

VITERBO UNIVERSITY

INSTITUTIONAL REVIEW BOARD POLICIES

AND PROCEDURES

FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

9/03

INSTITUTIONAL REVIEW BOARD POLICIES AND PROCEDURES
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Institutional Review Board Policies and Procedures

Viterbo University has established an Institutional Review Board (IRB) to review all research involving human participants and to implement institutional policies and procedures regarding such research. The use of human participants in research imposes both ethical and legal responsibilities upon the university, the project directors, and those conducting the research to ensure that the rights and welfare of those participants are adequately protected. The primary function of the IRB is to assist researchers in the protection of the rights and welfare of human participants. Review and approval by the IRB is meant to aid both the participants and the researchers by bringing scrutiny to projects by a group of peers who can objectively assess the potential risk and accommodations made to minimize it.

All research involving the human participants that is conducted by Viterbo faculty, staff, or students, or sponsored, in part or in whole, by Viterbo must be reviewed and approved prior to the start of the project and then conducted in full compliance with IRB policies and procedures. Research is defined by federal regulations as a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. It encompasses work which is conducted on or off campus and includes questionnaires, interviews, surveys, tests, observations, and other experiments, even if the work is preliminary to a more extensive study. It includes secondary analyses of data previously collected. It also includes any systematic collection of data from human participants that occurs in conjunction with classroom projects, unless the work is done as a learning exercise for the student and will never be published or presented outside of the course.

It is the responsibility of the researcher to refer his or her project to the IRB whenever humans are used as participants in research, even if the researcher does not consider the subjects to be at risk.' Current law places the burden of liability for negligence and harm directly on the researcher and the institution. The IRB policies and procedures are formulated to protect the university, the researcher, and in the case of the students, the faculty research advisor, from liability through imposition of minimal standards for research and through procedures for careful review of projects.

Questions about IRB policies and procedures should be referred to the IRB chairperson.

A. Background

The Public Health Service Act (Title IV, Part G, Section 491 a) required the Department of Health and Human Services (DHHS) to issue regulations for the protection of human participants of research and to implement a program of instruction and guidance in ethical issues associated with such research. The regulations are codified as Title 45 Part 46 of the Code of Federal Regulations, Protection of Human Subjects (45 CFR 46), issued on June 18, 1991. These regulations apply to all research involving human participants that is conducted or supported, in whole or in part, by DHHS in foreign or domestic settings.

The establishment of Viterbo University's IRB and its policies and procedures are primarily derived from 45 CFR 46. The policies and procedures are intended to provide a resource for the preparation and submission of research applications for IRB reviews. A copy of 45 CFR 46 is with Chair of the IRB and is available @ www.ohrp.osophs.dnns.gov

B. Ethical Principles and Issue Involving Human Participants in Research

The current regulations in 45 CFR 46 are based on *The Belmont Report*, which was developed in the 1970's by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report presented three basic ethical principles. These principles of respect for persons, beneficence, and justice remain as essential requirements for the ethical conduct of research involving human subjects. Respect for persons recognizes personal dignity and autonomy of individuals and protection of those that have diminished autonomy. Beneficence includes an obligation to protect individuals from harm by minimizing risks of harm and maximizing benefits. Justice requires that the burdens and benefits be distributed fairly.

In addition to *The Belmont Report*, Viterbo also is guided by the ethical principles regarding research involving human subjects as presented in *The Nuremberg Code* and the *World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*.

In addition to the aforementioned principles, the IRB will be considering the following ethical issues in determining the nature of the risks and extent to which the benefits of the study justify exposing the participants to risk:

- *Voluntary participation:*

Participation of human persons must be voluntary, i.e., must occur as a result of free choice, without compulsion or obligation, based upon disclosure of relevant information in a clear, concise, and understandable way. The researcher must take care to avoid coercing their participation.

- *Inducement to participate:*

Participants are frequently offered some form of incentive or reward for their participation, e.g. earning extra credit points from their professor, small gifts or prizes, a chance to win money in a lottery. In general, inducements are allowable as long as they are minimal and are not more attractive to some participants than to others. The primary ethical issue involves the extent to which an inducement might be sufficiently large enough to cloud the person's judgment about whether or not participation in the study is in their own best interest.

In cases where students may earn extra credit points from their professor, other options to earn extra credit besides research participation must be available. Researchers must not do the recruiting in their own classes (although they may have one of their colleagues or research students recruit for the study in their own classes.), nor should their names be

associated with the recruitment procedures if recruitment will take place in their own classes. This guards against the students' perception that they may be expected to participate in a study that their own professor is conducting in order to stay in good terms with that professor.

A second issue involves the extent to which the participants can reasonably choose not to participate, especially in a case where participants are approached in a large group (e.g., class) and asked to participate without standing apart from their peers. This is particularly a problem if participation involves a sensitive issue. For example, if the study focuses on AIDS and a person chooses not to participate, it might be interpreted that the person has AIDS. In such cases, the researcher/recruiter would need to demonstrate that this concern has been recognized and addressed (e.g., by providing a means for all potential participants to appear as if they are participating even if they are not).

