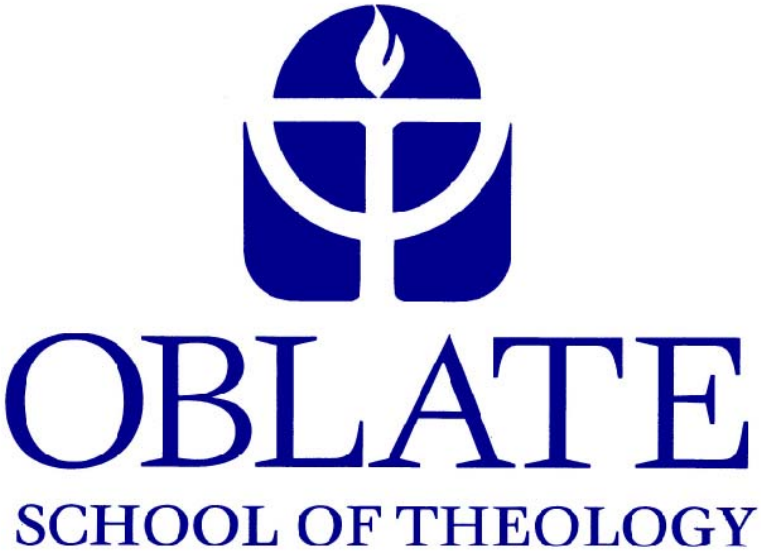
Institutional Review Board

Researcher Guidebook



UPDATED WITH 2018 FEDERAL POLICY FOR PROTECTION OF HUMAN SUBJECTS

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CHAPTER I - INTRODUCTION

The Institutional Review Board (IRB) of Oblate School of Theology was established in accordance with the guidelines of the federal government for institutions conducting research that involves human subjects. The IRB is housed within the Office of Academic Dean of the school and provides and maintains oversight of all research activities conducted at the school. It is the function of this IRB to assess the balance of risks and benefits to human participants that may be expected from the proposed research.

Mission of the Oblate School of Theology Institutional Review Board

The mission of the Oblate School of Theology IRB is to promote a research arena that protects the rights, privacy, and welfare of individuals participating in research activities conducted by the faculty, staff, and students at Oblate School of Theology. The IRB is committed to uphold the highest level of ethical and quality standards during the review process of human research and to approve sound research that adds to the knowledge of pastoral practice and the scientific community and the general public.

Purpose of This Guidebook

The purpose of the *IRB Guidebook for the Researcher* (*IRB Guidebook*) is to describe the different types of human subjects review, application forms and procedures, possible IRB dispositions of applications, and the definitions and examples of terms used in human subjects review applications. This *IRB Guidebook* also provides information, as applicable to the proposed research, required for developing informed consent and assent forms and conducting the informed consent and assent process. Examples of informed consent and assent forms are also provided in this *IRB Guidebook*.

The information in this *IRB Guidebook* applies to all forms of research proposed by *any* faculty, staff, or student of Oblate School of Theology, or by any researcher from outside the school who wishes to conduct research here on campus, and has received any relevant prior permissions to do so. *ALL* student projects, theses, and dissertations that involve recruitment of human subjects and/or review of human subject data (e.g., clinical chart review) must be reviewed by the IRB. The IRB may impose additional requirements at any time to help ensure that adequate information is presented in accordance with OST policies, federal, state, and local laws.

How to Use This Guidebook

- Review the entire *IRB Guidebook* and familiarize yourself with the regulations, processes, procedures, and terminology presented in Appendix III prior to beginning the preparation of your application to the IRB.
- Review the three types of applications that may be submitted to the IRB. Note that while some research is classified as *Exempt*, an Exempt Review Application **MUST STILL BE SUBMITTED** to the IRB. File the application that best represents the type of research being proposed. Note that only the IRB can make the final decision on how research will be classified and reviewed.

NOTE: Student, staff, or faculty projects that do not meet the National Institutes of Health (NIH) definition of human subject research are not required to be submitted for IRB review. Researchers should be cautious in interpreting these guidelines – when in doubt, please contact the IRB Office.

> The Department of Health and Human Services defines a Human Subject as a living individual about whom an investigator (whether professional or student) conducting research: (a) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or (b) obtains, uses, studies, analyzes, or generates private information or identifiable biospecimens (Protection of Human Subjects, 45 C.F.R. Part 46; §46.102(e)(1), 2018).

- Use the checklist entitled *Determining Which IRB Application to File: A Checklist* (see Chapter V of this *Guidebook*) as a worksheet to assist in deciding which application to submit. Review it prior to submitting an application, do not submit it with the application.
- Once you have determined which application to submit, follow the instructions for preparing the application provided in Chapter VI below, including submission of all supporting documentation and forms.
- Voluntary informed consent is one of the most important parts of the research process. Review Chapter VIII on Voluntary Informed Consent prior to preparing a consent form for the planned research.

- The forms provided in this Guidebook are samples only. The proper forms to be used for completing the application process are available online at the student Moodle site for the IRB.
- ***No research involving human subjects as defined by NIH Guidelines, by any person affiliated with Oblate School of Theology, may be initiated until the Oblate School of Theology IRB has granted a disposition of Full Approval or Approval with Recommendations.***

Effective Date of This Guidebook

This guide has been updated with the Federal Policy for the Protection of Human Subjects as finalized and published on January 19, 2017 ("Federal Policy"). These updates are called the "2018 Requirements" and they shall apply to the following research:

(i) Research initially approved by the IRB on or after January 21, 2019;

(ii) Research for which IRB review is waived on or after January 21, 2019; and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

CHAPTER II – REGULATIONS

The regulations set forth in this IRB Guidebook are based on the Belmont Report (from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and the Code of Federal Regulations, Title 45 - Public Welfare, Part 46 - Protection of Human Subjects). The Belmont Report is a statement of general ethical principles that are meant to act as a guide in resolving ethical problems that surround the conduct of research with human subjects., The Belmont Report is concerned with the ethics of research (https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) while Part 46 of Title 45 of the Code of Federal Regulations (which is based on the Belmont Report) addresses more specifically the recommended guidelines for the protection of human subject (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML).

The Belmont Report

The Belmont Report was developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. This Commission was created when the National Research Act (PL 93-348) was passed in 1974. The Belmont Report summarizes the general ethical principles identified by the Commission that should underlie the conduct of biomedical and behavioral research involving human subjects.

In carrying out its mission, the Commission considered the boundaries between biomedical/behavioral research and the accepted routine practice of medicine, the role of the assessment of the risk and benefit balance in determining whether humans should be used in the research, guidelines for the selection of human subjects, and the nature and definition of informed consent.

Since *research* and *practice* often occur together, it is necessary to distinguish between these two terms in order to know what activities ought to be reviewed for the protection of human subjects. The term *practice* is used to mean a commonly accepted intervention or procedure that is designed to enhance the well-being of an individual or client and is considered by the practicing community to have a reasonable expectation of success. *Research* is used to mean an activity designed to test a hypothesis or answer research questions, so that conclusions may be drawn and contributions to the general knowledge of a field may be made. While research and therapy, or research and education, may be carried out together, eg., when evaluating the safety and efficacy of a therapy or of an educational strategy. The general rule is that if there is an element of research in any activity involving human subjects, the activity should be reviewed by the IRB.

The following summary identifies the boundaries between medical/behavioral research and the practice, and the three basic ethical principles which, when practically applied, lead to informed consent, assessment of risk and benefits, and the selection of subjects. The three principles identified by the Commission as generally accepted in our cultural tradition are labeled: (a) respect for persons, (b) beneficence, and (c) justice. These principles are stated in a sufficiently general manner to allow scientists, subjects, reviewers, and informed citizens to understand the ethical issues that are an integral part of research using human subjects. In stating these principles, the objective is to provide an analytical framework that will guide the resolution of ethical problems involving research with human subjects.

Respect for Persons (see Respect of Persons, Chapter III, Definitions below)

The first principle is *Respect for Persons*. This principle entails two moral requirements: 1.) we acknowledge the autonomy of individuals, and 2.) we protect those individuals with diminished autonomy. The autonomous person is capable of deliberating a course of action and making a measured choice about their engagement based on their goals. They then act freely in the pursuit of chosen goals. In respecting autonomy, we allow the individual the freedom to pursue those goals without interference when there are no compelling reasons not to do so (i.e., actions that are detrimental to others).

The process of self-determination customarily matures with development during the lifespan. However, some individuals are unable ot exercise their autonomy due to mental illness, physical condition or developmental delay(s). Thus, not everyone is capable of exercising self-determination to the degree expected by chronological age. Those who have specific issue that interfere with self-determination need additional protections when asked to participate in research endeavors. The level of protection offered to individuals who are considering participation in a research activity depends upon an assessment of the risk of harm and the likelihood of benefit from the research. These individuals must also enter into the research activity voluntarily and with adequate information.

The Respect for Persons principle requires that individual participants be given adequate information and explanation to make an informed decision about their potential participation. A reasoned choice to participate or not participate is made more likely when three guiding ideals are present. The first of these is *Information*. This information includes the reason for the research, the processes and procedures of the research, the risk and benefits of the research, when potential participants are given a chance to ask questions about their participation. The second ideal to insure informed consent is C*omprehension*. This ideal is met when the information is given in a way the participant can fully understand. Thus, adaptation of the research information is needed so that the average person can fully understand the elements contained in ideal one above. the requirement for full comprehension is more serious as the potential of risk increases in the research design and methodology.

The last ideal is V*oluntariness*. Agreement to participate in research is valid only if the consent is voluntary. Thus, consent must be obtained without coercion, undue influence, unjustifiable pressure, or deception.

Beneficence (see Beneficence, Chapter III, Definitions below)

The second principle is *beneficence*. *Beneficence* is the responsibility to purposefully seek the well-being of participants by maximizing benefits and minimizing risks. Functionally speaking, this involves weighing when the benefits out weight the risk and research is undertaken or when the risks outweigh benefits and specific research is abandoned.

Risk-Benefit analysis requires the researcher to explore the probability of harm in research and to foresee potential positive and negative outcomes. This requires careful weighing of data collection, including consideration alternate ways of obtaining the same data and concern for the subject, the subject's family, and society at large. The IRB aids the researcher in evaluating these issues and arriving at a balanced approach to the potential research questions

Justice (see Justice Chapter III, Definitions below)

The third principle is *Justice*, this requires impartiality in processes and procedures for the selection of participants. Two relevant considerations are who ought to receive the benefits of research and who ought to bear its burdens. This principle is applicable at both the individual and social levels.

At the level of the individual, research is meant to benefit all subjects. Caution ought to be exercised not to seek vulnerable subjects.

At the level of the social, caution ought ot be exercised to assess the ability of the social class to bear the brunt of the research. With this in mind, the impact on the poor, ethnic minorities, and vulnerable populations are taken into consideration when designing research projects.

Justice demands that the results of publicly funded research be available to all individuals and not just to those who can afford the benefits, and that publicly funded research not be confined to groups of individuals who are unlikely to be among the recipients of the benefits. This principle is far too often overlooked. Therefore, the IRB must exercise a heightened degree of vigilance to ensure that the principle of justice is fully applied to all proposed research.

Summary

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. The Commission was charged to consider the boundaries between medical/behavioral research and medical practice, the role of risk benefit assessment, the appropriate guidelines for selection of human subjects, and the nature and definition of informed consent. The Report is a statement of basic ethical principles and guidelines to assist scientists in resolving the ethical problems surrounding the conduct of research with human subjects.

Code of Federal Regulations

The *Code of Federal Regulations* (CFR) is a codification of the general and permanent rules published in the *Federal Register* by the executive departments and agencies of the Federal Government. The CFR is divided into 50 titles, each representing subject areas of the Federal regulations. The purpose of the CFR is to present the official and complete text of agency regulations in one organized publication and to provide a comprehensive and convenient reference for all those who may need to know the text of general and permanent Federal regulations.

The *Code of Federal Regulations on Public Welfare Title 45 Part 46 Protection of Human Subjects* is disseminated by the Office for Human Research Protections (OHRP). The OHRP is part of the Office of the Assistant Secretary for Health (OASH) in the Office of the Secretary (OS), U.S. Department of Health and Human Services (HHS). Further information and frequently asked questions may be found at http://www.hhs.gov/ohrp/.

