAL CHART



APPENDIX II
IRB PROTOCOL REVIEW FLOWCHART