Institutional Review Board Handbook

Southern Nazarene University

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Introduction

The Southern Nazarene University (SNU) Institutional Review Board (IRB) is responsible for the protection and ethical treatment of human research subjects. The SNU IRB reviews all research involving human subjects that is sponsored by units of SNU or research involving human subjects that is conducted on the SNU campus which involves personnel (faculty, staff, and/or students) and/or facilities of these units.

This handbook is designed to assist student, faculty, or staff researchers affiliated with SNU in planning their research projects as well as applying for IRB approval prior to conducting their research. Anyone affiliated with SNU who is pursuing a research project must submit an IRB application and receive written approval from the IRB before soliciting any human subjects or collecting any data, including pilot data. For thesis and dissertation students, IRB approval is required before the study can be conducted regardless of the research methodology.

Statement of Ethical Principles

The SNU IRB views research proposals according to the three ethical principles summarized in the "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The principles from the Belmont Report are:

Respect for persons – protecting the autonomy of all people and treating them with courtesy and respect; providing for voluntary participation and informed consent

Beneficence – adhering to the philosophy of "Do no harm" while maximizing benefits for the research project and minimizing risks to the research subjects

Justice – ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly in the selection of research subjects

The Office for Human Research Protections (OHRP) gives oversight on human subjects research and establishes the framework for U.S. Department of Health & Human Services (HHS) regulations for the protection of human subjects. These regulations are set forth in Title 45 (Public Welfare), Part 46 (Protection of Human Subjects) of the Code of Federal Regulations (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). The SNU IRB follows these federal regulations, and is committed to ensuring that all human subjects research is conducted according to the highest ethical standards. Excerpts from and links to the 45 CFR Part 46 regulations (2018) will be included throughout this handbook.

IRB Membership

IRB members are appointed to two-year, renewable terms, staggered to ensure that no more than two members are replaced in a given year; the IRB Chair is expected to hold the position for several years. The composition of the IRB is designed to meet regulatory requirements and to provide a complete and careful review of all research projects submitted. The IRB is composed of the IRB chair, a representative from the department of Institutional Research and at least four faculty members: two from the College of Professional and Graduate Studies (with at least one representative being a dissertation advisor for the DEAL program) and two from the College of Undergraduate Studies. The IRB chair will collaborate with the Vice Presidents of Academic Affairs from the two colleges to identify and nominate qualified faculty, with a focus on fostering a board with diverse viewpoints from multiple academic areas.

The IRB includes at least one individual whose primary concerns are in nonscientific areas and at least one community representative with no SNU affiliation. The IRB may, at its discretion, invite outside consultants to assist in reviews requiring specialized expertise. Consultants may not vote on the review under consideration.

Pursuant to HHS CFR 45 § 46.107(e), "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB."

The term "conflict of interest in research" refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, a member's professional judgment in reviewing or evaluating a research project. The goal in adhering to this principle is to prevent conflicting interests from interfering with the review process either by competing with an IRB member's or consultant's obligation to protect participants or by compromising the credibility of the review process. A conflict of interest depends on the situation, and not on the character or actions of the individual member.

An IRB member is said to have a conflicting interest whenever that IRB member, or his/her spouse, domestic partner or first degree relative (e.g., child, sibling, or parent):

- is an investigator or key personnel on the protocol under consideration;
- acts as an officer or a director of the sponsor or an agent of the sponsor;
- is involved in the research as a coordinator, protocol consultant and/or primary advisor;
- is identified as a certifying member of the research proposal on submitted documentation;
- has received significant monetary or financial gifts, including direct payments, consultancy fees, equity interests, intellectual property rights.

If an IRB member recognizes a conflicting interest in an item under review at the IRB meeting, the IRB member must inform the Chairperson of the conflicting interest and leave the room during the final discussion and vote on the item. Their absence will not be counted against quorum.

