Asia-Pacific Nazarene Theological Seminary

RESEARCH APPROVAL PROTOCOL AND INSTITUTIONAL REVIEW BOARD HANDBOOK 2018-2023

Introduction

The policies and procedures presented in this handbook apply to all faculty, staff, and students of Asia-Pacific Nazarene Theological Seminary (APNTS) involved in research using human participants. The Seminary is committed to and guided by the ethical principles regarding all research involving human participants.

History of Human participants Protection

The history of protecting subjects in research began with the *Nuremburg Code*, developed by the Nuremberg Military Tribunal as a standard by which to judge human experimentation conducted by the Nazi regime. The Code captured many of what are now the basic principles governing the ethical conduct of research involving human participants, including capacity to consent, freedom from coercion, and comprehension of risks involved.

The APNTS Department of Research surveyed relevant models and documents, particularly the 2006 DOST-PCHRD National Ethical Guidelines for Research, the 2009 Code of Ethics of the Psychological Association of the Philippines, pertinent materials from other Nazarene universities, and research ethics standards of other countries. The *Belmont Report* sets forth three basic principles resulting in three basic requirements.

Principles	Requirements
Respect for Persons: demonstrate respect for individual autonomy and provide protection for individuals with reduced autonomy	*Respect for Persons*: assure informed consent, privacy and confidentiality
Beneficence: maximize benefits and minimize harms	*Beneficence*: conduct a risk/benefit analysis and determine scientific merit
Justice: distribute research burdens and benefits equitably	*Justice*: review of subject selection

No one should be involved in human subject research at any level without being familiar with these ethical principles and requirements.

The APNTS Institutional Review Board

Each institution engaged in research that involves human participants must establish an institutional review board to review and approve the research. An ethical directive of the Seminary's Institutional Review Board is the protection of the rights and welfare of human research subjects. The Seminary's Institutional Review Board is obligated to ensure that research studies do not endanger the safety or well-being of human participants or undermine the public confidence in the conduct of research. The Seminary requires that all research involving human participants, whether funded or not, and regardless of source funding, must be approved by the Seminary's Institutional Review Board. The APNTS-IRB office is at 126 NCEE Building, APNTS Campus.

Composition of the Institutional Review Board

The Institutional Review Board must have at least five members with varying backgrounds to maintain complete and adequate review of research activities commonly conducted by the institution. The institutional review board must be sufficiently qualified through the experience and expertise of its members and the diversity of members' backgrounds, including considerations of their racial and cultural heritage and their understanding of issues such as community attitudes, to promote respect for its guidance and counsel in safeguarding the rights and welfare of human participants.

In addition to possessing the professional competence necessary to review specific research activities, the institutional review board must be able to determine the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The institutional review board must include persons well-informed in these areas. No institutional review board may consist exclusively of members of one profession. IRB must be composed of the APNTS Research Director, a faculty, a lawyer, a counselor, and a social work practitioner.

If an institutional review board regularly reviews research that involves a vulnerable population of subjects, such as children, prisoners, pregnant women, handicapped or mentally disabled persons, the institutional review board must consider the inclusion of one or more individuals who are familiar with and have had experience with this category of subjects. It must also include at least one member who is not otherwise affiliated with the institution and who is not an immediate family member of a person who is affiliated with the institution.

Every effort must be made to ensure that an institutional review board does not consist entirely of men or entirely of women. However, selections must not be made solely based on gender.

An institutional review board may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to expertise available on the institutional review board. These individuals may not vote.

No institutional review board member may participate in the review of any project in which that member has a conflicting interest, except to provide information requested by the institutional review board.

Responsibilities and Authority of the Seminary's Institutional Review Board

The Seminary's Institutional Review Board has the authority to approve and require modification of to any seminary research involving human participants. The Institutional Review Board conducts continuing reviews of approved research at intervals appropriate to the degree of risk. However, no protocol will be approved for more than one year. As part of this responsibility, the Institutional Review Board has the authority to inspect research facilities, records and other relevant information relating to the use of human participants in research. Failure to comply with ethical standards may result to suspension of research.