- *Informed consent:*

Obtaining the informed consent of human participants in any research is a federally mandated safeguard for protecting the rights and welfare of all individual participants. Therefore, the IRB will carefully review the method of obtaining consent and the specific content of informed consent forms. Informed consent should be initiated in the recruiting process by providing specific information to the participants (as outlined in the Informed Consent guidelines) and having the participants read and sign an Informed Consent form before participating in the study.

For survey research projects, informed consent is obtained by providing the potential participants with a detailed explanation of the purpose for and the protocol of the research project. Completion of the survey instrument by the participant shall constitute informed consent, but this should be stated in the cover letter or in the survey instructions. It also is crucial that researchers ensure to the best of their ability that the potential subjects understand what is being communicated to them. Consent must be given freely with the participants understanding the nature and consequences of what is proposed. Consent also is an ongoing process, not just a single occurrence. Researchers must inform subjects and/or guardians of any important new information that might affect their willingness to continue in the study.

Federal law stipulates that a person must be 18 years or older to give legal consent for his/her own behalf. Subjects under the age of 18 years may participate in research only with the signature of their parent or legal guardian in addition to their own signature. This also applies to the completion of anonymous questionnaires, since persons under 18 are not permitted legally to make the informed choice to participate. Children should have the information about participation in the research explained to them in language that they can understand (by their parent), and, if possible, they should give their assent to participate in the study.

- *Identification and minimizing of risks:*

Virtually all research involves some risk, even though it may be slight (e.g., embarrassment over a performance on a task). A risk may be of a physical, social, and/or psychological nature. The IRB will consider the extent to which the researchers have attempted to identify the potential risks to the participant and the extent to which those risks have been minimized as much as possible without interfering with the validity of the research. In cases where there is the possibility of more than minimal risk to the subject, approval will depend on the benefits of the research, the expertise and prior experience of the researcher(s) in conducting this type of research, the level of inducement to participate, the extent to which the participant is fully informed of the possible risks, and the availability of compensatory treatment or follow-up designed to alleviate any negative consequences from participation. A research procedure may not be used if it is likely to cause serious and lasting harm to subjects (e.g., health problems).

- *Fairness*

The research should be designed to treat all individuals fairly. The selection of participants must be based upon fair procedures and not overburden, overuse, or unfairly favor or discriminate against any subject pool.

- *Deception:*

In some types of research it may be necessary to withhold some pertinent information from participants when disclosure of such information would likely impair the validity of the study. In all such cases, participants should be told that they are being invited to participate in research in which some features will not be revealed until the research is concluded. Complete nondisclosure of information about the study or its purpose is only justified when the research solely involves observation of a person's behavior in locations where the person might reasonably expect that his/her behavior could be observed by another.

In any research that involves incomplete disclosure, the following conditions must be met: 1) there are no undisclosed risks to participants that are more than minimal; 2) there is an adequate plan for debriefing participants, when appropriate; and 3) incomplete disclosure is truly necessary to accomplish the goals of the research. Truthful answers should always be given to direct questions about the research; this may include telling the subject that revealing certain information may impair the success of the study.

- *Confidentiality/Anonymity:*

In all research involving human participants, it is important to assure the participants of the confidentiality of their responses. This is especially important in cases where the study involves asking the participants personal questions about themselves or obtaining other information that might put the participant psychologically at risk, if the information was made

public. Total anonymity (e.g., where the subject's name or face is never associated with his/her responses, even to the researcher) is preferable, especially in the case of extremely sensitive or personal information. This generally means that the participant must be able to provide information in complete privacy and to submit the information in such a way that it is mixed in with other participants' data before it is retrieved by the researcher. Where it is necessary to have the participants' names or identification numbers associated with their responses (e.g., in order to collate several sets of responses by the same subject), the participants need to be told who will see their data and specifically how this information will be kept confidential.

- *Debriefing:*

In most cases, it is desirable for participants to be debriefed after their participation in the study (e.g., given further information about the study and given a chance to ask questions). There are three cases in which debriefing is required: first, when the research has involved incomplete disclosure; second, when participants may be left with a misleading or potentially harmful perception or inaccurate information; and third, when compensatory treatment or follow-up is needed. Such debriefing should not be treated as a substitute for informed consent prior to and during the individual's participation in the research.

In some cases, debriefing may not be possible immediately after the study due to concern about other potential participants finding out about a deceptive aspect of the study that would preclude further data collection. In these cases, debriefing statements or descriptions could be offered to the participants at a later date through the mail or other means. In rare instances, debriefing may itself pose a social or psychological risk to a participant; in which case it may be in the best interest of the participant to forego the debriefing procedure. In most cases, however, this can be avoided by disclosing to the individuals prior to their participation that some harmful information may be uncovered in the course of the study.

This would fall under the obligation to disclose any risks that are more than minimal (See *Deception.*).

- *Compensatory/follow-up:*

In cases where some physical or psychological harm might result from the subjects' participation, plans for compensatory treatment or follow-up counseling should be provided.

C. Type of Review

The type of review required depends upon the nature of the research, the participants, and the risk imposed upon the participants. In **all** cases the researchers must complete the *Application Cover Sheet for Review of Research Involving Human Participants*.