The CFR applies to all research involving human subjects and provides definitions for the terms *research* and *human subject*. The CFR defines *research* as a systematic investigation designed to develop or contribute to generalizable knowledge. *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.

The CFR describes four basic requirements for the conduct of an IRB: (a) a statement of principles, (b) designation of one or more IRBs, (c) appointment of IRB members, and (d) written procedures for the IRB. It is within these parameters that the Oblate School of Theology IRB operates.

Human Subjects vs. Non-Human Subjects Research

Under the Code of Federal Regulations (Protection of Human Subjects 45 CFR Part 46; §46.102(e)(1), 2018), Human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research: (a) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (b) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Health Insurance Portability and Accountability Act (HIPAA)

The *Health Insurance Portability and Accountability (HIPAA) Privacy Rule* establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Under the HIPAA Privacy Rule, research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." 45 CFR §164.501.

The Privacy Rule also defines the means by which research participants will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct research.

Oblate School of Theology enforces the HIPAA Privacy Rule. The IRB at Oblate School of Theology operates under the *Common Rule*, the federal policy for the Protection of Human Subjects.

Additional Readings

- The Federal Policy and 45 CFR 46, Pre-2018 and 2018 Requirements: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML
- HIPAA and Research: http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/
- Common Rule: http://www.hhs.gov/ohrp/humansubjects/commonrule/

CHAPTER III - DEFINITIONS AND TERMS

Anonymity

Anonymity refers to the best practices of data collection implemented by the researcher in order to secure the privacy of the research participant, by eliminating the "link" between the research participant's study data and personal identifiable information. Using these practices will not allow the researcher or any other individual to identify participants by the data collected. This approach is common in research involving one-time data collection, such as that which occurs when using survey methods, taking only one set of physical or psychological measurements, or having participants complete questionnaires without asking for their names.

It is important to inform potential participants that:

a) Surveys or questionnaires requiring extensive demographic data may violate the principle of anonymity by providing enough information to allow the researcher to indirectly identify one subject from all others.

b) When data are recorded anonymously, subjects will not have the right to withdraw from the research once the data have been collected, because it will not be possible to determine which data belong to which subject.

Assent

Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent (*Protection of Human Subjects, 45 CFR Part 46; §46.402(b)*, 2018). This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.

Although there is no prescribed minimum age at which subject assent is required, the researcher must consider the subject's age, maturity, and psychological state, as well as the complexity of the research tasks or activities the potential subject is being asked to perform. Based on available evidence, the IRB ultimately determines whether assent is required and when parental/guardian permission is also necessary (*Protection of Human Subjects, 45 CFR Part 46; §46.408*, 2018). There is an example of an Assent Form in Appendix B of this *Guidebook*.

Beneficence

Beneficence is one of three ethical principles in the Belmont Report. It refers to the action taken to treat persons in an ethical manner; not only by respecting their decisions and protecting individuals from harm, but also by making efforts to secure the well-being of participants in research. Beneficence comprises two fundamental rules: **(1)** do not harm, and **(2)** maximize possible benefits and minimize possible harms.

Child

Child is a person who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (*Protection of Human Subjects, 45 CFR Part 46; §46.402(a)*, 2018).

Coercion

Coercion means to compel or force someone to participate in or perform an action that would not ordinarily be done of the individual's own free choice. This involves influencing an individual's decision about whether or not to do something by using explicit or implied threats (loss of good standing in a job, poor grades, etc.). Coercion may be present even when not obvious when recruiting subjects for research. For example, telling parents or guardians of subjects or subjects themselves how much they will be helping the investigator by participating in research can be interpreted as coercive. Participation should be free and voluntary, with no overriding statements.

Mentioning a relationship that exists between the researcher and the potential subjects may be coercive. Subjects may feel obligated to participate because they know or have seen the researcher at various times. In cases of infants and children, mentioning that the researcher cares for or has cared for the child puts parents in a very awkward and unfair position.

Face-to-face recruitment has the potential to be coercive. It is difficult for individuals to say no to someone who is directly in front of them and talking about his or her research. Inflection, tone of voice, and nonverbal cues can inadvertently slip into the recruitment process without the researcher's awareness, thus implying threats that even the researcher is not aware are being conveyed. Coercion can be reduced if an impartial third party presents the request for participation.

Subjects should be protected from coercion. If subjects are not protected, the IRB application must include an explanation of why coercion is necessary as well as any possible repercussions of the coercion. The methods to be used for coercing subjects must be detailed in the research proposal. A plan for informing subjects at the end of the research of how and why they were coerced must be fully explained (see *Debriefing*). Potential physical and/or psychological risks that may be incurred by subjects due to the coercion must be identified, and procedures for addressing the risks must be established as part of the debriefing procedures.

Compensation

Compensation refers to the amount of payment a subject may receive for participation in a research study. The IRB should review both the amount of payment and the proposed method of disbursement to assure that neither entails problems of *coercion* or undue influence. Such problems might occur, for example, if the entire payment were to be contingent upon completion of the study, or if the payment were unusually large. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation.

Confidentiality

Confidentiality refers to protection of subjects' privacy so that information collected about them, as part of the research process, is not disclosed. Information may be revealed in group form, or as individual examples, but not in a way that an individual may be identified.

If the investigator collects information on subjects over a period of time, such as in test-retest reliability or in pretest-posttest study designs, there must be a mechanism to match various data to the same subject. This may be done by using codes or identifiers (e.g., subject ID numbers) on both sets of data that only the researcher can trace to a master name-number list. Because names and numbers can be related, this list must be kept confidential by storing it in a private and secure location, such as a locked file cabinet.

If data are recorded in cases where the researcher personally knows subjects, it must be acknowledged that the researcher knows the subjects personally, and the data must be treated confidentially, because anonymity is not possible. It is important to acknowledge that subjects may waive the right of confidentiality. This may occur, for example, when a subject specifically requests to be quoted.

In the United States, all confidential data must be stored by the researcher for at least three (3) years from the end of the study. In Canada, data must be stored for at least six (6) years from the end of the study.

Consent

Consent is defined as a willingness to participate as a subject in research by individuals 18 years of age or older. Consent is obtained from a research subject in one of two (2) forms: Implied Consent, or Informed Consent document. The Informed Consent document must be approved by the IRB. When the Informed Consent document is used, a copy shall be given to the person signing the form (Protection of Human Subjects, 45 C.F.R. Part 46; §46.117(a), 2018). An example of an Informed Consent Form is included in Appendix B of this *Guidebook*.

Consent Process

The *consent process* is defined as an active process of sharing information between the investigator/research personnel and the prospective subject and should ensure that: (a) all critical information about a study is completely disclosed, (b) the information must be conveyed in language understandable to those being asked to participate – or continuing to participate - as subjects in the research, and (c) that prospective subjects or their legally authorized representatives adequately understand the research so that they can make informed choices (Protection of Human Subjects, 45 CFR Part 46; §46.116, 2018).

The *informed consent process* is therefore an ongoing exchange of information between the investigator and the subject; it begins with the initial approach of an investigator or research personnel with the potential subject (e.g., through a flyer, brochure, or any advertisement regarding the research study) and continuing until the completion of the research study. The informed consent process could include, for example, use of question and answer sessions, community meetings, and videotape presentations. In all circumstances, however, individuals should be provided with an opportunity to have their questions and concerns addressed on an individual basis.

Informed consent must be legally effective and prospectively obtained (Protection of Human Subjects, 45 CFR Part 46; §46.116-117, 2018).

The informed consent process is the critical communication link between the prospective human subject and an investigator.

Debriefing

Debriefing is a process of informing the subject about all the information related to the research that was initially withheld, and explaining the reasons for withholding the information. Debriefing is used when subjects have been deceived or coerced, and as a means of briefly informing subjects about the research purpose(s) immediately after data have been collected (if possible without compromising the remaining data collection). Debriefing may take the form of desensitizing subjects which should not be confused with the release of a summary of the research results.

Deception

Deception is defined as the intentional action to misrepresent, trick, or mask some aspect of the research. Deception is common in some research. For example, in the Milgram (1963) experiments, the subjects were informed the purpose of the experiment was learning. However, the true purpose of the study was to measure subjects' obedience to presumed authority figures. The subjects must, of course, be aware of what measurements will be taken, what questionnaires will be administered, etc. so they can sign an informed consent to participate in the research, but the researcher may choose not to tell participants what is looked for in order to prevent the subjects from biasing the results.

Subjects should be protected from deception. If subjects are not protected, the researcher must explain in the IRB application why this is necessary, as well as any possible repercussions for the subjects. The methods to be used for deceiving subjects must be detailed in the research proposal, and a plan for informing subjects at the end of the research as to how and why they were deceived must be fully explained (see *Debriefing*). Potential physical and/or psychological risks that may be incurred by subjects due to deception must be identified, and procedures for addressing the risks must be established.

Desensitization

Desensitization is the process of helping subjects deal with information they learn about themselves as a result of participating in research. Again, consider the outcome of the Milgram (1963) study in which some subjects thought they had administered lethal electrical shocks to another person because the experimenter told them to do so. This knowledge of their behavior, coupled with their previous self- perception, required counseling for some subjects who became depressed as a result of participating in the study.

One way to desensitize subjects is to reinforce the idea that their behavior resulted from the circumstances of the research, and that their behavior was not abnormal or unusual. Desensitization is used to help subjects accept behaviors that were performed which seemed inconsistent with their self-perceptions.

Discomfort

Discomfort refers to the extent to which a subject may be made physically or psychologically uncomfortable by the topic or activity that is the focus of the research.

Guardian

A *guardian* is an individual authorized under applicable state or local law to consent on behalf of a child to general medical care (Protection of Human Subjects, 45 CFR Part 46; §46.402(e), (2018).

Health Insurance Portability and Accountability Act (HIPAA)

The *Health Insurance Portability and Accountability Act (HIPAA)* Privacy Rule provides federal protections for individually identifiable health information held by covered entities and their business associates and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of health information needed for patient care and other important purposes.

The HIPAA Privacy Rule also establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (Security and Privacy, 45 CFR 164.501, 2011). A covered entity may always use or disclose for research purposes protected health information that has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions below.

Human Subject

The Department of Health and Human Services defines a *Human Subject* as a living individual about whom an investigator (whether professional or student) conducting research obtains: (i) information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (Protection of Human Subjects, 45 C.F.R. Part 46; §46.102(f), 2018).

Identifiable Private Information

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information (Protection of Human Subjects, 45 C.F.R. Part 46; §46.102(e)(5), 2018).

Implied Consent

Implied consent means that subjects give their consent to participate in the research by virtue of their participation in a given research activity. That is, the subjects' voluntary participation in the research is accepted as their consent to be a part of the research. Completion of electronic or mail anonymous surveys, questionnaires, or interviews are examples of research activities where implied consent is used.

Implied consent is a type of a waiver of documentation of the formal informed consent. When reviewing a research project where an implied consent mechanism is used, the IRB may require the researcher(s) to disclose to the potential participants with a written summary or an information sheet about the research, including: (1) purpose of research; (2) time involved; (3) assessment of minimal risk; (4) statement regarding benefit to participants; (5) contact for questions about the research; and (6) contact for questions about rights as a research participant.

There are a number of instances where this type of consent is helpful. For example, research involving the mailing of a survey. If the survey does not ask for any identifiable information, the cover letter accompanying the survey could be written in such a manner as to serve as the "implied" informed consent form. The letter would need to contain a statement indicating that completion and return of the survey implies consent to participate in the research. As a result of such implied consent, subjects must be informed that they cannot withdraw their data once provided to the researcher, since there is no way to know which data are theirs.

Implied consent may be used when coding mechanisms, such as master name-number lists, are employed in the survey design such that the researcher knows which subject returned which survey, ONLY when (a) subjects are informed that coding is being used, (b) the researcher destroys the coding mechanism at the completion of data collection (thus, at this point, the once-confidential data become anonymous), and (c) subjects are informed of the date on which the coding mechanism is to be destroyed.