Responsibilities of Researchers, Faculty Advisors, Instructors, and Research Sponsors

- Employees of the Seminary (administrators, faculty and staff) conducting research on behalf of or as a part of their employment with the Seminary are responsible for knowing and complying with the provisions of the Seminary's human participants policy.

- Employees of the Seminary (administrators, faculty and staff) conducting research on behalf of their graduate degree requirements (including theses and dissertations) at Asia-Pacific Nazarene Theological Seminary or elsewhere must submit an application to the Institutional Review Board if the research involves Seminary faculty, staff or students as subjects, or if the research uses any Seminary resources (e.g., computer technology, departmental supplies, equipment, facilities, space, etc.) in the design or conduct of the research.

- Employees coordinating research on behalf of the Seminary are responsible for educating their subordinate support staff in human participants research policies and protocols, and monitoring compliance throughout the research process.

- Faculty serving as academic advisors to students are responsible for advising those students about the human participants research review process when the student seeks to enroll in courses (including honors research projects, independent studies, theses, etc.) that involve independent and/or collaborative research with human populations.

- Faculty engaged in research funded by the Seminary and/or using Seminary resources (e.g., laboratory and office facilities, equipment, computer technology, etc.) must seek and receive Institutional Review Board approval prior to soliciting or collecting data.

- Faculty who teach courses in which student research with human populations is a course requirement must inform the students of Seminary research policies and protocols, assist students with appropriate applications, and monitor the research activity from its initial design through dissemination of research findings.

- The syllabi for courses involving research with human participants as defined below must include references to the Seminary's human research policy.

- Faculty who sponsor independent student research with human populations (e.g., honors research projects, independent studies, practitioner projects, theses, etc.) must inform the students of Seminary research policies and protocols, assist students with appropriate applications, and monitor the research activity from its initial design through dissemination and/or publication of research findings.

Application Process

Determining When an Application to the Institutional Review Board is Required

It is the policy of Asia-Pacific Nazarene Theological Seminary (APNTS) that all research involving human participants conducted by faculty, students, or staff of APNTS shall be submitted to the Seminary's Institutional Review Board (IRB) for review before the research is initiated. This is true regardless of the location where the research is conducted.

For purposes of the Institutional Review Board, ***research*** is defined as a ***systematic investigation*** (i.e., the gathering and analysis of information) designed to develop or contribute to ***generalizable knowledge***. Any activity that fails to meet either of these criteria is not considered research for the purposes of the Institutional Review Board. This definition applies regardless of what a funding agency may call the activity (e.g. demonstration grant). Generalizable knowledge is determined by whether results are published, presented to the public, or developed for others to build upon. This includes theses, dissertations, creative components, oral histories, and in class research if results will be disseminated.

A ***human subject*** is defined as a living individual about whom an investigator conducting research obtains:

- data through intervention or interaction with the individual; or
- identifiable private information, which includes information about behavior that occurs in a context in which an individual can reasonably expect will not be made public (a medical record, for example); private information must be individually identifiable to constitute research with human participants.

Classroom Research

Research activities conducted for educational purposes sometimes do not fall within the definition of research as defined by the regulations governing human subject research. However, many do. If any of the following criteria are met, the project must be reviewed by the Institutional Review Board:

- research will be conducted with a special population (children, prisoners, decisionally-impaired);
- research will be conducted in a prison, nursing home, hospital or school;
- research will include collecting sensitive information such as sexual attitudes, preferences or practices, alcohol or drug use or other illegal conduct, depression or suicide;
- research will include audio or videotaping;
- participants will be directly identifiable; or

The Institutional Review Board encourages all faculty that plan to include classroom research with human participants in their curriculum to contact the Institutional Review Board office to verify review guidelines and ensure efficient review if necessary. Any questions regarding the need for review can be directed to the Institutional Review Board office.

Determining the Level of Review

Research involving human participants will be reviewed by the Institutional Review Board at one of three levels:

- ***exempt***;
- ***expedited***
- ***full board***.

The level of review depends on the Institutional Review Board's evaluation of the potential risk and benefits to the human participants and the guidelines that define the review process.

Risk is defined as the probability of harm or injury (physical, psychological, social, or economic) occurring because of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Regulations define only minimal risk.

A risk is ***minimal*** when the probability and magnitude of harm or discomfort 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. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination.