1. Research that qualifies for EXEMPT STATUS

All research involving human participants that is exempt from full or expedited IRB review must maintain an adequate standard of informed consent and confidentiality of data. The researcher must complete an application and submit it to the Program Director, Department Chairperson or designated representative(s) for review. No researcher may review his or her own application. If the researcher is a Department/Program Director, he or she may have the application reviewed by any IRB member. One copy of the application and appropriate signed documents must be filed with the appropriate School Dean or Designee.

Research activities are exempt from a full or expedited review when the information on participants is recorded so that participants cannot be identified directly or through identifiers linked to the participants. Research is also exempt when the only involvement of human participants is in one or more of the following categories:

- a. When educational research meets the following conditions, it is exempt from full or expedited IRB review and does not require consent from parents. The researcher and/or institution, however, may want this consent. The consent of a child should be obtained whenever possible.
 - (1). The research is conducted in established or commonly accepted educational settings involving normal educational practices. Examples are research on regular and special education instructional strategies or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - (2). If the research involves educational tests (cognitive, diagnostic, aptitude, achievement), this information must be recorded so that participants cannot be identified, directly or through identifiers linked to the participants.
 - (3). The research procedures do not represent a significant deviation in time or effort from those educational practices already existing at the research site.
 - (4). The research procedures do not involve an increase in the level of risk or discomfort compared to normal, routine educational practices. For example, studies in which parenting practices are criticized or teachers' jobs may be jeopardized are not exempt from review.
 - (5). Provisions are made to ensure the existence of a non-coercive environment for those students who choose not to participate.
 - (6). The research does not involve sensitive topics (e.g., sex education).

- (7). The institution where the research is being conducted grants written approval for the research to be conducted.
- b. When the research involving the use of surveys, interview procedures, or observation of public behavior is not part of educational research as defined in “a”, but meets the following conditions.
- (1). Information on these participants is recorded so that subjects cannot be identified directly or through identifiers linked to the subjects.
 - (2). Disclosure of participant responses outside the research setting would not place the participant at risk of criminal or civil liability or be damaging to the participant’s financial standing, employability, or reputation.
 - (3). There is no risk associated with a breach of confidentiality.
 - (4). The research does not deal with sensitive or highly personal aspects of the participant’s behavior, experiences, or attitudes (e.g., substance abuse, detailed health history, sensitive demographic data).
 - (5). The research does not involve children (subjects under 18 years of age).
 - (6). The research involves survey, interview procedures or observations of public behavior when the participants are elected or appointed public officials or candidates for public office.
- c. When the research involves the collections or study of existing data, documents, records, pathological specimens, or diagnostic specimens which either are publicly available or will be recorded in such a manner that participants cannot be identified directly or through identifiers linked to the participants.
- d. When the research involves taste and food quality evaluation and consumer acceptance studies where only wholesome foods without additives are consumed or that involves only a limited amount of consumption of a food additive at or below a level approved by the Food and Drug Administration, Environmental Protection Agency, and/or the United States Department of Agriculture.

2. Research that qualifies for EXPEDITED IRB Review

Applications that qualify for expedited review are read by two members of the IRB. In the event that either IRB member feels the proposal should receive full review, the investigator will be informed, and the proposal will be put on the agenda for the next full committee meeting.

- a. Applicability for Expedited Review
- (1). Research activities that (1) present no more than minimal risk to human participants, (2) involve only procedures listed in one or more of the following categories, or (3) has been approved within the previous year and is submitted again because of minor changes may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed under “research categories”

should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

- (2). The categories in this list apply regardless of the age of subjects, except as noted.
- (3). The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants – 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.
- (4). The expedited review procedure may not be used for classified research involving human participants.
- (5). IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review utilized by the IRB.
- (6). Categories pertain to both initial and continuing IRB review.

b. Research Categories

- (1). Clinical studies of drugs and medical devices only when the following condition is met:

Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- (2). Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a). from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (b). from other adults and children¹, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- (3). Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine

patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) muscosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

- (4). 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.)

Examples: (a) 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; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- (5). Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
- (6). Collection of data from voice, video, digital, or image recording made for research purposes.

¹Children are defined in the HHS regulations as “persons who have 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.” 45 CFR 46.402(a)

- (7). 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 survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

- (8). Continuing review of research previously approved by the convened IRB as follows:
 - (a). where (i) the research is permanently closed to the enrollment of new subjects; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - (b). where no participants have been enrolled and no additional risks have been identified; or
 - (c). where the remaining research activities are limited to data analysis.
- (9). Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (1) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. Research that requires FULL IRB Review

Unless research qualifies for exemption from full IRB review or expedited IRB review as previously described, it requires full review by the IRB. The application will be reviewed by the full IRB at its regularly scheduled meetings. Federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable participants, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Research involving these participants, sensitive behavioral research, research involving deception, or research that is harmful to the participants automatically requires full IRB review.

D. Student Research

For class assignments that are intended to provide research experiences and do not require approval by the IRB, the researcher must complete an application and submit it to the Program Director, Department Chairperson, or designated representative for review.

Instructors are responsible for screening student research projects and determining if they require approval by the IRB. If a project is assigned for the purpose of producing generalizable results that may be presented outside of the class, or published, or may involve risk to the participants, the researcher must comply with IRB procedures for full or expedited review. Submission of an application and appropriate approval must occur prior to initiating the research (e.g., data collection).