Human Subjects Training

SNU requires training for all faculty, staff, and students who plan to conduct research involving human subjects. Training includes, but is not limited to, topics such as ethics, federal regulations, risk assessment, informed consent, confidentiality, and vulnerable populations. The IRB Chair and all IRB members must complete human subjects training upon being appointed to the IRB and every three years for the duration of their membership.

IRB Responsibilities

The four primary responsibilities of the IRB at Southern Nazarene University include:

Review – The IRB reviews all proposed research projects involving human participants.

Policies and procedures – The IRB develops policies and procedures for review of human subjects research that are implemented at both the undergraduate and graduate levels.

Education – The IRB provides information regarding IRB training, policies, regulations, and procedures in support of campus research initiatives.

Records and files – The IRB maintains a record of review proceedings and decisions, in accordance with institutional and federal guidelines, for at least three years following termination of the projects.

Definition of Terms

The definitions below are excerpted from 45 CFR Part 46 and will be used throughout this document.

Human subject – a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

Interaction – includes communication or interpersonal contact between investigator and subject such as:

- Interviews
- Questionnaires and surveys
- Classroom instruments, evaluations, and exercises
- Examination of private records (e.g., medical, psychological, school records)
- Observations of public behavior by identifiable individuals (e.g., in a classroom)

Intervention – includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes

Principal investigator – the individual who has primary responsibility for designing and conducting the research project. Principal investigators (PIs) *must* have at least a bachelor's degree. For projects involving undergraduate students, the advisor or professor will need to be listed as the principal investigator.

Private information – includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record)

Minimal risk – 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

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

Research Contexts

As defined in the previous section, research is a systematic investigation designed to develop or contribute to generalizable knowledge. Any activity that meets this broad criterion and that is conducted by SNU faculty, staff, or students, or that uses SNU facilities, personnel, or students is considered research. It does not matter whether the activity takes place within and as a part of some other activity, however large or small, or whether the research is the whole of a project.

When data gathering within the context of training, demonstration, or service projects, researchers should ask several questions to determine if any aspect of the project will qualify it for human subjects review. Relevant questions are:

- Will the researcher seek out subjects (or settings that contain subjects) for the training or service project rather than the subjects seeking the training or service from the researcher in their normal pursuit of professional development?
- Does the researcher anticipate in advance of conducting the project that the findings of the research investigation will be analyzed, interpreted, and disseminated?
- Might the knowledge gained from interaction with subjects be applied beyond the service or training project to a similar situation, thereby leading to a new procedure or process?

If the researcher's response is "yes" to one or more of the preceding questions, then the training, demonstration, or service project must be submitted for review or for certification of exemption from review by the IRB.

A special context of data gathering is the thesis or dissertation. By accepting a thesis or dissertation, SNU disseminates its contents for use by others. Therefore, a thesis or dissertation that involves the use of human subjects must always be submitted for review or for certification of exemption from review by the IRB.

Informed Consent

The need for informed consent and the development of a legally appropriate consent document is a vital step in the design of research involving human subjects. Informed consent must be obtained before soliciting human subjects or collecting data. This section of the handbook includes the general requirements for informed consent, the basic elements of informed consent, and additional elements of informed consent taken from 45 CFR Part 46.116 of the Federal Code.

A consent form guideline should be used when preparing the consent form for any human subjects research project. A consent form guideline is included in Appendix B of this handbook. A copy of the consent form should accompany the Application for Review of Human Subjects Research form (included in Appendix A).