Informed Consent

Informed consent should be viewed as a process and not just a form. Full, accurate, and comprehensible information must be provided to individuals to enable them to voluntarily decide whether or not they want to participate in research. The explanation of procedures used to obtain informed consent should be presented to the individuals being asked to participate in the research in terms they can understand. Thus, the language of informed consent must be presented in lay terms. It must be made clear to individuals that their signature on the form serves as documentation of their consent to willingly participate in the research.

Informed Consent Elements—The Research Title

Researchers should include either the *title of the graduate research* in the Informed Consent, or the general topic of the research.

Informed Consent Elements—A Contact Person

The contact person for questions about subjects' rights, or the research, tasks, or activities subjects are asked to perform or complete must be someone other than the researcher. This person should not be the IRB Chair. Note that the title of the contact person refers to an administrative or academic designation such as *Thesis Director* or *Dissertation Director*; not to the contact person's professional credential or degree designation such as *RN*, *PT*, or *OTR*.

Informed Consent Elements—Compensation/Liability

A statement regarding subject compensation is a standard disclosure paragraph that is added to the Informed Consent. This disclosure is only necessary in research involving more than minimal risk 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. There is an example of an Informed Consent Form included in Appendix B of this *Guidebook*.

Interaction

Interaction includes communication or interpersonal contact between investigator and subject (Protection of Human Subjects, 45 CFR Part 46; §46.102(e)(3), 2018).

Intervention

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes (Protection of Human Subjects, 45 CFR Part 46; §46.102(e)(2), 2018).

IRB

The *Institutional Review Board (IRB)* is a committee whose primary responsibility is to protect the rights and welfare of people involved in research and which is established in accordance with the Federal Policy. While researchers may think of the IRB as an impediment or an imposed delay of their research, the IRB may also be viewed as an extra protection for inexperienced researchers, preventing difficulties arising from their lack of knowledge of safe and effective human subject research. The IRB thus provides a "free" and efficient service to researchers by providing considerable expertise and counsel regarding research activities across a breath of pastoral issues.

IRB Approval

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements (Protection of Human Subjects, 45 CFR Part 46; §46.102(h), 2018).

Justice

Justice is one of three basic ethical principles regarding the conduct of research described in the Belmont Report. This principle requires fair procedures and outcomes in the selection of research subjects.

Legal Age

Legal age is defined as 18 years old or older.

Legally Authorized Representative (LAR)

Legally authorized representative (LAR) means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, LAR means an individual recognized by institutional policy as acceptable as providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research (Protection of Human Subjects, 45 CFR Part 46; §46.102(i), 2018).

Maintenance of Data

Maintenance of data is an important responsibility of the researcher. Confidential data must be securely maintained in a locked file cabinet, locked desk, or through some other secure method. Applicants must specify where the data will be maintained. Data must be stored for at least three (3) years in the United States after completion of research. The institution or IRB may maintain the records in printed form or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner (Protection of Human Subjects, 45 CFR Part 46, §46.115(b), 2018). Student researchers must be aware of this requirement, and ensure that even after their research is completed, they have secured their data for the required time period.

Minimal Risk

Minimal risk means that 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 (Protection of Human Subjects, 45 CFR Part 46; §46.102(j), 2018). Such statements are often required on Informed Consent Forms (see examples of Informed Consent included in this *Guidebook*).

Non-Participation

Non-participation occurs when an individual who previously consented to participate in research fails to appear for scheduled sessions with the researcher, or who initially participates but then stops. Researchers may use all of the data that were collected on any individual who ceases participation in a study, but has not withdrawn from the study, as long as this was specified on the Informed Consent.

Permission

Permission is defined as "the agreement of parent(s) or guardian to the participation of their child or ward in research" (Protection of Human Subjects, 45 CFR Part 46; §46.402(c), 2018).

Physical Risk or Discomfort

Physical risks or discomforts are important considerations for researchers, as subjects should be protected from more than minimal physical risk/discomfort (see the definition of *minimal risk* above). If the planned research does not protect subjects, the researcher must indicate why this is necessary, the possible consequences for subjects, and what will be done to restore physical balance.

Further, subjects must be informed of any potential for physical risk or discomfort. For example, in testing the concurrent validity of two tests of hand dexterity, subjects may be required to perform tests that could cause fatigue or pain in the hand musculature. Subjects must be protected from this discomfort, or else informed of the possibility for this discomfort, and must have enough information to make an informed decision as to whether or not they still wish to participate in the research and endure the potential physical risk.

Privacy

Privacy refers to persons and their interest in controlling access to his/her personal information. Privacy of the individual should be respected and special provisions should be implemented on how research personnel receive and access private information of potential subjects. In research settings, private information can be received and accessed through, but not limited to, interventions, interactions, and collection of identifiable private information.

Private Information

Private information includes information about the behavior that occurs within a context that the individual can reasonably expect that no observation or recording is taking place. Private information includes information that has been provided for specific purposes by an individual that the individual can also reasonably expect will not be made public. (Protection of Human Subjects, 45 CFR Part 46; §46.102(e)(4), 2018).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by researcher or associated with the information) in order for obtaining the information to constitute research involving human subjects (Protection of Human Subjects, 45 CFR Part 46; §46.102(e)(5), 2018).

Procedures

The *Procedures section* of the proposal submitted with IRB applications contains similar information for students, faculty, or staff. For students, the Procedures include those sections normally found in Chapter III of the thesis or dissertation or relevant sections of the Project manuscript. For faculty and staff, the procedures include the elements of the research methodology section. Whether student, faculty, or staff, the Procedures section most often includes the following elements: introduction, setting, population and sample, data collection methods, human rights protection, tool(s), and treatment of data.

Protected Health Information

Protected health information is information, including demographic information, which relates to:

- the individual's past, present, or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual, and that identifies the individual, or for which there is a reasonable basis for believing that it can be used to identify the individual. Protected health information includes many common identifiers (e.g., name, address, birth date, Social Security Number) when they can be associated with the health information listed above.

The HIPAA Privacy Rule protects most "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or medium, whether electronic, on paper, or oral. The Privacy Rule calls this information *protected health information* (PHI).

Psychological Risk or Discomfort

Psychological risks or discomforts are also important considerations for researchers, as subjects should be protected from more than minimal psychological risk or discomfort (see the definition of *minimal risk* above). If the proposed research does not protect subjects, the researcher must indicate why this is necessary, what the possible consequences are for subjects, and what will be done to restore psychological balance.

Subjects must be informed of any potential for psychological risk or discomfort. For example, in a study of workplace job satisfaction, subjects may be surveyed about their evaluation of superiors, which may lead to psychological discomfort for some individuals. Subjects may feel they are *passing judgment* on their leaders, and their leaders may experience discomfort by evaluations (*judgments*) from their subordinates. Subjects must have enough information to make an informed decision as to whether or not they want to participate in the research and endure any potential psychological risks.

Research

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes (Protection of Human Subjects, 45 CFR Part 46; §46.102(l), 2018). Under the Federal Policy, the following activities are not deemed research: (1) scholarly and journalistic articles (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected, (2) public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority, (3) collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes, and (4) authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

Respect for Persons

Respect for persons is an ethical principle described in the Belmont Report that states that individuals should be treated as autonomous agents, and that individuals with diminished autonomy are entitled to extra protection.

Risk

Risk means the probability of harm or discomfort.

Subject/Participant

While the 6th Edition of the *American Psychological Association's Publication Guidebook* (see http://www.apastyle.org/) encourages using "participant" over "subject" to denote a human involved in a research study, the two words are interchangeable in this document.

Summary of Results

Subjects often agree to participate in research without compensation. One way to thank them and to educate them about the research in which they were involved is to *offer a summary of the research results*. To do so, the researcher should include space on the consent form for subjects to write their address, should they wish to receive a copy of the summary of results.

The researcher must be careful to write a summary of the results especially for the participants, and not simply give the participants a copy of the full results section of the research. Students engaged in graduate research should always seek the guidance of their graduate research director when preparing a summary of their results. In cases where research is performed at clinics or locations other than on the Oblate School of Theology campus, the researcher should prepare a draft of the summary of the results for review by the site supervisor or official assigned to the research project. No summary should be sent to participants without approval by the site official.

Researchers must also make sure to send a copy of the summary of results to all subjects who indicated a desire to receive this summary. In the rush to complete one's research, the researcher must keep in mind that it was the subjects' agreement to participate in the research that made completion of the research possible, and that the subjects' requests for results must be honored. The honoring of this agreement between subject and researcher encourages future participation in research efforts, while the failure to honor this agreement serves as a deterrent to all future research.

Withdrawal

Withdrawal refers to how subjects in a research study may discontinue their involvement prior to the completion of the research. When a subject exercises this right, the informed consent to participate in the research may specify whether the data collected from a subject's participation can be used in any analyses. If this is not specified in the informed consent, the data cannot be used in any analyses, and must be destroyed immediately upon notification of withdrawal from the study. This *Guidebook* includes an example of informed consent that states that if the subject decides to withdraw while the study is still ongoing, only the data collected up to that point may be used for data analysis purposes.

The Procedures section of the research proposal, the script of introduction to recruit subjects, and the Informed Consent form must specify how and when subjects may exercise this right, and that there are no consequences for the subject if this right is exercised.

As an example, a subject may agree to participate in a 30-minute exercise session, twice per week, for 6 weeks. If, after the fourth exercise session, the subject no longer wishes to participate in the research, the subject may choose to discontinue participation in the research, and notify the researcher of withdrawal from the research study.

How a subject may withdraw refers to procedures established by the researcher for the subject to exercise this right. For example: "Subjects may withdraw from the study by informing (specify name of a person) either verbally or in writing, of their desire to withdraw." Verbal notification allows the subject to notify the contact person, either face-to-face, or over the telephone. Written notification may be in the form of a letter or handwritten note delivered to the contact person.

The subject may withdraw from the research study at any time.

There can be no penalty or loss of benefits for subjects to which they are otherwise entitled, if they choose to withdraw from the study.

CHAPTER IV – IRB APPLICATION GUIDELINES

The IRB Guidelines describes the application process thoroughly, and provides forms for IRB Application completion, as well as directions for submission of materials for IRB review. The Guidelines may be periodically updated on the Moodle website, should policies and procedures change. The website guidelines, therefore, will remain more current than the ones presented here, as the IRB Guidebook is more typically updated annually.

The Guidelines are summarized here:

1. Read this entire *IRB Guidebook for the Researcher* (*IRB Guidebook*).

2. Submit documentation of completing a course which includes discussion of human subjects research, research design, and ethics of human subjects research content.

3. After you have reviewed this *IRB Guidebook*, you should understand which type of research you are proposing: Exempt, Expedited, or Standard. You will then need to submit one of the following completed forms and all associated documentation to the IRB committee (Office of the Dean).

Only the Electronic Forms may be submitted. Any additional or supplemental application materials should be scanned and submitted to the IRB Moodle site.

- IRB Review Application (choose one):
  - Standard (PDF)
  - Exempt (PDF)
  - Expedited (PDF)
- Any supporting documentation
- NIH certificate of completion OR documentation of course completion

Complete **electronic applications** should be scanned and emailed to IRB@ost.edu.

Important considerations when preparing IRB Applications:

- The IRB **requires electronic applications.** Materials should be scanned into a single electronic file and submitted as an email attachment.
- **PAGE NUMBERS MUST BE INCLUDED** on all EXPEDITED and STANDARD application materials. While IRB Forms do not include page numbers, **all other supporting materials, including appendices and any tools or surveys to be used in the research, must be on numbered pages, or the application will be returned to the applicant without review.**
- The **IRB MAY RETURN ANY APPLICATION WITHOUT REVIEW** if the application does not carefully follow the school's Guidelines for IRB submission. Researchers should be careful to observe ALL of the required documentation, and include ALL required signatures on forms.
- Students **should not** submit entire Project, Thesis, or Dissertation Proposals for IRB review. The directions for submitting materials makes clear that supplemental information should be provided; but unnecessary materials, i.e., literature review, copyright pages, lists of references, etc. should not be included with IRB application materials.