The risks to subjects in social and behavioral research are more often psychological and social than physical; however, these risks are just as real to the subjects who experience them.

Powerful emotions that may be drawn out through participation in certain social and behavioral research can result in both short and long- term suffering. Breaches of confidentiality that can occur in behavioral and social research can be stigmatizing, place a subject at risk of criminal or civil liability, or result in serious, and perhaps permanent, damage to a subject's financial standing, employability, insurability, or reputation.

Many risks can be minimized considerably with careful planning. As an example, when strong emotions may be released because of participation, appropriate interventions need to be identified beforehand and clearly stated in the application and be a part of the consent process.

When breaches of confidentiality can be a source of risk, investigators should attempt to identify potential opportunities for breaches and should document mitigating measures. An example of this is the storage of sensitive data with identifiers in a database on a computer connected to the internet. Connection to the internet increases the potential for the database to be accessed by unauthorized individuals (hacked). A mitigating measure would be to store data on a password protected, non-networked computer.

When issues of risk are clearly explained in the application and the research plan, it is often possible for the Institutional Review Board to conclude that the research presents no greater than minimal risk to the subjects, and that the risks to the subjects are no greater than those subjects might encounter in everyday life. Often, too, when this is the case, the research may qualify for a waiver from the requirements for written documentation of consent, if the process for obtaining voluntary and informed consent is clearly an integral part of the methodology.

Exempt Status

To determine ***exempt status***, researchers must submit an application for review to the Institutional Review Board office. Regulations allow some human subject research of minimal risk to be exempted from review by the full Institutional Review Board. However, the Seminary does not authorize investigators to make this determination. Application for exempt status does not absolve the investigator(s) from ensuring that the welfare of the subjects is protected and that methods used to gain subjects' informed and voluntary consent are appropriate.

To be considered for exempt status, the research must qualify as one or more of the categories listed below. To qualify for a category, the research must meet all the conditions of that category.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

    a. research on regular and special education instructional strategies; or

    b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Note: This category may apply to research involving children

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior if:

    a. information obtained is recorded in such a manner that human participants cannot be identified directly or through identifiers linked to the subjects; and

    b. any disclosure of the human subject's responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; and

    c. subjects are not under the age of 18 or members of a vulnerable class, including prisoners, pregnant women, or individuals who are mentally disabled or economically or educationally disadvantaged.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item 2 above if

    a. the human participants are elected or appointed public officials or candidates for public office; or

    b. Statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if

    a. these sources are publicly available; or

    b. the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

5. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads and that are designed to study, evaluate, or otherwise examine

    a. public benefit or service programs; or

    b. procedures for obtaining benefits or services under those programs; or

    c. possible changes in or alternatives to those programs or procedures; or

d. possible changes in methods or levels of payment for benefits or services.

Expedited Review

An ***expedited review*** process is available for research activities that present no more than minimal risk to human participants and that involve only procedures in one or more of the categories listed below. Some of the categories overlap with those used to assess exempt status. The distinction between exempt and expedited review is based on the sensitivity of the data and/or the risk of compromised confidentiality (such as a relatively small sample size).

1. 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). NOTE: Some research in this category may qualify for exempt status (see item 4 in Exempt Status). This category refers only to research that does not qualify for exempt status.

2. Collection of data from voice, video, digital, or image recordings made for research purposes.

3. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. NOTE: Some research in this category may qualify for exempt status (see items 2 and 3 in Exempt Status). This listing refers only to research that does not qualify for exempt status.

4. Continuing review of research previously approved by the convened Institutional Review Board

    a. where

        i. the research is permanently closed to the enrollment of new subjects, and

        ii. all subjects have completed all research related interventions, and

        iii. the research remains active only for long term follow up of subjects; or

    b. no subjects have been enrolled and no additional risks have been identified; or

    c. the remaining research activities are limited to data analysis.

Vulnerable populations require special protection, and include children, wards, prisoners, pregnant women, fetuses, human in vitro fertilization, and economically or educationally

disadvantaged persons. More information on the special requirements for working with these subjects is found in the ***Special Populations*** section of this document.