E. Cooperative Research with Another Institution

When cooperative research occurs with another institution, one institution may agree to delegate responsibility for initial and continuing review of all or a portion of the research activity to another IRB. This can occur if the other institution and IRB agree to assume responsibility for the review and if the delegating institution agrees to abide by the reviewing IRB decisions. For any portion of a research activity which researchers do not delegate to another IRB, the researchers remain responsible in complying with these policies and procedures.

Researchers and IRB need to bear in mind the following when contemplating the use of another institution's IRB to review its protocols: local laws, institutional policies and constraints, professional and community standards, and population differences. Researchers should seek IRB counsel prior to engaging in cooperative research involving the use of human subjects.

The agreement for IRB review of cooperative research must be documented in writing with copies to be furnished to all involved with the agreement and those ensuring compliance with IRB determination. No matter what the agreement, each institution is responsible for safeguarding the rights and welfare of human participants.

F. International Research

Procedures for reviewing research in foreign countries may differ from those set forth in this document and in federal regulations. Such international standards as the Nuremberg Code and Declaration of Helsinki present broad policies, but are not considered sufficient for an institution having an assurance with a federal agency such as DHHS. Because of the varied policies and procedures involved with conducting research in foreign countries, it is best that researchers discuss research projects with the IRB during the planning phase of the project.

G. Institutional Review Board (IRB)

1. Membership

The IRB will consist of seven members. The Academic Vice-President will appoint one faculty member from each of the five schools and one person from outside the university community. Each of these six members will serve a two-year term. The seventh IRB member will be the Director of Ethics in Leadership. This person will also serve as the Board chairperson. If a member of the IRB is involved as an investigator in a research proposal, she or he will be excused from the deliberations and decisions of the IRB. If the chair is involved as an investigator in a research proposal, she or he will be excused and appoint another member of the IRB to serve as chair for that review.

If the IRB regularly reviews research that involves a vulnerable category of subjects, such

as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals will not vote.

Members are appointed for a two-year term and may be re-appointed when the term expires. It is recommended that no more than 1/3 of the board be replaced each year. The IRB Chairperson may request that any board member who frequently does not submit reviews in a timely manner and/or misses meetings be replaced.

2. Meeting Times

IRB meetings should be scheduled as needed to meet student and faculty needs during the academic year. The IRB will be regularly scheduled to meet twice per semester. If a proposed study does not fit this timetable, the investigator should contact the Chairperson of the IRB who will make a reasonable effort to prevent delay of the research project. IRB may convene during summer sessions or, in exceptional cases, may conduct business via telephone, mail or electronic mail.

3. Expedited Review

Research activities that qualify for expedited review will be reviewed by the IRB Chairperson or designee and one other IRB member.

4. Update of Policies and Procedures

The IRB will meet annually to review and if necessary update the policies and procedures handbook.

H. IRB Deadlines

Applications for review by the full IRB must be submitted in a timely manner to permit the IRB to meet and review proposals. Applications for expedited review may be submitted to the IRB at any time.

I. Decision Process

Approval of new protocol by the IRB is required prior to the initiation of any research study involving human participants. The IRB will approve or disapprove studies by a simple majority.

The IRB may disapprove or require modifications, limitations or conditions. If the application is disapproved, the researcher has the right to appeal to the IRB. Every attempt will be made to resolve the identified problem(s). A protocol approved by the IRB may be rejected by any other body having the power of review. A negative decision by the IRB cannot be altered or modified by other individuals or groups at Viterbo University. The IRB, however, retains final absolute authority over whether or not an application is approved.

J. Communication of IRB Decisions

The Chair of the IRB shall notify the researcher in writing of the decision of the IRB. The notification shall include:

- That the researcher report any changes in the research protocol and any unanticipated problems involving risk to the participants promptly to the IRB. Changes in protocol may not be initiated without IRB approval except when necessary to eliminate immediate hazards to research participants.
- That the researcher submit updated progress reports of approved research as required in the original approval and at the termination of the research.

RESEARCH INVOLVING SPECIAL POPULATIONS

Federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable participants. For example, the DHHS requires additional safeguards for research involving fetuses, pregnant women, and human *in vitro* fertilization (45 CFR 46, Subpart B), prisoners (45 CFR 46, Subpart C), and children (45 CFR 46, Subpart D). If faculty, staff, or students are associated with research involving fetuses and *in vitro* fertilization, they should consult with the IRB chairperson and/or the Assistant Academic Dean. Some of the federal regulations, state, and local laws need to be strictly adhered to concerning these areas. For example, in some instances the DHHS requires approval by their Ethical Advisory Board prior to conducting a study.

Research involving any of the other special populations must follow all requirements as indicated in 45 CFR 46. The remainder of this section concentrates on some aspects of research involving children, incapacity, and AIDS/HIV – related research studies.

A. Research Involving Children

The special vulnerability of children makes consideration involving them as research participants important. Special procedures are required for research involving children except for research that is conducted in educational settings as described on page 6 of the document. Whenever feasible, appropriate studies should be conducted on non-vulnerable populations or older children before young children are involved as research participants.