The *general requirements for informed consent* include:

- Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
- An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
- The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
- No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

The *basic elements of informed consent* include the following information that shall be provided to each subject or the legally authorized representative:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation 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 may be obtained;

- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
    - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

One or more of the *additional elements of informed consent*, when appropriate, also shall be provided to each subject or the legally authorized representative:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- The approximate number of subjects involved in the study;
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Alteration or Waiver of Informed Consent

The IRB may approve a consent procedure which does not include, or modifies, some or all of the basic elements of informed consent (see previous section), or may waive the requirement to obtain informed consent. In order for an IRB to alter or waive consent, the IRB must find and document that:

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;

- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Inclusion of Vulnerable Populations

When research subjects are incapable of protecting their own interests and/or are likely to be vulnerable to coercion or undue influence, additional safeguards must be taken to protect their rights and welfare. Vulnerable populations include children, prisoners, pregnant women, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, and persons not proficient in the language of the research study. Plans for implementing additional safeguards must be described in the IRB application. Special procedures for protecting vulnerable populations are addressed in:

46.116 Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

46.116 Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

46.116 Subpart D – Additional Protections for Children Involved as Subjects in Research

Documentation of Informed Consent

According to 45 CFR Part 46.117, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the

person signing the informed consent form. The informed consent form may be either of the following:

- A written informed consent form that meets the requirements of 45 CFR Part 46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.
- A short form written informed consent form stating that the elements of informed consent required by 45 CFR Part 46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the basic elements of informed consent key information were presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy

of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Organizational Permission

In addition to obtaining informed consent from individuals, any organization where participants are being recruited should grant the researcher permission to solicit subjects. Organizational permission includes social media as well. For example, a researcher who wants to solicit subjects from a LinkedIn group should obtain permission from the founder, administrator, or organization responsible for the social media site. It is the researcher’s responsibility to provide a document (usually a letter) from each organization that grants permission to recruit participants for human subjects research. Organizational permission should be included in the IRB application materials.

Use of Existing Instruments

Researchers may use existing instruments, e.g., questionnaires and psychological tests, to collect data if permission is granted by the original author, institution, or organization. Or, researchers may modify existing instruments to collect data. In either case, proof of permission to use existing, including modified, instruments should be included in the IRB application materials.

Non-Disclosure by Project Assistants

Individuals who assist in ancillary capacities with research projects and who have access to raw data and/or participant information should sign a non-disclosure document. Examples of these individuals include those who administer surveys or tests, record participants via audio or video, or transcribe interviews or recordings. The non-disclosure document is a safeguard for protecting confidentiality of human subjects and should be addressed in the IRB application.

Categories of Human Subjects Research

Depending on the risk level and the human subjects demographic, a proposal will fall into one of three categories: exempt, expedited, or full board review. Investigators should request the level of review they feel is appropriate; however, the IRB Chair (or the board in special cases) will determine the correct level of review.

Exempt Category

Although this category is labeled "exempt," this type of research does require IRB review and registration. This type of research presents the lowest amount of risk to human subjects because it often involves the collection of anonymous or publicly available data. An exempt review does not absolve the investigator from ensuring the welfare of subjects is protected and that methods used to gain subject consent and provide information are appropriate. To qualify, research must fall into one or more of the exempt categories detailed in 45 CFR Part 46.104. These categories are briefly summarized as:

- Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).
- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording.
- Secondary research for which consent is not required, including secondary research uses of identifiable private information or identifiable biospecimens.
- Research and demonstration projects that are designed to study, evaluate, improve, or examine public benefit or service programs.
- Taste and food quality evaluation and consumer acceptance studies.

Expedited Category

This type of research involves collection of samples and data in a manner that is not anonymous and that involves no more than minimal risk to subjects. To qualify, research must fall into one or more of the exempt categories detailed in 45 CFR 46.110. These categories are briefly summarized as:

- Clinical studies of drugs and medical devices
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- Prospective collection of biological specimens for research purposes by noninvasive means
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in medical practice

- Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis)
- Collection of data from voice, video, digital, or image recordings made for research purposes
- Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Full Board Category

A full board review is required for research that is not eligible for exempt or expedited review. Research that involves more than minimal risk, vulnerable populations, intentional deception, or personally intrusive procedures must undergo a full board review. Examples that require full board review include surveys or questionnaires that solicit information regarding sexual practices, instances of child or sexual abuse, criminal activities, drug and alcohol use, or eating disorders.