Full Board Review

Any protocol that uses a methodology that is sensitive and of higher probability for causing harm or distress to subjects is subject to ***full board*** review. Additionally, any protocol using prisoners as subjects or involving pregnant women. Research in which the risks versus the expected benefits are relatively high is also likely to be reviewed by the full board.

Applicants who are not sure which category to select should contact the Institutional Review Board chair or the Institutional Review Board staff-administrator as noted above on page 2.

Completing the Application

Applications submitted to the Institutional Review Board require an APNTS faculty or staff member or a pre-approved community researcher or a thesis/dissertation writing student as principal investigator (PI). All persons working on the protocol must be listed. If persons are added to the protocol after its initial approval, a modification form requesting approval to add personnel must be submitted. (See the ***Protocol Renewal*** section.)

The applicant should carefully and thoroughly answer all questions on the application form. Most applications that are returned for revisions have incomplete responses. If the research is externally funded, materials submitted must include the funding proposal and budget. The Seminary's Institutional Review Board requires documentation of approval from appropriate authorities for research conducted at any location outside of the Seminary. This should be submitted with the application, prior to approval, and any time a location is added as a modification.

A complete application to the Institutional Review Board includes the following items:

- completed, signed (principal investigator and all co-investigators) application form;
- documentation of approval from authorities if research is conducted outside Asia-Pacific Nazarene Theological Seminary
- informed consent or assent forms (if used);
- recruitment script;
- all instruments (e.g., questionnaires, surveys, tests, etc.);
- research plan (a brief summary of the research, methodology, risks to subjects and benefits, which is generally used for thesis or dissertation research or other unfunded research; however, this is not the submission of several chapters from the thesis or dissertation it is a clear and concise definition of the methodology);

- grant proposal and budget (if for funded research); and
- biography, résumé, or vita for all principal investigators (student, faculty or community researcher) and advisor.

Submitting the Application

The complete application must be submitted to the Institutional Review Board office located as noted on page 2. The number of copies to submit and the schedule for submission are dependent on the level of review. **This process must be started at least four 4 weeks prior to the thesis/dissertation proposal defense schedule.**

Type of Review	Submission	Number of Copies
Exempt Status	Any time	Original + 1 copy
Expedited	Any time	Original + 2 copies
Full Board	One week prior to meeting date*	Original + 6 copies

Guide to the Completion of the Institutional Review Board Application

This guide is intended to provide helpful points for the completion of the application questions.

1. Research Adviser

The research adviser is an Asia-Pacific Nazarene Theological Seminary professor or a person that has been approved by the Seminary's chair of the Institutional Review Board or Academic Affairs.

2. Principal Investigators

The student(s) conducting the research are to be listed under that heading.

3. Time Frame

Describe the length of time the subjects will be actively involved in the study, including the number of individual interactions.

Provide the calendar time frame during which active data collection will occur.

4. Expedited Review

This is applicable when the research involves no more than minimal risk and for minor changes in approved research.

5. Research Objectives

Clearly describe the purpose of the research and the problem to be investigated. This also sets the stage for the reviewers to understand the project.

6. Location of the Research

Describe where the study will take place. The Institutional Review Board requires documentation of approval from appropriate authorities for research at any location outside of the Seminary.

7. Research Methods and Procedures

Describe what subjects will be asked to do. If an observational study, describe any manipulations of the subjects and the behaviors to be recorded. Include copies of all questionnaires, tests, surveys, instructions or scripts to be used. Describe exactly what each subject will be asked to do including:

the topic areas of any instruments or tests;

- interviews;
- any other activities that the subjects will be asked to complete;
- audio or video taping;
- identification of any procedures or products that are experimental; or
- any possible discomforts or inconveniences that the subject might experience.

If medical clearance is required for participation, explain how this will be obtained and documented.

Describe any follow-up the investigators may have with subjects. This might include later clarification of responses, providing reports from the study, recommendation of further treatment or assistance.

8. Subject Population

Describe the population from which the subjects will be selected. Be as specific as possible. Specify if they are members of a vulnerable population as defined by Institutional Review Board policy.

Include an estimate of the maximum number of subjects that may be impacted by the study. This number should include the total number to be contacted, not just expected to respond or participate.