For All Researchers Conducting Research at an Institution other than OST

When research is being conducted at a location other than Oblate School of Theology or its academic site(s), the researcher is encouraged to obtain written permission from the other institution to conduct the study at that location. The letter giving written permission shall be submitted to the Oblate School of Theology IRB Office as supporting documentation of the researcher's IRB submission packet. If the selected institution also has an IRB that requires review and approval of the research study, the OST researcher should first ***formally apply for approval through the Oblate School of Theology IRB***. Once Full Approval or Approval with Recommendations has been granted by the Oblate School of Theology IRB, the researcher will ***then formally apply for approval at the other institution***. Once the other IRB approves the research, the researcher must provide the external IRB approval letter to the Oblate School of Theology IRB.

Note: Formal submission to other institution IRBs may noy be initiated until approval from the OST IRB has been received.

IRB Application Submission Deadlines

The following Application Deadline schedules apply for the following submissions:

Expedited AND Exempt applications	These may be electronically submitted to the IRB at any time. They will be reviewed over a period of 7-10 working days, and replies will be directed to the Researcher Applicant by email contact.
Standard IRB applications	These may also be submitted electronically to the IRB at any time. However, these applications are reviewed on a monthly basis. Therefore, for any Standard application's materials to be included in any single review board meeting, lead time is necessary for IRB Members in anticipation of the regular meetings. **Thus, STANDARD applications will be included in the next IRB's scheduled meeting ONLY IF they are received in the IRB Chairperson's office by the stated deadline.**

CHAPTER V - TYPES OF HUMAN SUBJECTS REVIEW

There are three (3) types of human subjects review: EXEMPT, EXPEDITED, and STANDARD. The criteria for each are detailed here.

Exempt

Any form of research which does not utilize human subjects, such as historical and library research will be considered for approval as EXEMPT. Some EXEMPT categories, such as those outlined in paragraphs (5), (6), and (7), are not exempt from all of the requirements of the Common Rule.

As defined by the Code of Federal Regulations Title 45 Public Welfare Part 46 Protection of Human Subjects 45 CFR 46.104, research activities in which the only involvement of human subjects will be in one or more of the following categories will qualify for Exempt review (Protection of Human Subjects, 45 CFR Part 46; §46.104 (2017)) are outlined below.

1. Research conducted in established or commonly accepted educational settings, specifically involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. 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.

2. Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), **survey or interview procedures**, or **observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met**:

    (i) information obtained is recorded in such manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

    (ii) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation; or

    (iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts **a limited IRB review** to make the determination that there are adequate provisions for protecting privacy and to maintaining confidentiality of data. *See* 38 C.F.R. § 16.111(a)(7).

3. Research and demonstration projects which are conducted by or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, and which are designed to study, evaluate, improve or otherwise examine:

    (i) public benefit of service programs;
    (ii) procedures for obtaining benefits or services under those programs;
    (iii) possible changes in or alternatives to those programs or procedures; or,
    (iv) possible changes in methods or levels of payment for benefits or services under those programs.

4. 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 if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

    (i) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

    (ii) any disclosure of human subjects' responses would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

    (iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifies linked to the subjects, and the IRB conducts a limited IRB review.

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purpose of the research, this exemption is not applicable UNLESS the subjects authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purpose of the research.

5. Research that involves taste and food quality evaluation and consumer acceptance studies, if: (i) wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA, or approved by the EPA, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

6. While an exempt category, storage or maintenance of identifiable private information or identifiable biospecimens for ***potential*** secondary research requires a broad consent and limited IRB review and approval that broad consent is obtained, broad consent is appropriately documented or a waiver is obtained and if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

7. Research involving the use of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

    (i) the identifiable private information or identifiable biospecimens are publicly available;

    (ii) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

    (iii) the research involves only information collection and analysis involving the investigator's use of identifiable health information when that is use is regulated under HIPAA, for the purposes of "health care operations" or "research" or for "public health activities and purposes; or

    (iv) the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if:
    - the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note;
    - all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a and if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

8. While an exempt category, research involving the use of identifiable private information or identifiable biospecimens for secondary research use requires broad consent if certain requirements are met:

    (i) broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens is obtained;

    (ii) documentation of informed consent or waiver is obtained;

    (iii) the IRB conducts a limited IRB review, approves, and makes the determination that the research to be conducted is within the scope of the broad consent;

    (iv) the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Only the IRB Chair or IRB Chair designee may determine whether a submitted research project meets the requirements for exemption from IRB review. If the research project does not meet criteria for exemption, the researcher will be notified and the project will require resubmission for either expedited review or standard review by the full IRB.

These are some examples of research for which the **Exempt review will not be allowed**:

- prisoners, pregnant women, children under the age of 18, or those decisionally impaired,
- deception,
- the use of school records of identifiable students or interviewing instructors about specific students if it does not meet the requirements of an exempt category,
- survey or interview procedures with children (participants under the age of 18 years),
- observation of public behavior when the researcher(s) participates in the activities being observed,
- data collected that includes protected health or medical information when there is a direct or indirect link that would identify the participant if it does not meet the requirements of an exempt category,
- sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol.

Expedited Review

Research activities that **present no more than minimal risk to human subjects**, and involve only procedures listed in one or more of the following categories, will be reviewed by the OST IRB through the Expedited review procedure. Expedited review **may not be used** where identification of the subjects and/or their responses would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects such as compromise the financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risks (http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html):

1. 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, and social behavior) or research employing **confidential** surveys, interviews, oral histories, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies.

2. Research involving materials (data, documents, records) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

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

4. Continuing review of research previously approved by the convened IRB as follows:

   (i) where (a) the research is permanently closed to the enrollment of new subjects; (b) all subjects have completed all research-related interventions; and (c) the research remains active only for long-term follow-up of subjects; or
   (ii) where no subjects have been enrolled and no additional risks have been identified; or
   (iii) where the remaining research activities are limited to data analysis.

Standard Review

Any type of research involving human subjects that the Oblate School of Theology IRB determines to involve more than minimal risk cannot be approved through either Exempt or Expedited human subjects. This review must be processed through Standard review procedures.

Therefore, research activities conducted with vulnerable or special subject populations, i.e., minors, prisoners, and decisionally-impaired subjects; and involve elements, procedures, or interventions that require additional provisions or safeguards will be reviewed by the Standard IRB Committee.

Determining Which IRB Application to File: A Checklist

To determine which IRB application to file for the proposed research, answer each of the questions below with yes or no. Then follow the directions listed after each set of questions to complete the appropriate IRB application.

Does the proposed research involve:

1. Y N the use of human subjects or information about human subjects?

Check: ***If you answered no to question 1 STOP. You may choose to complete the Exempt Review Application following procedures listed in this Guidebook. If you answered yes, continue to questions 2 through 6 that follow.***

2. Y N secondary research uses of identifiable private information or identifiable biospecimens (for which no consent is required) if at least one of these are met: the identifiable private information or identifiable biospecimen are publicly available; information (which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects, or the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA, or the research is conducted by, or on behalf of a federal department or agency using government-generated or government-collected information obtained for non-research activities if certain other requirements are met as outlined in Section 7 of the Exempt Categories section of this *Guidebook*.
3. Y N normal educational practices, such as research on regular or special education instructional strategies that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, including research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods in established or commonly accepted educational settings?
4. Y N the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) and one of the following criteria is met: the information obtained is recorded by the investigator in such a manner that the identity of subjects cannot readily be ascertained, directly or through identifiers linked to the subjects, or any disclosure of the human subjects' response outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation, or the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and that confidentiality of data will be maintained?
5. Y N research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects) and that are designed to study, evaluate, improve or otherwise examine public benefit or service program as outlined in the Exempt section of this *Guidebook*.
6. Y N taste and food quality evaluation and consumer acceptance studies if (i) wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA, or approved by the EPA, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
7. Y N Storage or maintenance of identifiable private information or identifiable biospecimens for ***potential*** secondary research? If yes, this is still an exempt category, however, the IRB needs to conduct a limited IRB review and determine that broad consent is obtained, the broad consent is appropriately documented or waived, and if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Y N Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research? If yes, this is still an exempt category if: broad consent is obtained for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens, the IRB conducts a limited IRB review and determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data and that the research is to be conducted within the scope of the broad consent; and the investigator does not include returning individual research results to subjects as part of the study plan.

Check: ***If you answered yes to any of questions 2 through 8 STOP. You may complete the Exempt Review Application following procedures listed in this Guidebook. If you answered no to all questions 2 through 8, continue to questions 9 through 13 that follow.***

9. Y N individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, or research involving **confidential** surveys?
10. Y N moderate exercise muscular strength testing, where suitable, given the age, weight, and health of subjects?
11. Y N the study of data, documents, records, or specimens collected solely for non-research purposes?
12. Y N voice, video, digital, or image recordings made for research purposes such as investigations of speech defects?

Check: ***If you answered yes to any of questions 10 through 13 you may complete an Expedited Review Application. If you answered no to all questions 10 through 13, you must complete a Standard Review Application. Follow the procedures listed in this Guidebook for each application.***

CHAPTER VI – IRB APPLICATION SUBMISSION INSTRUCTIONS

This section of the Guidebook provides instructions on how to satisfy the research training requirements and what to submit to the Oblate School of Theology IRB.

Complete applications must be submitted to the Institutional Review Board (IRB) to obtain approval to begin the collection of data for any research project, thesis, or dissertation.

Research Training Certification Requirements

All members of the research team involved in the design, conduct, or reporting of the research must demonstrate training in research methods. Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human subjects until the research certification requirements are satisfied.

All applications to the Oblate School of Theology IRB regardless of the type of submission **must** include current documentation of research training of the researcher(s). The Oblate School of Theology IRB will **accept ONLY** documentation of research training that has been **successfully completed within the last three (3) years** and applicants **must** include documentation of training with their IRB submission. This training may be completed through course work at OST; if the course includes discussion of human subjects research, research design, and ethics of human subjects research content.

Currently, it is encouraged that faculty, students and staff of Oblate School of Theology who are involved in research activities complete the National Institutes of Health (NIH) Online Research Training Certificate.

Depending on the type of research, the research team may require additional research training as mandated by other federal, state, or organizational policies. The Oblate School of Theology IRB encourages researchers to contact the Academic Dean or IRB chair directly for questions related to research training requirements.

National Institutes of Health (NIH) Online Research Training Certificate Instructions

The NIH Online Research Training Certificate can be accessed by clicking on the link above.

This module will take approximately four hours to complete, depending on prior knowledge of the presented material. Once a profile has been created, the website enables the trainee to save the work and return to the site at a later time to complete the training modules. The following instructions describe the login procedures.

For **New user**, go to the link above. In the right side top window, click on "Registration". Follow the directions to the free education module. In the center of the page you will see "New Student". You will need to enter your e-mail, click the link and complete the section modules.

Under the "Main Menu" section, five (5) modules will appear; the researcher is responsible for completing all five modules.

At the completion of the course, you will be able to print a certificate of completion. The researcher must attach an electronic copy of the certificate with the IRB application.

Financial Conflict

Researchers at OST will disclose any financial ties that impact their research in any way, They also abide by the constraints of the Common Rule when undertaking research which is funded through any public monies.

Individual IRB Application Form Completion

All applicants must complete at least one of the three possible Forms of IRB Applications: EXEMPT, EXPEDITED, or STANDARD. Every one of these Application Forms requires the following general information:

SECTION 1 – IDENTIFYING INFORMATION: the applicant must include the applicant's name (for students, this is their own name). Applicants must record the address, phone number, and email address to which questions may be directed, or correspondence from the IRB may be sent. The IRB and Academic Dean's Office should be notified immediately of any change in address, name, or email address. Program refers to the student's degree program. The title of the research may be abbreviated as necessary to fit on one line. The name of the graduate program director must be provided for all student applications.

In order to facilitate IRB Reviews and replies, **IRB dispositions will ONLY be sent to the applicant via email**. Therefore, applications missing email addresses may experience delays in IRB replies.

SECTION II – CRITERIA: the applicant must indicate under which criterion the applicant seeks review. Most graduate research will require marking only one criterion. Applications without ANY selected criteria (X in any of the boxes preceding criteria) will be returned to the applicant. **This section is NOT INCLUDED for STANDARD applications**.