The Review Process

The principal investigator initiating a project involving human subjects is responsible for ensuring appropriate IRB review before submitting an off-campus proposal or undertaking any research activities. The review process and time will vary with the category of research (exempt, expedited, full board).

The principal investigator is responsible for preparation of the Application for Review of Human Subjects Research (see Appendix A). This application should be completed and submitted to IRB@snu.edu for all categories of research.

Exempt review: Applications for exempt research are sent for review to one reviewer to certify exemption. This process takes approximately three to five working days.

Expedited review: Expedited research applications are sent for review to two IRB members. The reviewers are selected based on expertise; however, applications are not reviewed by a member from the originating department. Review time is approximately two weeks.

Full board review: Applications requiring full board review are first sent to two IRB members to determine if all required application components are completed or if additional information is needed. After receipt of any requested information or changes, the application is then submitted to the full IRB board for review. The application must be complete before the review is initiated, including receipt of any revisions requested by the preliminary review. Total review time ranges from three to six weeks.

The board convenes on the last Thursday of each month, unless there are no applications or other business to attend to. Applications for full board review, appeals and other agenda items need to be submitted no later than 10 days before the scheduled meeting. The IRB chair is responsible for ensuring the IRB website (snu.edu/irb) is up to date with the correct dates and information.

Criteria for IRB Approval of Research

The IRB uses the following criteria from 45 CFR Part 46.111 when reviewing applications for approval:

- Risks to subjects are minimized (1) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk and (2) by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- 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.
- Selection of subjects is equitable, taking into consideration the purposes of the research and the setting in which the research will be conducted.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with 45 CFR Part 46.116.
- Informed consent will be appropriately documented or appropriately waived in accordance with 45 CFR Part 46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When research involves subjects who are considered a vulnerable population, additional safeguards are included to protect their rights and welfare.

Results of IRB Review

The IRB can take the following actions based upon an application review:

- *Approved*: The IRB approves or certifies exemption of the project as submitted. The primary investigator receives written notification of approval or exemption and may proceed with solicitation of participants and data collection.
- *Approved pending site permission*: The IRB approves the project prior to receiving organizational permission(s) to conduct the project. After documentation of organizational permission(s) is filed with the IRB, the primary investigator receives written notification of approval and may proceed with solicitation of participants and data collection.
- *Revise and resubmit*: This decision necessitates that revisions and/or clarifications addressing issues raised during the review be submitted to the IRB. The IRB will provide specific guidance regarding the changes that will be required for resubmission. After revisions are made, the principal investigator must wait for written notification of approval before proceeding with solicitation of participants and data collection.
- *Disapproved*: Applications are disapproved if the proposed project does not meet the criteria for the protection and ethical treatment of human research subjects. The IRB will provide the principal investigator a written statement of the reasons for its decision.

IRB Appeals Process

Principal Investigators (PIs) may disagree with an IRB decision regarding the PI's application. The PI may appeal the IRB's decision by submitting a request in writing including information about the reason for the appeal and any materials supporting the request. Supporting materials may include revised application documents, current literature, letters of support, and/or other information relating to the proposed research. Appeals must be made within 30 days of PI notification of the initial IRB decision.

All appeals will be heard in a full board review, regardless the category of the initial application (exempt, expedited, full board). The request to appeal will be reviewed by the convened IRB at the next possible meeting. The PI will be invited to attend the meeting to discuss the appeal. If appropriate, the IRB Chair may invite an expert consultant to participate in the review discussion. After the review discussion, all non-IRB members will be asked to leave and the IRB will deliberate and vote on the appeal. Possible outcomes of the appeal include:

- Accept the appeal and continue with the IRB review process;
- Require modifications to the research protocol and/or investigator and team members; or
- Deny the appeal and the original IRB determination stands.