9. Subject Selection, Identification and Recruitment

Describe the subject selection methodology, i.e., random, snowball, etc.

Describe the procedures to be used to recruit subjects. Include copies of scripts, flyers, advertisements, posters, letters that may be used.

List who will recruit the subjects.

If the research subjects are under 18, the investigator must comply with special regulations for using children as subject. Please refer to the Institutional Review Board website or handbook for guidance.

10. Use of Deception

If subjects are to be deceived or mislead in any way for purposes of the research, please explain and justify why the methodology requires deception. Subjects who have been deceived must be debriefed at the completion of the study about the true or complete intent of the research. Please detail debriefing procedures.

11. Incentives to Participate

Describe any compensation (financial, extra credit, etc.) to be offered for participation, when it will be given, and any conditions of full or partial payment. Describe any alternatives to participating in the research.

12. Informed Consent Process

The informed and voluntary consent of each potential subject is required for all human subject research.

Indicate if a written informed consent form will be used.

If a written consent will not be used, provide detailed explanation of how informed and voluntary participation will be obtained.

Include copies of all related materials that will be used to explain to the subjects of all the elements of informed, voluntary consent.

13. Privacy and Confidentiality

Confidentiality should be maintained in human subject research.

Identifying information should not appear on data without justification. If identifiers of any sort (names, ID numbers, email addresses, etc.) are to be associated with data, justification must be provided.

Address how the data will be handled and stored in such a way that the privacy of the subjects is protected. This information should include where the data will be stored, who will have access to the data, how long the data will be kept and how the data will be reported.

The increasing vulnerability of networked, Internet accessible computers may dictate that sensitive data be stored on media that are inaccessible by networks or the Internet.

Be aware that some funded projects mandate that data be retained for a specific period of time.

Specifically address the use, storage and disposition of audio tapes, video tapes, CDs or DVDs. If electronic media is to be used for future research or training, this must be specifically stated in the consent form.

14. Risks, Harms, and Discomforts

If data of a personal or sensitive nature will be requested, detail what information will be collected, and any risks associated with compromise of confidentiality.

If the subjects' participation in the study will be made part of a record accessible by a supervisor, teacher or employer, please address the risk to the subject that this information could generate.

15. Minimizing Risks

If materials that might be interpreted as threatening, degrading, or offensive are to be presented to subjects, please explain their role in the research and any planned measures for intervention if subjects react adversely.

16. Reasonably Anticipated Benefits

Discuss any direct benefits to subjects resulting from their participation (i.e., results of testing, etc.). Do not include payments or extra credit as these are considered compensation and should be addressed in the response to question 22. If there are no known benefits to the subjects, please state so.

Discuss benefits to the general class of subjects (e.g., veterans with post-traumatic stress syndrome [PTSD], etc.) and/or the society at large.

17. Compensation

Describe any compensation (financial, extra credit, etc.) to be offered for participation, when it will be given, and any conditions of full or partial payment. Describe any alternatives to participating in the research.

Special Population Groups

Children

Prisoners

Pregnant Women, Fetuses, and Human In Vitro Fertilization

Decisionally-impaired Persons

Non-English Speaking Persons

The Review Process

Faculty members, staff members, or students who are planning research projects involving human participants are responsible for initiating the review process by submitting a completed application, along with supporting documentation to the Institutional Review Board. Application to the IRB must be done at least **four weeks prior to thesis/dissertation proposal defense**.

The Seminary's Institutional Review Board office coordinates the receipt and review of all Institutional Review Board applications. The Institutional Review Board administrative staff will pre-review the application and supporting documentation to ensure that all of the necessary materials are provided for Institutional Review Board review. If additional information is needed before review can begin, the principal investigator will be contacted by phone or email. Once complete, the application is entered in the Institutional Review Board database and assigned a unique number that is used to track it through the review process and beyond.

Exempt from Review

It is the policy of the Seminary's Institutional Review Board that all human participants research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the exemption categories described in the ethical standards of the *Belmont Report*. The standard requirements for informed consent (or its waiver, alteration, or exception) apply to all Institutional Review Board approvals regardless of the type of review.

Research falling into the exempt level of review is based on the determination that the human subject research in question meets the requirements to waive full Institutional Review Board review. Although the category is called "exempt," this type of research does require Institutional Review Board staff review and registration. However, the exempt registration process is much less rigorous than an expedited or full-board review.