SECTION III – DESCRIPTION: the applicant must (1) describe the nature of the research and, even more importantly, (2) **how the research meets the criteria checked in Section II** of the form. This description should not simply repeat the criteria marked in Section II, but instead should elaborate on the reasons for choosing the criteria marked in Section II. **This section is NOT INCLUDED for STANDARD applications.**

SECTION IV – SIGNATURES: for student applications, **BOTH** the applicant and the Program Director must sign. The student and the Director should read carefully this section of the Form that describes what their signatures mean before signing these Forms.

ALL IRB Applications require:

1. Properly completed **Application Forms** as described above,

2. The **Research Training Certification** described above reflecting completion of the National Institutes of Health (NIH) training modules, or documentation of relevant training through class work at OST within the past three (3) years.

3. One (1) electronic **copy of an abstract** detailing the proposed research. A 1-page abstract that describes the research with details about how the research will be conducted is required. Applicants should include details (as applicable) about human subjects, recruitment techniques, study methods, potential risks and benefits, management of any risks, and additional details for protection of human subjects. The abstract is a summary of the *who, what, why, when, where,* and *how* of the proposed research. The study abstract provides the IRB with an overview of the planned research.

Any IRB Application failing to include all of these necessary elements cannot be accepted, and will instead be returned to the applicant.

Where to Submit the IRB Review Application Packets

Applicants are encouraged to submit ELECTRONICALLY by including the scanned document packets described below as attachments, and sending these to the IRB Committee thru the Moodle website for the OST IRB.

NO paper copies will be accepted by the IRB.

IRB Decision Guidelines

Four decisions are possible from these reviews:

- **Full Approval,**
- **Approval with Recommendations,**
- **Approval with Conditions,**
- **Disapproval**

Explanations of each of these decisions are included in the section on IRB Dispositions below in this *Guidebook*.

The applicant is notified by email of the IRB decision. The letter will be emailed to the address provided on the application form. When other than a Full Approval disposition has been made, the letter includes the recommendations, conditions, or reasons for disapproval. IRB DECISIONS ARE NOT GIVEN IN PERSON OR OVER THE PHONE. Graduate Program Directors are also notified of the IRB decisions via email when the studies involve student research.

EXEMPT or EXPEDITED Review Application Instructions

One (1) electronic copy of the following application packet must be submitted to the Oblate School of Theology IRB. Once again, **Applicants are required to submit ELECTRONICALLY** by including the following scanned document packets. NO paper copy submissions will be accepted.

The material must be submitted in the order listed below.

☐ One (1) electronic copy of the **Research Training Certification or document certifying completion of training in the ethics of human subjects research through course content**. For applications that involve more than 1 researcher, every researcher involved must submit their own certificates of completion of research training**.**

☐ One (1) electronic copy of the completed *EXEMPT* or *EXPEDITED* Application Form.

☐ One (1) electronic copy of the complete Human Subjects Research Proposal Form, if research involves research subjects ONLY. ALL EXPEDITED applications **require** these Forms.

☐ One (1) electronic copy of an abstract detailing the proposed research. A 1-page abstract that describes the research with details about how the research will be conducted is required. Applicants should include details (as applicable) about human subjects, recruitment techniques, study methods, potential risks and benefits, management of any risks, and additional details for protection of human subjects. The abstract is a summary of the *who, what, why, when, where,* and *how* of the proposed research. The study abstract provides the IRB with an overview of the planned research.

☐ One (1) electronic copy of any surveys or interview materials used in the proposed research, along with a brief summary of administration procedures.

☐ **FOR STUDENTS ONLY**: Prior to IRB submissions, student applicants are responsible for, and **required** to obtain signatures of full approval by their Graduate Program Director on the Approval of Graduate Research Topic and Approval of Graduate Research Proposal forms **AND** file the signed forms with the Academic Dean's Office. The steps to complete these forms are detailed by the student's Graduate Program Director. Oblate School of Theology IRB will not review the IRB Application unless these forms have been filed with the Dean's Office.

For EXPEDITED applications only, the following **additional materials** must be included:

☐ One (1) electronic copy of the Description of Procedures of the research:
- Setting of the research
- Population and Sample
- Data Collection Methods
- Human Rights Protection
- Tool(s) to be used for data collection

☐ One (1) electronic copy of any data gathering tools

☐ One (1) electronic copy of the information used to recruit subjects (e.g., postings, newspaper ad, verbal presentation to classes, etc.)

☐ One (1) electronic copy of the information to be provided to subjects to obtain Informed Consent

☐ One (1) electronic copy of the Informed Consent form (actual form; not a "reduced copy")

STANDARD Review Application Instructions

One (1) electronic copy of the following application packets must be submitted to the Oblate School of Theology IRB – Graduate Studies Office. Once again, **Applicants are encouraged to submit ELECTRONICALLY** by including the following scanned document packets. NO paper copies will be accepted by the IRB.

The material must be submitted in the order listed below.

☐ One (1) electronic copy of the **Research Training Certification**. For applications that involve more than 1 researcher, every researcher involved must submit their own Research Training Certification**.**

☐ One (1) electronic copy of the complete **Human Subjects Research Proposal Form**.

☐ One (1) electronic copy of the completed STANDARD Review Application Form.

☐ One (1) electronic copy of the **Description of Procedures** of the research:

- Setting of the research
- Population and Sample
- Data Collection Methods
- Human Rights Protection
- Tool(s) to be used for data collection

☐ One (1) electronic copy of any **surveys, interview materials or other data gathering tools**

☐ One (1) electronic copy of the information used to **recruit subjects** (e.g., social network postings, verbal classes presentation)

☐ One (1) electronic copy of the **Informed Consent and/or Assent form** (actual form(s); not "reduced copy(s)" of the form(s))

☐ **FOR STUDENTS ONLY**: Prior to IRB submissions, student applicants are responsible for, and **required** to obtain signatures of full approval by their Graduate Research Directors on the Approval of Graduate Research Topic and Approval of Graduate Research Proposal forms **AND** file the signed forms with the Graduate Studies Office. The steps to complete these forms are detailed by the student's Graduate Research Director. The Oblate School of Theology IRB will not review any IRB Application unless these forms have been filed with the Graduate Studies Office.

THE HUMAN SUBJECTS RESEARCH PROPOSAL (HSRP) FORM: Instructions

The Human Subjects Research Proposal Form (Appendix A) contains 13 questions to be answered by the applicant regarding the protection of human subjects in the proposed research. Applicants should take care to answer each question concisely but fully, to complete the yes/no answer blocks in Questions 1, 4, 5, and 6, the anonymous/confidential answer block in Question 9, and the data storage answer block in Question 10. Incomplete forms will not be reviewed by the IRB Committee which will result in delay with the review process.

FOR STUDIES THAT DO NOT INVOLVE HUMAN SUBJECTS, THIS FORM IS NOT REQUIRED.

Question 1: ***Are subjects exposed to any possibility of physical or psychological risk or discomfort? If yes, describe how subjects are exposed, the methods to be used to protect subjects, and what will be done to restore physical and psychological homeostasis.***

The purpose of this question is to determine whether subjects will be exposed to any risk or discomfort, and if so, how they are exposed, how subjects will be protected, and what will be done to diminish the effects of the risk or discomfort after the research (restore physical and/or psychological balance). Review the definitions of *risk, discomfort, physical risk or discomfort,* and *psychological risk or discomfort* in Chapter III - Definitions and Terms of this *Guidebook*. An explanation is necessary for each occurrence of a "yes" response to the four risk and discomfort questions. If "no" is checked for all four options, no explanation is necessary.

Question 2: ***What are the possible benefits that can be derived by subjects who participate in the research?***

The purpose here is simply to determine whether subjects who participate in the study can expect to receive any benefits from their participation in the research, and what those benefits may be. Note that this question applies to participants, and not to the community or society as a whole. *Benefits* are broadly defined in this question to include psychological or physical benefits, but the specific benefits must be listed. Most importantly, the benefits must be realistic and equally possibly attainable by most participants. In other words, do not list benefits that only a minority of participants might receive, but rather list those benefits that most participants are likely to receive. Often, researchers will indicate that there will be no direct benefit to the participants.

Question 3: ***What are the possible benefits that can be derived from the research?***

While Question 2 was concerned with the benefits to be derived by the participants in the research, this question pertains to the possible benefits that may be provided to the broader community or society. Again, the benefits must be realistic and not overstated.

Question 4: ***Are subjects members of any of the following vulnerable populations? If yes, explain why the research is not conducted with members of less vulnerable populations, and what special protections or safeguards will be used to protect the welfare of members of a vulnerable population (see Question 4 of the HSRP Form in Appendix A for list of vulnerable populations).***

This question pertains to the equity of subject selection. The IRB takes into consideration the purposes of the research and the setting in which the research will be conducted. The purpose of this question is to determine whether subjects are being selected from vulnerable populations, and if so, how the inclusion of those subjects, rather than subjects from less vulnerable populations, is justified. Another purpose is to determine whether members of a vulnerable population are adequately protected in the proposed research.

The issue of concern is that members of vulnerable populations are at increased risk for coercion or undue influence than are members of less vulnerable populations. For example, when asked by a researcher to participate in a study, children are more likely to feel compelled to agree than adults. The same may be true for institutionalized individuals versus noninstitutionalized individuals.

If "yes" is checked to any of the populations listed, the applicant must clearly state why members of that group are needed for the research, versus members from a less vulnerable population, and how the subjects' rights will be protected. **It is important to note that research for the benefit of vulnerable population is not to be discouraged**.

Questions 5 and 6: ***Are subjects exposed to deception/coercion? If so, explain how, why it is necessary, and possible risks or discomforts to subjects.***

The purpose of these questions is to determine whether subjects will be exposed to deception or coercion, and if so, how they are exposed, why this is necessary, and the possible risks or discomforts to subjects resulting from the deception or coercion. Review the definitions of *coercion* and *deception* in Chapter III - Definitions and Terms of this *Guidebook*. An explanation is necessary only if the "yes" response is checked.

Question 7: ***If either Question 5 or 6 was answered yes, explain debriefing procedures to be used to desensitize, dehoax, or otherwise inform subjects of the true intent of the research and why deception and/or coercion was necessary.***

This question should be completed only if either Question 5 or 6 was answered "yes". This question is concerned with debriefing and is used to determine if the researcher's plans for informing subjects, desensitization, and/or dehoaxing are adequate in the view of the IRB. Review definitions for *debriefing, dehoaxing,* and *desensitization* in Chapter III - Definitions and Terms of this *Guidebook*.

Question 8: ***What is the relationship between the researcher and the potential subjects? Explain how the potential subjects will be protected from coercion during the recruitment and research processes based on this relationship.***

This question is used to determine the potential risk of coercion in the recruitment and research processes. Identify the relationship; then explain how subjects will be protected from coercion.

For example, if the researcher provides nursing/therapy/educational, etc., services to subjects who will be recruited, this relationship should be specified and the researcher must explain how coercion will be prevented or reduced. In this case, the researcher may ask another person to ask subjects to participate in the research to prevent subjects from feeling compelled or obligated to participate because their nurse, therapist, or teacher is asking them to be subjects in his or her study.

This does not mean that researchers may not collect data from their patients, clients, students, employees, and so on. The researcher, however, must demonstrate that he or she has evaluated the impact of his or her relationship on the recruitment and research processes, based on the nature of this relationship.

Question 9: ***How will subjects' data be maintained?***

The purpose of this question is to determine whether subjects' data will be maintained anonymously or confidentially. Review the definitions of *anonymity* and *confidentiality* in Chapter III - Definitions and Terms of this *Guidebook*.

Question 10: ***How long will subjects' data be stored?***

In the United States, all confidential data must be stored by the researcher for three (3) years. In Canada, data must be stored for six (6) years.

Question 11: ***Where and how will subjects' data be stored?***

Confidential data must be securely maintained in a locked file cabinet, locked desk, password-protected documents, or through some other secure method. Applicants must specify where the data will be maintained.

Question 12: ***How will research findings be disseminated to subjects?***

The purpose of this question is to determine how research findings will be provided to subjects. Review the *Summary of Results* definition in Chapter III - Definitions and Terms of this *Guidebook*. Researchers are not required to provide research participants with a summary of results, but if a summary is provided, all subjects must have equitable access to the findings.