What constitutes minimal risk is central to the IRB's consideration of research involving children. The IRB also must determine that adequate provisions have been made for getting the permission (assent) of children and the permission (informed consent) of their parents or guardians. The IRB's policy regarding obtaining consent and assent are as follows:

1. In most situations, parental consent is required if the research involves minors (under the age of **18**). Unless the requirement is waived by the IRB, a parent or guardian must complete an informed consent form.
2. Unless the requirement is waived by the IRB, assent is required from all children. In most situations, a written form should be used to document assent. The form should include a simplified version of the contents of the informed consent. This explanation should be written so as to be understandable to the child. If the child's developmental ability does not enable him or her to understand the written explanation, documented oral assent is appropriate.

B. Research Involving Subjects with Incapacities

Incapacity refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Persons with incapacities who either have been adjudicated to lack the capacity to give informed consent or have been judged by the researcher to lack the capacity cannot participate as research participants unless proxy consent is obtained by their legally authorized representative. The assent of these persons must be obtained whenever possible. Depending on their situation and the research being planned, durable power of attorney may be requested by the IRB.

C. AIDS/HIV – Related Research

A paramount concern in HIV research is confidentiality. Breaches of confidentiality could have severe adverse consequence such as loss of employment or insurance coverage, or criminal charges. For example, if identifiers are not needed, they should not be recorded. If they are recorded, they should be separated, if possible, from the data, and combined with the data only when necessary. It also has been suggested that no lists should be retained identifying those who elected not to participate.

The procedure for obtaining informed consent needs to be accurate and complete. Participants should be informed of exactly what information will be recorded and whether any state laws require disclosures of information.

SECTION II

INSTRUCTIONS FOR APPLICATION FOR REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Prior to submitting an application, ensure that you understand the IRB Policies and Procedures involving human participants. A description of how to prepare an application and the required forms are contained in the following pages.

Required Forms

Each Application for Review of a new research proposal should contain the following materials:

1. Application Cover Sheet
2. IRB Questionnaire
3. The appropriate Request for Approval Form (EXEMPT or EXPEDITED and FULL REVIEW form)
4. Researcher's Assurance Statement
5. Informed Consent form that will be used for the project

Submission of Application Materials

1. If the research qualifies for EXEMPTION from IRB review, complete the Request for Approval for EXEMPT STATUS form (green). Submit two copies of the application to your Program Director, Department Chairperson, or designated representative. You will receive one of the following decisions:
 - a. protocol approved as submitted,
 - b. approval withheld pending submission of revisions and/or additional information, or
 - c. protocol requires either expedited or full IRB review.
2. If the research qualifies for EXPEDITED review, complete the Request for Approval for Expedited and Full Review (yellow). Submit three copies to the IRB Chairperson; you will receive one of the following decisions:
 - a. protocol approved as submitted,
 - b. approval withheld pending submission of revisions and/or additional information, or
 - c. protocol requires full IRB review.
3. If the research requires FULL IRB review, complete the Request for Approval for Expedited and Full Review (yellow) form. Submit Seven copies of the application to the IRB Chairperson. You will receive one of the following decisions:
 - a. protocol approved as submitted,
 - b. approval withheld pending submission of revisions and/or additional information.
4. All notifications are in writing.

Applications for expedited reviews will require at least 10 work days for the dissemination of materials and the review process by IRB members. Full IRB reviews will require at least 21 work days and will occur during fall and spring semesters on a regular basis.

Continuing Review and Submission of the Annual Update

Expedited and Full Review applications are approved for a maximal period of one year. For research projects that continue beyond one year, it is the responsibility of the researcher to submit an annual update; researchers should submit a **Request for Annual Update** to the IRB. The first update is due 12 months following the date the application was approved. If the IRB determines that a project requires review more often than annually, the researcher will be notified. Projects can be updated annually for a maximum of five years. Continuation of projects beyond five years requires resubmission.

Reporting Changes in a Research Protocol

Any change in a protocol that affects the human participants must be approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate a hazard to the subjects. Researchers should submit a **Request for Change in Protocol** to the IRB. If the change in the protocol requires changes in the consent form, attach the new consent form to the Request for Change.

Reporting End of Project

When the project is completed, the researcher must submit an **End of Project Report** to the IRB. This is not required for EXEMPT STATUS projects.

Submission of a Report of Injury

If a subject sustains an injury during research, the researcher must take immediate action to assist the subject and notify the IRB of the injury within 48 hours.

Reporting Non-Compliance with IRB Policies and Procedures

Any incident of non-compliance with IRB policies and procedures should be reported immediately to the IRB.