Research activities involving human participants that are exempt from the requirement that they receive full Institutional Review Board review or expedited review are identified six specific categories of activities that may qualify as exempt. A description of these categories is located on the Institutional Review Board website and earlier in this document. The Institutional Review Board may not create new categories for exempt research.

As noted, investigators do not have the authority to make an independent determination that research involving human participants is exempt. It must be reviewed according to the following procedures.

Procedure

This procedure provides guidance in accordance with regulations to review and approve human participants research in an exempt category.

1. Investigator Responsibilities

    a. The application is completed in its entirety and submitted to the Institutional Review Board office for processing. The application and instructions to complete it are located on the Institutional Review Board website and earlier in this document.

    b. The investigator replies to all requests for revisions and/or clarifications requested by the pre-reviewers or reviewers, when applicable.

    c. The investigator is responsible for assuring that the exempt research is carried out in an ethical manner that includes appropriate participant protections (i.e., informed consent, voluntary participation).

2. Institutional Review Board Staff-Administrator Responsibilities

    a. An Institutional Review Board staff member conducts a pre-review for studies submitted requesting exemption.

    b. The Institutional Review Board staff member determines whether the application includes all information required and requests additional information, if needed, from the investigator, to assist the Institutional Review Board reviewers in making a determination.

    c. The Institutional Review Board staff member presents the chair with the application and additional materials for review of the project.

    d. Amendments, adverse events, and continuing reviews are processed according to corresponding Institutional Review Board policies and procedures.

    e. Letters requesting revisions from reviewers and decision letters are drafted according to the appropriate template and forwarded to the Institutional Review Board chair for signature.

    f. Appropriate database entries are completed, including notification of approval on the next agenda for the full Institutional Review Board.

3. Institutional Review Board Responsibilities

    a. Exempt applications will receive a review by the Institutional Review Board chairperson and by at least one other Institutional Review Board member. At the chair's discretion, a representative of the Institutional Review Board may take the place of the chair.

    b. The reviewers review the application and validate or decline the investigator's claim for review under the exempt process.

c. The reviewers will also review the proposed project to determine if the research meets the ethical standards of the *Belmont Report*.

d. The reviewers may:

   i. approve the request;

   ii. request minor revisions to the submitted documents in order to approve the request, and review and approve the revisions prior to granting final approval; or

   iii. disapprove the request.

e. Both reviewers must be in agreement for approval of the application. Should there be a split vote, the proposal will move to a full Institutional Review Board review.

f. If the reviewers disapprove the request, these individuals will determine the appropriate level of review, communicate this to the investigator, and guide the investigator through the submission.

g. If the reviewers approve the request, the chair signs and sends a letter of final approval.

Expedited Review

Regulations allow the Institutional Review Board to review certain applications on an expedited basis if they meet specified criteria. A description of the criteria is located on the Institutional Review Board website and earlier in this document. It is the policy of the Seminary's Institutional Review Board that all human participants research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the expedited categories described in the regulations and complies with the ethical standards of the *Belmont Report*. The standard requirements for informed consent (or its waiver, alteration, or exception) apply to all Institutional Review Board approvals regardless of the type of review.

In an expedited review, the Institutional Review Board chair or his/her designee and at least two other board members review the application. In reviewing the research, the reviewers may exercise all the authorities of the full Institutional Review Board except that the reviewers may not disapprove the research. Additionally, the reviewers may refer the application to the full Institutional Review Board for full review as warranted.

Procedure

This procedure provides guidance for the review of human participants research activities that qualify for expedited review under the regulations.

1. Investigator Responsibilities

a. The application is completed in its entirety and submitted to the Institutional Review Board office for processing. The application and instructions to complete it are located on the Institutional Review Board website and earlier in this document.

b. The investigator replies to all requests for revisions and/or clarifications requested by the pre-reviewers or reviewers, when applicable.

c. The investigator is responsible for assuring that the expedited research is carried out in an ethical manner that includes appropriate participant protections (i.e., informed consent, voluntary participation).

d. The investigator must receive written Institutional Review Board approval before implementing any changes to the research study.