Question 13: ***How will subjects' voluntary informed consent be obtained and documented? Specify any accommodations.***

Review Chapter VIII on Voluntary Informed Consent in this *Guidebook* prior to completing this question. It is not necessary to explain the consent form in the answer to this question, since IRB members use an internal document to verify that all required elements of informed consent are present in the consent form. Instead, describe the process to be used or steps to be followed to explain the study to prospective subjects. The applicant may refer to a script included in the research proposal, but this script must be included with the materials submitted to the IRB (Refer to *Determining Which IRB Application to File: A Checklist* in Chapter V of this *Guidebook*).

The applicant must specify any accommodations made to the consent form and or consent process for special populations. For example: (a) using enlarged print on the consent form or using a Braille consent form for visually impaired subjects, (b) paraphrasing the title of the study rather than using the actual title when the latter is confusing to subjects, and (c) paraphrasing the purpose of the study rather than stating the actual purpose when the latter would bias subjects' performance. In this last example, the researcher must include a written debriefing procedure in the research methodology to inform subjects of the deception at the completion of data gathering.

Criteria To Review All Research Proposals Submitted To The IRB:

The criteria listed below are used by the IRB to evaluate the plan for the protection of human subjects as described on the Human Subjects Research Proposal Form. This Criteria Form is an internal IRB document used by the IRB Members to review any IRB application. Applicants may utilize the form as a "double check" to ensure the application is clear, consistent, and complete.

This form is NOT completed by the applicant!

Yes	No	N/A		
☐	☐	☐	1.	Risks to subjects are minimized by using procedures which:
☐	☐	☐		a. are consistent with sound research design.
☐	☐	☐		b. do not unnecessarily expose subjects to risk (pregnant women excluded from exercise).
☐	☐	☐		c. when appropriate, are already being performed for diagnostic or treatment purposes.
				Risks to subjects are reasonable in relation to anticipated benefits.
☐	☐	☐	2.	Selection of subjects is equitable and subjects will be selected from the least vulnerable population possible given the nature of the planned research.
☐	☐	☐	3.	Risk/benefit ratio of exposure to deception is acceptable.
☐	☐	☐	4.	Risk/benefit ratio of exposure to coercion is acceptable.
☐	☐	☐	5.	Plan for desensitization and/or dehoaxing is acceptable.
☐	☐	☐	6.	Subjects are protected from coercion related to researcher-subject relationship. 9/11. Procedures for maintenance of subjects' data are acceptable for the planned design.
☐	☐	☐	7.	All subjects have equitable access to research findings.
			8.	Required elements of INFORMED CONSENT:
☐	☐	☐		a. statement that the study involves research.
☐	☐	☐		b. name of primary researcher.
☐	☐	☐		c. title of research or general topic of research.
☐	☐	☐		d. explanation of the purposes of the research.
☐	☐	☐		e. expected duration of the subject's participation.
☐	☐	☐		f. description of the procedures to be followed.
☐	☐	☐		g. identification of any experimental procedures to be used.
☐	☐	☐		h. description of possible (reasonably foreseeable) risks and/or discomforts.
☐	☐	☐		i. Description of realistic and reasonably expected benefits to the subject or others.
☐	☐	☐		j. disclosure of appropriate alternate procedures and/or treatments, if any, that might be advantageous to subjects.
☐	☐	☐		k. a statement describing the extent to which confidentiality or anonymity will be maintained.
☐	☐	☐		l. statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which subject is otherwise entitled.
☐	☐	☐		m. statement that subject may withdraw participation at any time.
☐	☐	☐		n. contact person for questions about research and subject's rights.
				In studies of more than minimal risk or questionable liability:
☐	☐	☐		o. explanation as to whether compensation is provided and what it consists of.
☐	☐	☐		p. name, title, and phone number or address of contact person in event of research-related injury.
☐	☐	☐		q. explanation as to whether medical treatments are available if injury occurs and what they consist of, or where further information may be obtained.
☐	☐	☐		r. consent is documented/dated with signature of subject or subject's legal representative.
			9.	Required elements of IMPLIED CONSENT (when coding mechanisms are used):
☐	☐	☐		s. subjects are informed that coding is being used.
☐	☐	☐		t. researcher destroys coding mechanism at completion of data collection.
☐	☐	☐		u. subjects are informed of date on which coding mechanism is to be destroyed.

10. Required elements of BROAD CONSENT (when required for EXEMPT research categories):

☐	☐	☐	v.	description of any reasonably foreseeable risks or discomforts to the subject.
☐	☐	☐	w.	description of any benefits to the subject or to others that may reasonably be expected.
☐	☐	☐	x.	statement describing the extent, if any, to which confidentiality of records will be maintained
☐	☐	☐	y.	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 subject is otherwise entitled.
☐	☐	☐	z.	general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. The description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted.
☐	☐	☐	aa.	description of the identifiable private information or biospecimens that might be used in research and types of institutions or researchers that might conduct such research.
☐	☐	☐	bb.	description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (period of time could be indefinite).
☐	☐	☐	cc.	description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite).
☐	☐	☐	dd.	A statement that the subject will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purpose of the research and that the subject might have chosen to consent to some of those specific research studies unless the subject or the subject's legally authorized representative will be provided details about specific research studies.
☐	☐	☐	ee.	information of whom to contact to answer questions about the subject's rights and about storage and use of the identifiable private information or identifiable biospecimens or in case of a research-related harm.

CHAPTER VII - IRB DISPOSITIONS

Four dispositions are possible from the IRB review: Full Approval, Approval with Recommendations, Approval with Conditions, or Disapproval.

Full Approval

Upon notification of Full Approval, the applicant may begin formal application as needed to other IRBs at the facilities/agencies in which data are to be collected.

The applicant is required to immediately notify the IRB for additional review in the event that ANY of the following occurs:
- a major change in the method of data collection
- unanticipated problem or unanticipated adverse effects on the human subjects
- unanticipated difficulties in obtaining informed consent or maintaining confidentiality

Approval With Recommendations

Upon notification of Approval with Recommendations, the applicant may begin formal application as needed to other IRBs at the facilities/agencies in which data are to be collected. Note, however, that while the IRB has approved the research, the IRB has chosen to make recommendations to the applicant regarding possible improvements to the research plan or appearance of written materials to be used in the research. These recommendations should be addressed prior to application to other IRBs as needed.

The applicant is required to immediately notify the IRB for additional review in the event that ANY of the following occurs:
- a major change in the method of data collection
- unanticipated adverse effects on the human subjects
- unanticipated difficulties in obtaining informed consent or maintaining confidentiality

Approval With Conditions

If Approval with Conditions is granted, the letter from the IRB committee specifies what conditions must be met before Full Approval will be granted. The applicant, in consultation with the graduate program director, must address each of the conditions and report in memo format back to the IRB via the Dean's office.

When submitting revised materials, the applicant must include: **(a) a memo signed by the graduate research director indicating that the changes have been approved by the director, (b) a copy of the previous approval with conditions letter the applicant received, and (c) all supporting documentation providing evidence of the revisions in final form.**

Upon subsequent review, the application may be granted any of the four possible dispositions. The proposed research may not begin until Full Approval or Approval with Recommendations has been granted by the IRB.

Disapproval

If the IRB disapproves of the research, the applicant (and for students, the Graduate Program Director) is notified of the specific reasons for disapproval. (Student applicants should then schedule a meeting with their Graduate Program Director to discuss the research and what actions need to be taken to remediate the problems). When an application is disapproved by the IRB, the applicant must submit a new application with updated supporting materials to the IRB for subsequent review.

When submitting the new application, the applicant must include a copy of the disapproval letter received after the first review.

The proposed research may not begin until Full Approval or Approval with Recommendations has been granted by the IRB.

Continuing Approval

If the research is not completed within 12 months of the notice of approval from the IRB, the applicant must notify the IRB of the status of the project. The Researcher(s) must provide a formal letter notifying the IRB of the progress of the research, and the reasons and rationale for requesting the extension.

Common Reasons For Conditions Rather Than Full Approval

The following are common reasons research applications receive approval with conditions rather than full approval from the Oblate School of Theology IRB. The applicant is responsible for reviewing the application to ensure that none of the following scenarios will prevent full approval of the submitted research.

1. Missing proper signatures on IRB forms, or for students - failing to have on file fully approved and signed graduate forms.

2. Failure to proofread materials; missing page numbers; missing appendices, missing supporting documents, etc. There should be no spelling errors or grammatical errors in Recruitment scripts or on Informed Consent Forms.

3. Missing required elements, or inconsistencies, on the Informed Consent form. These are detailed in Chapter VIII on Voluntary Informed Consent in this *Guidebook*.

4. Failure to provide complete details of research procedures, such as missing steps in the procedures, or inconsistencies in different section(s) of submitted materials.

5. Inconsistencies on Recruitment script(s) or in the explanation of the study. Different sections of supplied materials make conflicting statements, such as varying time commitments of 15 minutes at Recruitment and 30 minutes on Informed Consent.

6. Failure to provide complete details on how subjects will be contacted, what will be said to them - missing scripts.

7. Failure to provide complete details on recruitment of subjects for participation.

8. Terminology in subject recruitment or instruction scripts not easily understandable by the target group.

9. Failure to accurately specify for how long data will be securely maintained. The U.S. requires 3 years; Canada requires 6 years.

10. Confusion regarding anonymity vs. confidentiality. Face-to-face contact with subjects, or signatures on Consent Forms often make it impossible for data to be collected anonymously.

11. Not giving a name and title of a contact person (other than the researcher) and providing a phone number or address at which he or she may be contacted. Do not include personal or home phone numbers.

12. Not clearly specifying withdrawal procedures and/or the time frame within which the withdrawal option may be exercised by subjects. Avoid language that suggests that subjects may withdraw “at any time”, as this suggests that subjects may withdraw after the study has been completed.

13. Coercive recruitment procedures or script. For example, a therapist recruits subjects for research and even states that participation is voluntary, but implies that the patient/client should participate in order to help the therapist.

14. Requiring more than one yes or no answer on a screening tool or health questionnaire (see an example in Appendix B of this *Guidebook*). The screening criteria should be presented as a list, asking potential subjects to answer only one yes-or-no question about whether **any** of the exclusion criteria apply.

15. Not specifying the subject's duration of commitment (such as two 45-minute sessions a week for 6 weeks).

16. Not including the *no loss of benefits* phrase on the consent form when necessary.

17. Not clearly stating how data will be securely maintained (e.g., use of subject ID numbers and a master ID number/name coding list), or where data will be stored (e.g., locked file cabinet).

18. Insufficient sample size to detect a hypothesized effect. Small effects cannot easily be detected by small samples; this raises the question of whether the subjects' time is being wasted in a study that cannot detect the effect under investigation.

CHAPTER VIII - VOLUNTARY INFORMED CONSENT

Except for Exempt research, no researcher may involve a human being as a subject in a research study unless the researcher has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (e.g., guardian).

Informed consent is not just a form or signature, but a process of information exchange. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism ensuring respect for persons through provision of thoughtful consent for a voluntary act.

The procedures used in obtaining informed consent should be designed to educate prospective subjects in terms they can understand.

Therefore, the language and its documentation (especially the explanation of the study's purpose, duration, experimental procedures, alternatives, risks, benefits, and so on) must be written in simple language that is fully understandable to the people being asked to participate. The written presentation of information is used to document the basis for consent and for the subjects' and researcher's future reference.