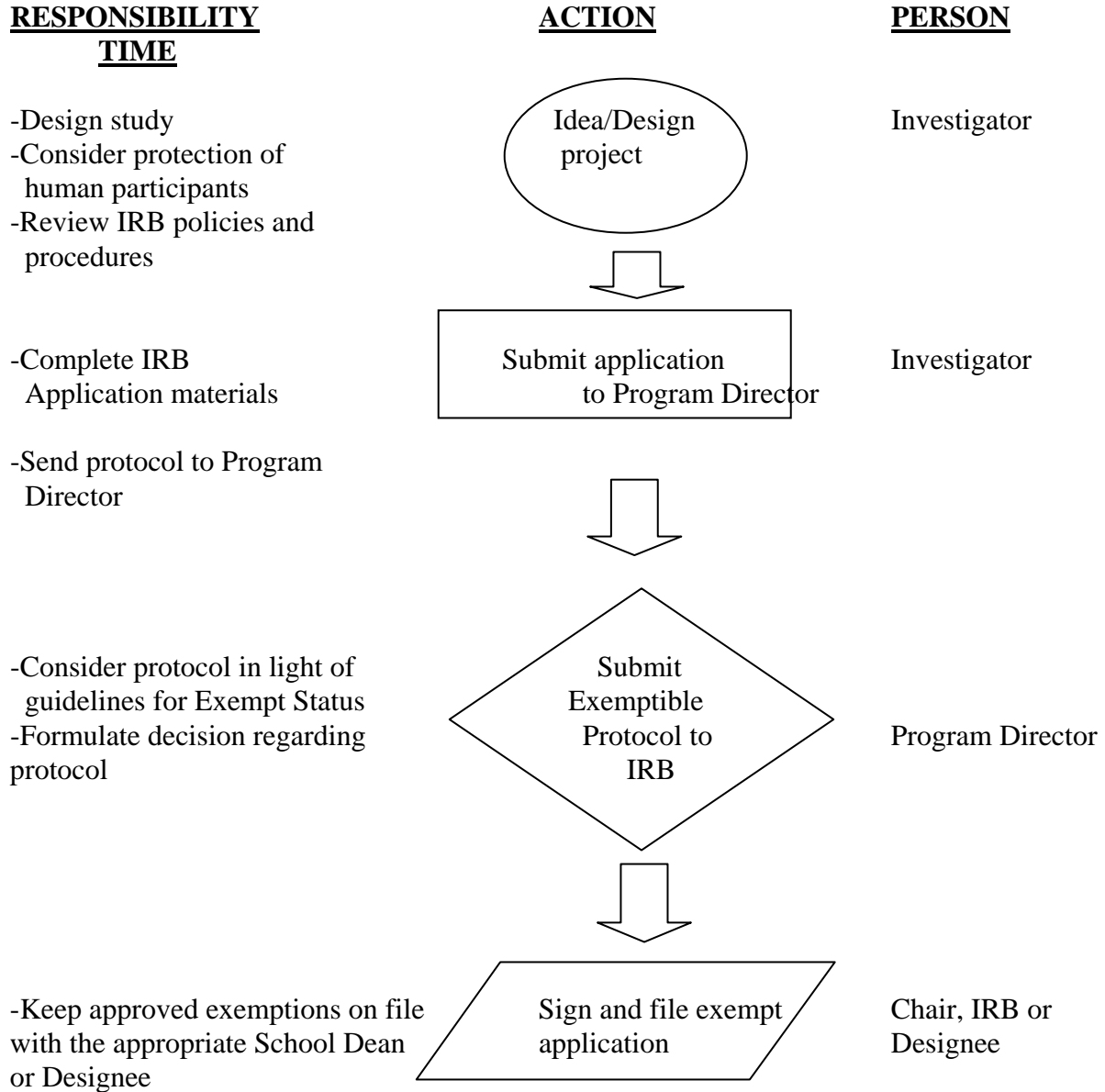
Record Keeping

Keep records, documents, and informed consent forms for at least three years following the completion of the research project, or for longer if judged necessary. The IRB may request copies of signed consent forms of all subjects who participated in the research project and/or guardians.