2. Institutional Review Board Staff-Administrator Responsibilities

a. An Institutional Review Board staff member conducts a pre-review for studies submitted requesting expedited review.

b. The Institutional Review Board staff member determines whether the application includes all information required and requests additional information, if needed, from the investigator, to assist the Institutional Review Board reviewers in making a determination.

c. The Institutional Review Board staff member presents the chair with the application and additional materials for review of the project.

d. Amendments, adverse events, and continuing reviews are processed according to corresponding Institutional Review Board policies and procedures.

e. Letters requesting revisions from reviewers and decision letters are drafted according to the appropriate template and forwarded to the Institutional Review Board chair for signature.

f. Appropriate database entries are completed, including notification of approval on the next agenda for the full Institutional Review Board.

3. Institutional Review Board Responsibilities

a. Expedited studies will receive a review by the Institutional Review Board chairperson and by at least two other board members. At the chair's discretion, a representative of the Institutional Review Board may take the place of the chair.

b. The reviewers review the application and validate or decline the investigator's claim for review under the expedited process.

c. The reviewers will also review the proposed project to determine if the research meets the ethical standards of the *Belmont Report*.

d. The reviewers may:

i. approve the request;

ii. request minor revisions to the submitted documents to approve the request, and review and approve the revisions prior to granting final approval; or

iii. disapprove the request.

e. All reviewers must agree for approval of the application. Should there be a split vote, the application will move to a full Institutional Review Board review.

f. If the reviewers disapprove the request, these individuals will determine the appropriate level of review, communicate this to the investigator, and guide the investigator through the submission.

g. If the reviewers approve the request, the chair signs and sends a letter of final approval.

Full Review

Investigators designing research that fails to meet the provisions for exemption from review, expedited review, or expedited review with special population must complete an Institutional Review Board application and submit it to the board for pre-view by the staff-administrator and the full board.

Procedure

This procedure provides guidance for the review of human research activities that qualify for full Institutional Review Board review under the regulations.

1. Investigator Responsibilities

a. The application is completed in its entirety and submitted to the Institutional Review Board office for processing. The application and instructions to complete it are located on the Institutional Review Board websites and earlier in this document.

b. The investigator replies to all requests for revisions and/or clarifications requested by the pre-reviewers or reviewers, when applicable.

c. Any proposed changes to Institutional Review Board approved documents are submitted to the Institutional Review Board through the amendment process.

d. The investigator receives written Institutional Review Board approval before implementing any changes to the research study.

2. Institutional Review Board Staff-Administrator Responsibilities

a. An Institutional Review Board staff member will conduct a pre-review for studies submitted requiring full Institutional Review Board review.

b. The Institutional Review Board staff member requests any additional documents needed for the review, as well as any pre-review changes.

c. If the staff member determines that the study meets criteria for exempt or expedited review, the investigator will be notified.

d. The Institutional Review Board staff presents the chair with the application and additional materials for review of the project.

e. Once the documents are deemed complete, the Institutional Review Board staff member places the new study on the next available Institutional Review Board agenda and prepares the primary or secondary reviewer and other Institutional Review Board member review materials.

f. The Institutional Review Board staff member (in consultation with the Institutional Review Board chair) assigns a primary and secondary reviewer with expertise in the research adequate to the scope and complexity of the research. If the Institutional Review Board does not have at least one member available with expertise adequate to the scope and complexity of the research, the Institutional Review Board staff member will assist in arranging review by a consultant with the required expertise. The Institutional Review Board staff member may be asked to arrange for the consultant to attend the Institutional Review Board meeting. The consultant may not count toward the quorum or vote.

g. The Institutional Review Board staff member attends the Institutional Review Board meetings and documents the processes. The minutes of the Institutional Review Board meeting should clearly reflect the determinations regarding risk and approval period (review interval). If a member has a conflict of interest, it is noted in the minutes that a conflict exists and that the Institutional Review Board member with the conflict, was absent during the discussion and vote for that specific research study.

h. Letters requesting revisions from reviewers and decision letters are drafted according to the appropriate template and forwarded to the Institutional Review Board chair for signature.