Required Elements of Informed Consent

The following are all required elements of the informed consent form. The language in all of these elements should be easily understood by the prospective subjects or his/her legally authorized representative or parent/guardian. (Protection of Human Subjects, 45 CFR Part 46; §46.116, 2018)

1. Statement that the study involves research.
2. Name of the primary researcher.
3. Title of study (or) general topic of research.
4. Explanation of the purposes of the research. Translate the purpose statement(s) from the research proposal technical language to language easily understandable to the prospective subjects.
5. Expected duration of subjects' participation. Be specific as to the number, frequency, and duration of sessions or visits.
6. Description of possible (reasonably foreseeable) risks and/or discomforts to the subjects. Distinguish between possible & remotely possible, using the definition of *minimal risk*.
7. Description of the procedures to be followed. Write using terms understandable to the prospective subjects.
8. Identification of any experimental procedures to be used.
9. Description of realistic and reasonably expected benefits to the subjects or others. Do not overestimate the possible benefits that may be derived from the proposed research. Often, there are no direct benefits to participate in various research studies.
10. Disclosure of appropriate alternate procedures, if any, that might be advantageous to subjects.
11. A statement describing the extent to which confidentiality of records identifying the subjects or subject's anonymity will be maintained.
12. Statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
13. Provide a statement that subjects may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
14. Provide the name, *title*, and phone number or address of a contact person for questions about the research or the subject's rights. This person should not be the IRB Chair. However, avoid providing home or other personal phone numbers; use business or office telephone numbers whenever possible. **Note**: *Title* refers to an administrative or academic designation such as Graduate Research Director, not to the contact person's professional licensure designation such as RN, PT, or OTR.

15. Provide an explanation as to whether any compensation for participating in the study is provided and, if so, provide full details regarding the nature and amount of the compensation.
16. *Provide the name, title, and phone number or address of a contact person in the event of a research-related injury to the subject.
17. *An explanation as to whether compensation and/or medical treatments are available if injury occurs as a result of the study and, if so, what they consist of, or where further information may be obtained.
18. Consent must be dated and signed by the subject or the subject's legally authorized representative.

* Note that items 16-17 are required only when there is more than minimal risk or when the study involves deception and/or coercion.

Broad Consent Requirements (45 C.F.R. § 46.116(d))

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is permitted as an alternative to the informed consent requirements. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

1. The following requirements which are also required for regular Informed Consent:
   (i) A description of any reasonably foreseeable risks or discomforts to the subject;
   (ii) A description of any benefits to the subject or to others that may reasonably be expected from the research.
   (iii) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
   (iv) 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 subject is otherwise entitled;

2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

3. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

4. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

5. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purpose of the research, and that they might have chosen to consent to some of those specific research studies;

6. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Additional Informed Consent Elements as Appropriate

- 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), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject'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, which 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

The Oblate School of Theology IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in the methods or levels of payment for benefits or services under those programs; or
(iv) possible changes in or alternatives to those programs or procedures; or
(v) possible changes in methods or levels of payment for benefits or services under those programs; and
(vi) The research could not practicably be carried out without the waiver or alteration.

Furthermore, the Oblate School of Theology IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) If the research involves using identifiable private information or identifiable biospecimens, the research could not be practically carried out without using such information or biospecimens in an identifiable format;
(4) The research could not practicably be carried out without the waiver or alteration; and
(5) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The informed consent requirements in the Federal Policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

Tips on Informed Consent

- Do not begin phrases with "I understand that ...", as these can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence.

- Use of scientific jargon and legalese is not appropriate. While the consent form is a legal document, also think of it as a teaching tool.

- Describe the overall experience that will be encountered. Explain the research activity and, if experimental, how it is experimental, such as requiring extra tests or separate research records.

- Inform prospective subjects of any foreseeable harm, discomforts, inconveniences, or risks that may be associated with the research.

- If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are re-contacted or newly contacted.

- Describe the benefits that subjects may reasonably expect to encounter. There may not be any, as studies are often conducted to determine whether there are any benefits from the research.

- If payment is given to defray the incurred expense of participation, it must not be coercive in amount or method of distribution.

- Describe alternatives to participating in the research. For example, in some drug studies, the medication(s) may be available through a family doctor or clinic without the need to volunteer for the research activity.

- The regulations require naming knowledgeable contact persons to answer subjects' questions about the research, their rights as subjects, and research-related injuries. A single person is not likely to be appropriate to answer questions in all of these areas because of potential conflicts of interest or the appearance of such. While questions about the research itself are best answered by the investigator, other questions may best be referred to those not on the research team.

- Voluntary participation and the right to withdraw at any time are essential. It is also important to point out that no penalty or loss of benefits will occur as a result of either not participating or withdrawing.

- Health surveys or other screening tools should require only one yes or no answer to the entire screening to protect potential subjects' privacy (See example later in this Guidebook).

- Health surveys screening for exercise precautions should determine whether there is any possibility that a female subject is pregnant, and if so, exclude her from any research involving exercise.

EXEMPT REVIEW APPLICATION

Appendix A

IRB Application Forms

EXEMPT REVIEW APPLICATION

HUMAN SUBJECTS RESEARCH - OBLATE SCHOOL OF THEOLOGY INSTITUTIONAL REVIEW BOARD

IDENTIFYING INFORMATION

Researcher: _____ Telephone Number: _____

Address: _____ Program: _____

_____ Research Director: _____

Email Address: _____ (IRB disposition letter will be electronically emailed)

Research Title: _____

☐ If Checked, The student ensures that the proposed research has not yet begun, but this application is written in the past tense as directed by the Graduate Program Director.

I. CRITERIA

Place an X next to the criterion or criteria under which you are seeking Exempt review:

☐ The project is not "research" as defined by the federal guidelines. (See the Common Rule (45 CFR 46 subpart A))

☐ Research which does not utilize human subjects.

☐ Research involving the collection or study of existing data, documents, or records from publicly available sources or if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects such as in content or secondary data analyses.

☐ Research on normal educational practices, such as research on regular or special education instructional strategies that are not likely to adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction, including research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods in established or commonly accepted educational settings.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording), and one of the following criteria is met: the information obtained is recorded by the investigator in such a manner that the identity of subjects cannot readily be ascertained, directly or through identifiers linked to the subjects, or any disclosure of the human subjects' response outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation, or the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or indirectly through identifiers linked to the subjects and IRB will conduct a limited IRB review.

☐ Taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or in which a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration, or approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research? If yes, broad consent is required.

☐ Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research? If yes, broad consent is required.

☐ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ Secondary research uses of identifiable private information or identifiable biospecimens (for which no consent is required) if at least one of these are met: the identifiable private information or identifiable biospecimen are publicly available information (which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects, or the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA, or the research is conducted by, or on behalf of a federal department or agency using government-generated or government-collected information obtained for non-research activities if certain other requirements are met as outlined in Section 7 of the Exempt Categories section of this *Guidebook*.

EXEMPT REVIEW APPLICATION

II. DESCRIPTION

Summarize specifically but concisely the purpose, source(s) of data, and HOW the planned research meets the above criteria (attach additional pages as needed).

III. SIGNATURES

The researcher's signature indicates that during all phases of the conduct of this research he or she will ensure the practical application of the general ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, including respect for persons, beneficence, and justice. The researcher will respect the confidentiality of information obtained from or about subjects in this research and will protect all subjects' privacy by not disclosing any information in a way in which an individual may be identified.

The Program Director's signature indicates that all IRB application materials have been reviewed and approved by him/her prior to submission to the IRB.

Researcher's Signature	**Date**	**Graduate Program Director's Signature**

Note: The proposed research may NOT begin until a formal Letter of IRB Approval has been issued.

EXPEDITED REVIEW APPLICATION

HUMAN SUBJECTS RESEARCH - OBLATE SCHOOL OF THEOLOGYINSTITUTIONAL REVIEW BOARD

I. IDENTIFYING INFORMATION

Researcher: _____ Telephone Number: _____

Address: _____ Program: : _____

Research Director: _____

Email Address:_____ (IRB disposition letter will be electronicallyemailed)

Research Title: _____

☐ If checked, the student ensures that the proposed research has not yet begun, but this application is written in the past tense as directed by the Graduate Program Director.

II. CRITERIA

Place an X next to the criterion or criteria under which you are seeking expedited review:

☐ 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, and social behavior) or research employing **confidential** surveys, interviews, oral histories, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies.

☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy. It includes such procedures as weighing or testing sensory acuity, magnetic resonance imaging, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.

☐ Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 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 (such an investigation of speech defects), video, digital, or image recordings made for research purposes. Clinical studies of drugs or devices only when an IND or IDE are not required.

☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from adults, considering amounts drawn, and the age, weight, and health of the subjects.

☐ Prospective collection of biological specimens for research purposes by noninvasive means, such as hair and nail clippings in a non-disfiguring manner; deciduous or permanent teeth if routine patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; supra- and subgingival dental plaque and calculus, provided the collection procedure is not invasive and the process is in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; or sputum collected after saline mist nebulization.

☐ Continuing review of research previously approved by the convened IRB.

III. DESCRIPTION

Summarize specifically but concisely HOW the planned research meets the above criteria (attach additional pages as needed).

IV. SIGNATURES

The researcher's signature indicates that during all phases of the conduct of this research s/he will ensure the practical application of the general ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, including respect for persons, beneficence, and justice. The researcher will respect the confidentiality of information obtained from or about subjects in this research and will protect all subjects' privacy by not disclosing any information in a way in which an individual may be identified.

The Graduate Research Director's signature indicates that all IRB application materials have been reviewed and approved by him/her prior to their submission to the IRB.

_____	_____	_____
Researcher's Signature	**Date**	**Graduate Research Director's Signature**

Note: <u>The proposed research may NOT begin until a formal Letter of IRB Approval has been received.</u>

STANDARD REVIEW APPLICATION

HUMAN SUBJECTS RESEARCH - OBLATE SCHOOL OF THEOLOGYINSTITUTIONAL REVIEW BOARD

I. IDENTIFYING INFORMATION

Researcher: _____ Telephone Number: _____

Address: _____ Program: _____

_____ Research Director: _____

Email Address: _____ (IRB disposition letter will be electronicallyemailed)

Research Title: _____

If checked, the student ensures that the proposed research has not yet begun, but this application is written in the past tense as directed by the Program Director.

II. ABSTRACT

III. SIGNATURES

The researcher's signature indicates that during all phases of the conduct of this research s/he will insure the practical application of the general ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, including respect for persons, beneficence, and justice. The researcher will respect the confidentiality of information obtained from or about subjects in this research and will protect all subjects' privacy by not disclosing any information in a way in which an individual may be identified.

The Graduate Research Director's signature indicates that all IRB application materials have been reviewed and approved by the Graduate Research Director prior to their submission to the IRB.

Researcher's Signature	Date	Graduate Research Director's Signature

Note: <u>The proposed research may NOT begin until a formal Letter of IRB Approval has been received.</u>

HUMAN SUBJECTS RESEARCH PROPOSAL FORM

HUMAN SUBJECTS RESEARCH - OBLATE SCHOOL OF THEOLOGY INSTITUTIONAL REVIEW BOARD

Researcher: _____ Date: _____

1. Are subjects exposed to any possibility of:

Risk:	Y:	N:	Discomfort:	Y:	N:	
Physical	☐	☐	Physical	☐	☐	☐
Psychological	☐	☐	Psychological	☐	☐	☐

If yes, describe how subjects are exposed, the methods to be used to protect subjects, and what will be done to restore physical and psychological homeostasis.

2. What are the possible benefits that can be derived by subjects who participate in the research?

3. What are the possible benefits that can be derived from the research?

4. Please indicate below whether subjects are members of a vulnerable population. If yes, explain why the research is not conducted with members of less vulnerable populations, and what special protections or safeguards will be used to protect the welfare of members of a vulnerable population. Check all that apply.

☐ No, subjects are not members of a vulnerable population

Y:	N:		Y:	N:	
☐	☐	Children	☐	☐	Mentally disabled
☐	☐	Economically disadvantaged	☐	☐	Pregnant women
☐	☐	Educationally disadvantaged	☐	☐	Prisoners
☐	☐	Institutionalized persons	☐	☐	Other (specify) _____

HUMAN SUBJECTS RESEARCH PROPOSAL
OBLATE SCHOOL OF THEOLOGY INSTITUTIONAL REVIEW BOARD

5. Are subjects exposed to deception? If so, explain how, why it is necessary, and possible risks or discomforts for subjects. **Y:** ☐ **N:** ☐

6. Are subjects exposed to coercion? If so, explain how, why it is necessary, and possible risks or discomforts for subjects. **Y:** ☐ **N:** ☐

7. If either question 5 or 6 was answered yes, explain debriefing procedures to be used to desensitize, dehoax, or otherwise inform subjects of the true intent of the research and why deception and/or coercion was necessary.