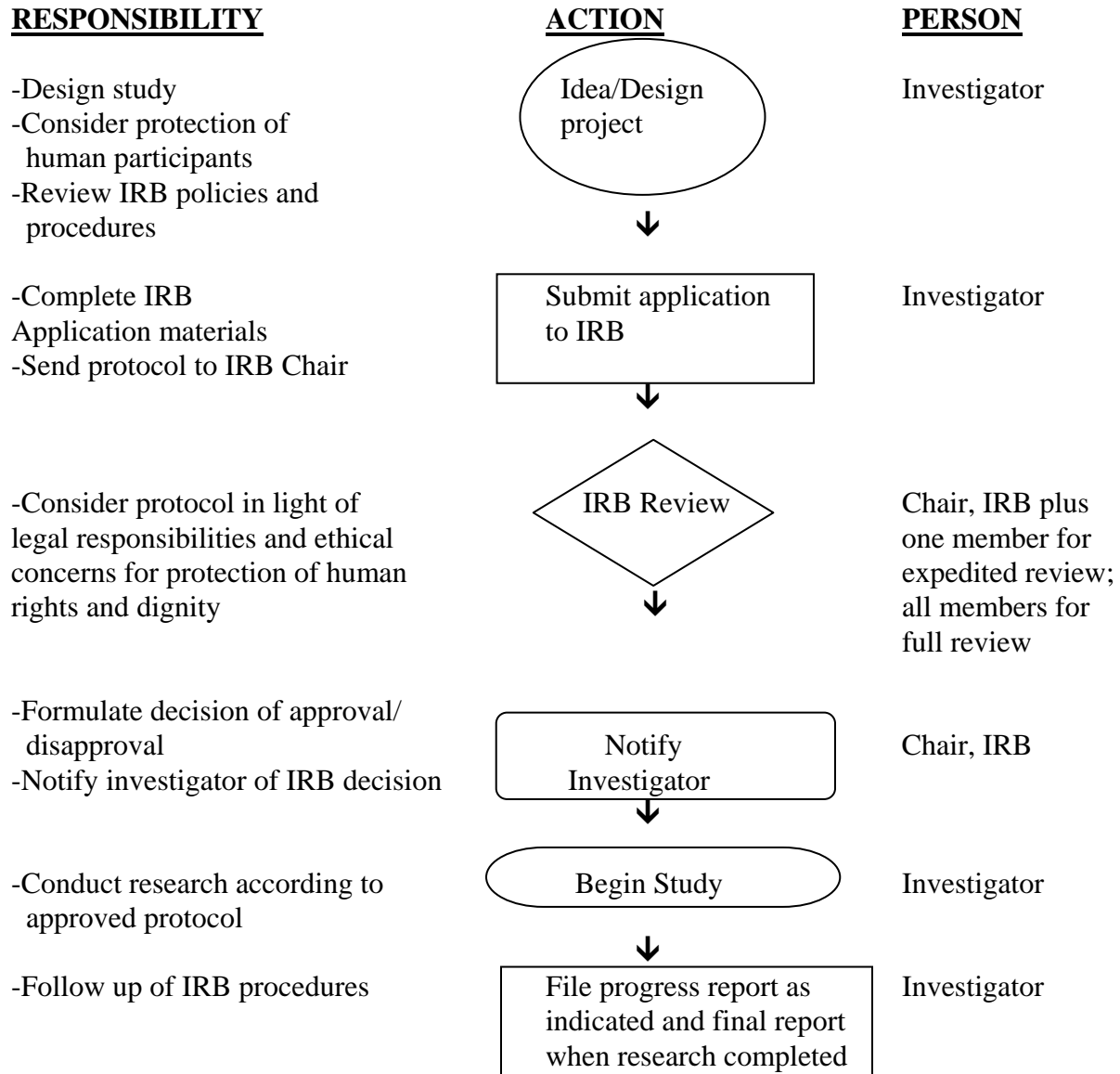
Forms

The forms are in Section III of this document

EXEMPT REVIEW PROCESS



EXPEDITED AND FULL IRB PROCESS



Notes:

SECTION III
IRB APPLICATION FORMS

**VITERBO UNIVERSITY
APPLICATION COVER SHEET FOR REVIEW OF
RESEARCH INVOLVING HUMAN PARTICIPANTS**

Exempt from IRB Review Expedited Review Full Review

Name of primary investigator: _____ Dept/Program: _____
(Contact)

Mailing Address: _____ Phone: _____

Faculty Research Advisor: _____ Advisor's Phone: _____
(for student research)

Project Title: _____

Proposed Project Dates: from ____/____/____ to ____/____/____

NOTE: Do not begin your collection of data until you receive notification that your application has been approved by the IRB or has received exemption status.

Research exempt from IRB review:

Action taken:

- approved as submitted
- approved pending submission of revision and/or additional information received ____ (date)
- requires expedited review
- requires full IRB review

Signature of Program Director Date
(or designated representative)

Research requiring expedited review:

Action taken:

- approved as submitted
- approved pending submission of revision and/or additional information received ____ (date)
- Requires full IRB review

IRB member's signature Date _____ Date
IRB member's signature

Research requiring full IRB review:

Action taken:

- approved as submitted
- approved pending submission of revision and/or additional information received ____ (date)
- disapproved

IRB Chairperson's Signature Date

IRB QUESTIONNAIRE

This questionnaire must be submitted with the Application Cover Sheet for all review requests to the IRB. If a particular item does not relate to your study, indicate NA (not applicable) next to that item.

Title of Project: _____

Name of Investigator: _____

Source of Funding: _____

General characteristics of the sample population:

Number: _____ Males _____ Females

Race or ethnicity (if known): _____

Age range: _____

General mental/physical health: _____

Other unique characteristics: _____

Dates of Data Gathering: From: _____ To: _____

Expected Date of Project Completion: _____

1. Include a brief statement of purpose of the proposed research.

2. Who are the research participants? Include a rationale for using that particular population/sample.

3. Are there any anticipated risks/inconveniences that might be experienced by the participants?
 ____ No ____ Yes
 If the response to the previous questions is Yes, please describe the anticipated risks/inconveniences and the procedures that will be used to minimize potential risks/inconveniences to participants. Also, please circle the number below the bar that most closely represents the amount of risk.
 GREAT RISK _____ NO RISK
 5 4 3 2 1 0

4. How will the confidentiality of the participants be ensured?

5. Describe the procedures and/or activities that participants will undergo. Also, please circle the number below the bar that most closely represents the amount of discomfort or disruption of normal activities that the participants in this study may experience.

GREAT _____ NONE
 5 4 3 2 1 0

6. Describe why any vulnerable populations are necessary to the research project (e.g., prisoners, children not in normal education setting, persons with disabilities, pregnant women, or any group whose ability to give a voluntary informed consent may be questionable).