3. Institutional Review Board Responsibilities

   a. The chair, in conjunction with Institutional Review Board members, determines the Institutional Review Board meeting schedule based on availability, holidays, and Seminary scheduled closures. The meeting schedule will be posted on the Internal Review Committee's website.

   b. The assigned Institutional Review Board member receives a copy of the review materials five (5) working days prior to the scheduled meeting to allow adequate time for review and the request of additional information, if needed (e.g., supporting documentation from the investigator, literature search, etc.).

   c. Each study is assigned a primary and secondary reviewer. The reviewers assigned will have expertise in the research adequate to the scope and complexity of the research. The reviewers conduct an in-depth review of all pertinent documentation.

      i. The primary reviewer is to present the study in summary form to the full Institutional Review Board highlighting any research related issues and recommending modifications, if applicable.

      ii. The secondary reviewer is prepared to provide any additional information not presented by the primary reviewer highlighting any additional research related issues and recommending modifications, if applicable.

      iii. If the Institutional Review Board does not have a member available with expertise adequate to the scope and complexity of the research, a consultant with expertise in the area of research will be asked to review the study and provide written recommendations or may be asked to attend the Institutional Review Board meeting. The consultant may not count toward the quorum or vote.

      iv. The reviewers will assess the protocol for both scientific and scholarly merit in relationship to the level of risk.

      v. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, the reviewers determine if additional safeguards need to be included in the study to protect the rights and welfare of these subjects.

      vi. All Institutional Review Board members are given the opportunity to review, ask questions of the reviewers, and request modifications in the proposal.

      vii. The Institutional Review Board reviews the proposed research, consents, and applicable documents to determine whether the study

adheres to the ethical guidelines found in the *Belmont Report*. To provide written documentation of these criteria, the primary or secondary reviewers complete the worksheet identifying that each of these criteria are met.

viii. The Institutional Review Board determines the review interval appropriate to the degree of risk, but not less than once per year.

ix. It is typical, although not required, that the primary reviewer make the motion regarding the status of the study in accordance with applicable Institutional Review Board policies and procedures.

Voting

The Institutional Review Board may vote to approve, approve with explicit conditions, disapprove, or table an application. A simple majority vote from the voting members of the Institutional Review Board is required on any application receiving a full committee review. The number of members voting for or against a proposal or abstaining is recorded in the minutes. If the vote is not unanimous, the minority opinion must be recorded in or attached to the minutes as well. An Institutional Review Board member may abstain from voting for any reason without explanation.

Any Institutional Review Board member having an interest in any protocol being reviewed by the committee cannot participate in the review or vote.

Institutional Review Board Decisions

After reviewing the application, there are three possible outcomes:

Approved

Accepted and endorsed as written with no conditions.

Approved with Explicit Conditions

Accepted and endorsed with explicit minor changes or simple concurrence of the principal investigator. All explicit conditions requested of the principal investigator (Institutional Review Board chair sends formal letter) must be completed and documented prior to beginning the research. For these conditions, the Institutional Review Board chair or designated reviewer can, upon reviewing the principal investigator's response(s) to stipulations, approve the research on behalf of the Institutional Review Board. If a study has received approval with explicit conditions, investigators are to return one copy of the corrections to the Institutional Review Board office with any changes underlined or in bold.

Tabled

Generally, the protocol or consent form has deficiencies that prevent accurate determination of risks and benefits or requires significant clarifications, modifications or conditions that, when met or addressed, require full Institutional Review Board review and approval of the private investigator's responses and revisions. The deficiencies will be specified to the principal investigator (Institutional Review Board chair sends a formal letter), and on occasion the private investigator is asked to attend the full board meeting to clarify the points in question. If a study is tabled, the private investigator is to re-submit revisions to the Institutional Review Board office.

Protocol Continuation or Renewal

Purpose

Ensuring responsible conduct of research must be an on-going process. The Institutional Review Board should ensure that human participants are protected from any degree of risk. The Institutional Review Board should re-evaluate the acceptability of risks/benefits ratio and subject safeguard annually.

The renewal letter should state the following:

- status of research activity;
- subject enrollment numbers for the approval period and total;
- research purpose and progress data;
- past and/or proposed modifications to the protocol;
- adverse events; and
- subject withdrawals.