8. What is the relationship between the researcher and the potential subjects? Explain how the potential subjects will be protected from coercion during the recruitment and research processes based on this relationship.

9. How will subjects' data be maintained?

___ anonymous (unknown to the researcher)
___ confidential

10. How long will subjects' data be stored?
___ at least 3 years
___ at least 6 years

11. Where and how will subjects' data be securely stored and maintained?

12. How will research findings be disseminated to subjects?

13. How will subjects' voluntary informed consent be obtained and documented? Specify any accommodations made to the consent form or consent process for special populations.

Appendix B

INFORMED CONSENT & ASSENT TEMPLATES

INFORMED CONSENT [TEMPLATE]

The purpose of this form is to assure that you have sufficient information to make an informed decision as to whether you will agree to be a subject in a study involving research.

Study Title: *Insert study title*

Version Date: *Insert a version date here corresponding to the date of submission to the IRB*

Name of Study Investigator(s): *Insert name(s) of Investigator(s)*
Address of Study Investigator(s): *Insert address of Investigator(s)*
Phone number of Study Investigator(s): *Insert phone numbers of Investigator(s)*

Name of Study Co-Investigator(s): *Insert name(s) of Co-Investigator(s)*
Address of Study Co-Investigator(s): *Insert address of Co-Investigator(s)*
Phone number of Study Co-Investigator(s): *Insert phone numbers of Co-Investigator(s)*

Invitation to take part in a research study

Discuss the voluntary nature of the research study. The section should include instructions for the potential research subject to read the consent document carefully and ask questions before they agree to participate.

EXAMPLE:
You are invited to take part in a research study about [*include what the study is planning to study*]. This document will provide you with important information about the study, its purpose, what will happen if you decide to participate in the study and the potential risks and benefits of taking part in the study.
Please take the time to read this document carefully. Participation in this study is voluntary and you can change your mind and withdraw from the study at any time before the study is completed and your decision will not be held against you. Please ask any questions you may have before you agree to take part in the study. If you decide to take part in this study you will be asked to sign this form and comply with the study procedures as described below.

Who can I talk to if I have questions about the research study?

Provide contact information for the study team and for the person responsible to answer questions related to subject research rights.

EXAMPLE:
If during the course of the study you have questions about the research, tasks, or activities you are asked to perform or complete, or think the research has hurt you, you may contact *[Name and Title of the Researcher]* at *[phone #],* and all your questions will be answered.

If you have questions about your rights as a research subject you may contact *[Name and Title of Contact Person other than the researcher]* at *[phone #]*

What is the purpose of this research study and why am I being asked to take part in this study?

Explain in lay terms the purpose of the study, who is sponsoring the study (if applicable) and explain why the subject was invited to participate in the study. Also describe those conditions that would not make the subject eligible to participate. Details of the study should not be included in this section.

EXAMPLE:
The purpose of this research study is to *[include information].* This study is sponsored by *[include information].*
You are being asked to participate in this study because *[include information].*

How many people will to take part in this research study and how long will the research study last?

Explain the length of subject's participation and total number of subjects participating in the study. If this is a study recruiting subjects from multiple locations, include names of locations, total number of subjects recruited at this site and at each location and overall total number of subjects recruited for the entire study.

EXAMPLE:

If you decide to take part in the study you will be one of [*insert number]* people involved in the study.
Your participation may last up to *[insert time frame]*

Will the study involve experimental procedures?

Explain in lay terms if the study involves experimental procedures (including experimental drugs and/or devices) and clearly differentiate the experimental procedures from standard of care procedures.

EXAMPLE:

The procedures in this study [are] [are not] considered experimental. (If experimental, describe what is experimental).

What will happen to me if I decide to participate in this research study?

Provide a clear, concise description of the protocol to be followed, number of study visits and procedures to be performed, in a language understandable to the subject. This section should explain exactly what the subject's participation would involve. Describe the procedures to be employed, screening or exclusion tools, tests and/or treatments to be administered, review of medical records, forms to be completed.

EXAMPLE:

Your participation will involve [#] session(s) for [#] minutes, [#] time(s) per_____for [#]_____(s). As a subject, you will be asked to *[describe procedures to be employed, screening or exclusion tools, tests and/or treatments to be administered, review of medical records, forms to be completed].*

What are my responsibilities if I decide to participate in this research study?

Clearly describe any responsibilities of the subject. Explain what the subject is expected/not expected to do.

EXAMPLE:

If you take part in this research, your responsibilities as a study participant will be to [explain any responsibilities of the subject].

What other options do I have if I decide to not take part in the study?

Describe the alternatives and include the risk/benefits of those alternatives, if known. Always include the option for the subject to not participate in the study.

EXAMPLE:

You are not required to take part in this study. If you decide not to take part in this research study, there may be other options available to you *[list other options, if applicable]. [Enter Researcher's name*] will discuss alternative options with you.

What happens if I decide to not participate in the study OR change my mind after I decided to participate in this research study?

Clearly state what will happen if the potential subject decides to participate or decides to terminate participation in the study after singing the Consent form.

EXAMPLE:

Taking part in this research study is voluntary and your choice. You may say no if you do not want to take part in the study. You will not be treated differently if you choose not to take part in the study now.
If you decide to take part in the study, you may change your mind at any time and withdraw your consent. If you decide to withdraw before the end of the study, there [may be] [may not be] risks associated with this decision. Therefore, you are encouraged to notify *[Name of Person]* at *[phone #]* as soon as possible. You will not be treated differently if you later decide to stop taking part in the study. There is no penalty or loss of benefits to which you are otherwise entitled if you withdraw from the study, or if you choose to not participate. You do not need to give a reason.

However, whether you formally withdraw from the study or fail to appear for scheduled study visits for unforeseen reasons, the information that has already been collected for study purposes will be retained and analyzed.

What are some possible risks or discomforts if I decide to participate in this research study?

If there are known possible risks (e.g., physical, legal, psychological, confidentiality, financial, social), clearly identify them. If the study does not involve more than minimal risk, clearly explain it to the subject.

EXAMPLE:

There are no more risks or discomforts associated with the procedures involved in this study than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

OR

The currently known possible risks are [list the risks and their probability to occur if know and their magnitude]. The person you can contact with is [INSERT NAME AND PHONE NUMBER OR ADDRESS] if you believe you have suffered a research-related injury.

What will happen if I get sick or hurt as a result of my participation in this research study?

Define if research study provides reimbursement for study-related injuries.

EXAMPLE:

The researcher and Oblate School of Theology assume no liability for any discomfort or injury you may incur as a result of your participation in this study. If a medical emergency arises during your performance of the procedures in this study, the researcher will assist you in obtaining medical care at your expense. You are responsible for obtaining any other medical care on your own, and at your own expense.

In some cases, health insurance may not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

You should contact [Name and Title of Contact Person] at [phone #], in the event of a research-related injury.

What are some possible benefits if I decide to participate in this research study?

If there are known possible benefits clearly identify them. If there are no direct benefits to the subject or others, clearly explain this to the subject.

EXAMPLE:

There may be no direct benefits to you or others for participating in this research, but your participation could be helpful in *[describe realistic possible benefits such as testing current or new tests and treatments, developing new tests and treatments, etc. …]*.

OR

The possible benefits of the study are *[list expected benefits]*

Can the Researcher remove me from the research study?

Describe the reasons for terminating subject's participation in the study.

EXAMPLE:

The study researcher may decide to remove you from the study without your approval for the following reasons *[list reasons such as, subject does not keep appointments, does not follow study instructions, developed a condition that makes the participation in the study unsafe, etc.]*

Will participating in the research study cost me anything?

Clearly indicate costs to the research subject and state whether additional costs may result from participation in the research study.

EXAMPLE:

You will be responsible for the costs of transportation to participate in the study.

OR

Participating in this research study will not cost you anything.

Will I be compensated for taking part in this research study?

Describe whether the subject will be paid for participation or for reimbursement of expenses, and if so, describe method of payment, how much and when. Indicate if the payment or reimbursement is prorated, paid at each visit or paid upon completion of the study.

EXAMPLE:

You will receive no payment or reimbursement for participating in this research study.

OR

It is recognized that you will incur travel costs, use of your time and a measure of inconvenience to participate in this study. To help cover expenses associated with your participation, you will receive a total of [$.....] which will be divided as follows: [$.....] for attending Visit [#]; $.....] for Visit [#]. In the event that you do not complete all visits, you will be reimbursed only for the visits that you have completed.

If I take part in this research study what confidential information about me will be collected, used and shared with others?

EXAMPLE:

If you agree to be in this research study, *[insert appropriate names]* will collect health information that identifies you such as *[insert type of health information].* We may collect the results of tests, questionnaires and interviews, such as (*insert specific examples).* We may also collect information from your medical record, such as (*insert specific examples)*. We will collect only information that is needed for the research.

If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization.

How will the researcher protect my privacy and keep my personal information confidential?

Explain the extent (if any) to which confidentiality of records will be maintained

EXAMPLE:

All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information. Information related to you will be treated in strict confidence to the extent provided by law.

Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Researcher. In order to monitor this research study, representatives from federal agencies such as National Institutes of Health and the Office of Human Research Protection or representatives from the Oblate School of Theology Institutional Review Board may inspect the research records which may reveal your identity. Therefore, we cannot promise complete confidentiality.

Any information you provide during the course of the study will be recorded in such a way that your identity will remain *[confidential] [anonymous].* (If confidential) This means that number codes will be used to record your information, no one but the researcher will have access to the information, and it will be securely stored. Your identity will never be revealed and information about the study will be reported in group form only. (If anonymous) This means that your name will not be associated with your information, no one will be able to identify you, and information about the study will be reported in group form only.

You are receiving two copies of this form. Return the signed copy to the researcher and keep the other for your future reference. If you would like to receive a summary of the results of the study upon its completion, record your full address on the reverse side of this form.

- -

STATEMENT OF CONSENT

I have read this form and the information in it was explained to me. I agree to take part in this research study. All of my questions were answered. My taking part in the study is completely voluntary and I can withdraw my consent to participate in this study at any time. I will receive a copy of this document for my records. I am not giving up my legal rights by signing this form.

My signature below also indicates that I understand the procedures to be employed in this study, and I also agree to allow the researcher to present his or her findings publicly or privately, for educational purposes, and orally or in written form.

Subject's Signature Date

Subject's Printed Name

Person Obtaining Consent Signature Date

Person Obtaining Consent Printed Name

Parent/Legal Guardian's Signature Date

Parent/Legal Guardian's Printed Name

ASSENT FORM [TEMPLATE]

Let us tell you who we are

EXAMPLE:
My/Our name(s) is/are *[Researcher's Name(s)],* and I/we want to tell you about a research study I/we am/are doing on *[provide general topic of research]*.
It is OK for you to ask questions about anything we are telling you. You can ask us questions now and anytime thereafter.

Why are we doing this research study?

EXAMPLE:
A research study is a way to find out how things work or to learn information about something. We are conducting this research study because *[provide in lay terms the reasons why you are conducting this study]*

Why are we asking you to participate in this research study?

EXAMPLE:
Like other children, we are asking you to be in this study because *[provide in lay terms the reasons why you are asking the child to participate in this study]*. However, for you to be in this study we would also need to have your parent's or legal guardian's permission.

You need to know that you do not need to be in this research study if you do not want to and no one will be upset about your decision. Also remember that you can say okay now and then change your mind later. Just tell us or your parent or guardian if you want to stop being in the study.

What will we ask you to do if you decide to participate in this research study?
Use simple terms to describe procedures to be employed, screening or exclusion tools, tests and/or treatments to be administered. Provide simple, easy-to-read and easy-to-understand examples.

EXAMPLE:
If you decide to be in this research study and your parent or guardian also says yes, this is what will ask you to do:
You may choose to be in the study or not, and you may choose to do, or stop doing, the activities I described any time you want to.

What may happen to you if you decide to be part in this research study?
Clearly state the risks and benefits for being part of this study. If no risks or benefits are expected, please state so.

EXAMPLE:
There is a chance that during the research study you could *[clearly state what it may happen to the child]*.