The IRB Chair will notify the PI of the IRB's decision regarding the appeal in writing. The IRB's ruling on the appeal is final. Other institutional officials may not approve human subjects research that has not been approved by the IRB.

Noncompliance

Researchers affiliated with SNU may not solicit human subjects or collect data, including pilot studies, prior to receiving IRB approval. Not following this policy is considered a serious ethical offense in the academic community and the researcher will be subject to an IRB investigation. Any reported significant deviation in research activities previously approved by the IRB must be investigated as an issue of noncompliance. The IRB Chair shall brief the board, at the next scheduled meeting or at a specially convened meeting, on the details of an allegation of noncompliance by a principal investigator. The IRB will determine whether or not there was a violation of regulatory or institutional policies. If a violation occurred, the IRB will notify the principal investigator and the undergraduate Research Director or the Dissertation/Thesis Chair in writing of the restrictions, conditions, or other actions necessary to resolve the noncompliance.

Project Completion Report

The last step in the IRB review process is the submission of the Project Completion Report (see Appendix C) at the conclusion of the research project. For doctoral students, the form is completed after the dissertation defense and is submitted as part of the final defense paperwork. For other research projects, it is submitted at the conclusion of the research project. Submission is the responsibility of the principal investigator and the undergraduate Research Director or the Dissertation/Thesis Chair. Once a Project Completion Report is filed, the IRB Chair will reply with an acknowledgement of filing.

Extenuating Circumstances

The above policies are subject to change in the event of national emergencies or recommendations from federal, state and/or local bodies that limit personal interaction. Should these emergencies arise, the IRB will post updates on its website. These changes may come with little to no notice depending on the nature of the emergency. Existing IRB studies will be expected to comply with the new rules and new applications will need to adhere to the new guidelines until their removal. Changes may include, but are not limited to:

- Requiring existing IRB studies to submit a change of protocol form
- Extending the turnaround time for approvals of applications
- Requiring that in-person studies comply with guidelines outlined by Centers for Disease Control, Department of Homeland Security and/or other federal, state and/or local institutions

Amendment Process

The Principal Investigator may apply for changes in ongoing research studies that have been previously approved by the IRB. Minor modifications can be made through the expedited review process. Non-minor modifications will be reviewed in a convened meeting of the IRB. In order to be approved, a Modification of a Previously Approved Protocol Form must be submitted by the PI to the IRB Office along with all pertinent documentation, including the original proposal. The outlined materials are used to determine whether the amendment will be approved, whether changes will be required, or whether the PI will need to submit a new IRB application.

Appendix A

IRB#_____

APPLICATION FOR REVIEW OF HUMAN SUBJECTS RESEARCH
(PURSUANT TO 45 CFR PART 46)
SOUTHERN NAZARENE UNIVERSITY INSTITUTIONAL REVIEW BOARD

THIS FORM MUST ACCOMPANY ALL REQUESTS
PLEASE TYPE ALL INFORMATION OTHER THAN SIGNATURES

Title of Project (please type):

_____

_____

Anticipated Start Date:_____Anticipated End Date: _____

I agree to provide the proper surveillance of this project to ensure that the rights and welfare of the human subjects are properly protected. Additions to or changes in procedures affecting the subjects after the project has been approved will be submitted to the committee for review.

PRINCIPAL INVESTIGATOR(S) – Undergraduate Research

_____ _____
Student Researcher Signature

_____ _____
Research Director Signature

_____ _____
Department Chair Signature

PRINCIPAL INVESTIGATOR(S) – Graduate Research

_____ _____
Student or Faculty/Staff Researcher Signature

_____ _____
Dissertation or Thesis Chair Signature

_____ _____
Dissertation Director or Program Chair Signature

TYPE OF REVIEW EXPECTED:
[ ] EXEMPT [ ] EXPEDITED [ ] FULL BOARD

1. **Briefly** describe the background and purpose of the research.

2. Who will be the subjects in this study, and how will they be solicited or contacted?
   Subjects must be informed about the nature of what is involved as a participant, particularly a description of anything they might consider to be unpleasant or a risk. Please provide an outline or script of the information that will be provided to subjects prior to their volunteering to participate. Include a copy of the written solicitation and/or statement of the oral solicitation.

3. **Briefly** describe each condition or manipulation to be included within the study.
   Include the details of interventions or manipulations for your study, including control groups (if any), and describe how and when interventions (experimental manipulations) will be administered.

4. What measures or observations will be taken in the study?
   You must include copies of any questionnaires, tests, or other written instruments that will be used.

5. Will the subjects encounter the possibility of stress or psychological, social, physical, or legal risks that are greater, in probability or magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests?

   Yes [ ] No [ ]

   If **yes,** please describe.

6. Will medical clearance be necessary before subjects can participate due to tissue or blood sampling, or administration of substances such as food or drugs, or physical exercise conditioning?

   Yes [ ] No [ ]

   If **yes,** please describe.

7. Will the subjects be deceived or misled in any way?

   Yes [ ] No [ ]

   If **yes,** please describe.

8. Will there be a request for information that subjects might consider to be personal or sensitive?

   Yes [ ] No [ ]

   If **yes,** please describe.

9. Will the subjects be presented with materials that might be considered offensive, threatening, or degrading?

   Yes [ ] No [ ]

   If **yes,** please describe

10. Will any inducements by offered to the subjects for their participation?

Yes [ ] No [ ]

If **yes,** please describe.

If extra course credit is offered, what alternative means of obtaining additional credit are available for non-participants?

11. Will a written consent form be used?

Yes [ ] No [ ]

If **yes,** please include the form, and if **not,** please indicate why not and how voluntary participation will be secured.

12. Will any aspect of the data be made a part of any record that can be identified with the subject?

Yes [ ] No [ ]

If **yes,** please explain.

13. Please describe, in detail, the steps to be taken to ensure the confidentiality of the collected data.

14. Will the fact that a subject did or did not participate in a specific experiment or study be made a part of any record available to supervisor, teacher, or employer?

15. Describe the research benefits that might accrue to either the subjects or society.

In addition to completing the application, attach any supporting documents appropriate for your project. Examples of supporting documents are:

- Completion of required IRB training
- Informed consent/assent forms
- Recruitment materials, script, flyers, letters
- Instruments (questionnaire, survey, test, field)
- Permission to use or modify existing instrument(s)
- Documentation of approval from any other IRB or proposed data collection site
- Vitae (required only for investigators not affiliated with SNU)

Appendix B

Consent Form Guidelines

"I, (participant's name) , hereby authorize or direct (researcher's name), or associates of his/her choosing, to perform the following treatment or procedure."

NOTE: The researcher should include the following elements in his/her description of the procedure:

- Purpose of the research
- Procedure – describe the general procedure; specifically indicate (if relevant) that portion of treatment or procedure that is experimental
- Duration of subject's participation (How much of their time will it take?)
- Extent, if any, to which confidentiality of records identifying the subject will be maintained
- Possible appropriate alternative methods of treatment (if relevant)
- Possible discomforts or risks
- Possible benefits for subjects/society

"I understand that participation is voluntary, that there is no penalty for refusal to participate, and that I am free to withdraw my consent and participation in this project at any time without penalty."

I may contact (project director's or researcher's name) at (phone number) or at (email address).

I may also contact Southern Nazarene University's Institutional Review Board at IRB@snu.edu.

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy has been given to me.

_____ _____

Signature of subject Person authorized to sign for subject (if required)

_____

Date

Appendix C

Project Completion Report

Please type the following information:

Principal investigator _____

Mailing address _____

_____

Email _____

Telephone _____

Title of project _____

_____

Date of completion _____

Brief summary of outcome:

_____

Research Director or Dissertation Director signature and date

_____

IRB Chair signature and date