7. How will voluntary informed consent be obtained? Informed consent from parents of children as participants is not required if the conditions under EXEMPT STATUS are met.

8. If successful, do you think that the research will provide any long term or short term benefits for the participants or for others?

BENEFITS FOR THE PARTICIPANTS

GREAT BENEFIT _____ NO
 BENEFIT
 5 4 3 2 1 0

BENEFITS FOR OTHERS (Identify for Whom):

GREAT BENEFIT _____ NO
 BENEFIT
 5 4 3 2 1 0

9. How much significance will this research have for the advancement of knowledge in the field?

GREAT _____ NONE
 5 4 3 2 1 0

10. Does the study require significant cost or time of the participant? ___No ___Yes
 (If yes, please explain)

11. Will compensation be provided to the investigators and/or participants? ___No ___Yes
 (If yes, please explain)

 Signature of Principal Investigator

 Date

VITERBO UNIVERSITY
REQUEST FOR APPROVAL OF RESEARCH INVOLVING
HUMAN PARTICIPANTS

Screened for Exempt Status Form

Complete and return this form to:

**Institutional Review Board for the Protection
of Human Participants in Research
Office of the Academic Vice President
815 S. 9th Street
La Crosse, WI 54601**

TITLE OF PROJECT: _____

NAME OF INVESTIGATOR: _____

PHONE: _____

This study is covered under exemption category for the following reason(s): (check all that apply)

1. _____ This study will be conducted in an established or commonly accepted educational setting involving normal educational practices.
2. _____ This study involves the use of educational tests and participants cannot be identified.
3. _____ This study involves surveys and/or interview procedures or observations of public behavior and
 - a. _____ participants cannot be identified, either directly or through the identifiers linked to the subject.
 - b. _____ the participant's responses, if they become known outside the research, cannot place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability.
 - c. _____ the research does not deal with sensitive aspects of the participant's own behavior.
4. _____ Participants are 18 years of age or older.
5. _____ This study involves the use of existing data.
6. _____ This study is an evaluation of Federal Research and/or Federal program(s).

Researcher's Signature

Date

Advisor's Signature

Date

**VITERBO UNIVERSITY
REQUEST FOR APPROVAL RESEARCH INVOLVING
HUMAN PARTICIPANTS**

Expedited or Full Review Form

University and federal policies require that each project involving studies on humans be reviewed to consider: 1) the rights and welfare of the individual(s) involved, 2) the appropriateness of the methods used to secure informed consent, and 3) the risk and potential benefits of the investigation.

Complete and return this form to:
**Institutional Review Board for the Protection
of Human Participants in Research
Office of the Academic Vice President
815 S. 9th Street
La Crosse, WI 54601**

This proposal is submitted for: Expedited Review _____ Full Review _____

TITLE OF PROJECT: _____

NAME OF INVESTIGATOR: _____

PHONE: _____

Proposal has been (will be) submitted to funding agency (give agency and date).

Name and address of person(s) at funding agency and/or college who should receive notice of IRB approval (other than investigator):

Researcher's Signature

Date

Advisor's Signature

Date

Expedited review status will be reviewed by at least two IRB members. The researcher shall be notified of the IRB decision by mail within 10 days. If applicable, a copy of the decision will be mailed to the advisor.

Full review status requests will be reviewed at a full meeting of the IRB. A majority of the IRB must be present and include one member whose primary concerns are non-scientific. The researcher shall be notified of the IRB decision within four weeks. If applicable, a copy of the decision will be mailed to the advisor.

Approved by: _____
Signature of IRB Chair

Reviewers: _____

This approval is valid for a period of one year from above date. Should your research extend beyond this period you are required to submit the Annual Update Form in order to continue with your project.

**VITERBO UNIVERSITY
RESEARCHER ASSURANCE STATEMENT FOR
RESEARCH INVOLVING HUMAN PARTICIPANTS**

I understand Viterbo University's policies concerning research involving the use of human subjects and agree:

1. To accept responsibility for the ethical conduct of this research project;
2. To obtain approval from the University's IRB prior to instituting any change in the research project;
3. To report to the University's IRB serious adverse reactions or unexpected effects on subjects' and
4. To submit to the IRB an End of Project Report at the completion of the research project (if not exempt).

a. _____
Researcher's printed name Department/Program

Researcher's signature Date

b. _____
Researcher's printed name Department/Program

Researcher's signature Date

c. _____
Researcher's printed name Department/Program

Researcher's signature Date

d. _____
Researcher's printed name Department/Program

Researcher's signature Date

For student research

I have approved the procedures of the research project described in the attached application. I agree to assist the student with the policies for conducting research involving human subjects.

Faculty research/instructor's advisor's printed name Department/Program

Faculty research/Instructor's advisor's signature Date

Date received by IRB: _____ Date approved by IRB: _____

INFORMED CONSENT GUIDELINES

Obtaining the informed consent of potential human participants in any research (whether an experiment, survey, interview, or demonstration) is a federally mandated safeguard for protecting the rights and welfare of all individuals, and, in fact, constitutes the very essence of protecting those rights.* Therefore the IRB will very carefully review the method of obtaining and the content of informed consent listed below. When consent forms require signatures of research subjects and/or their parents or legal guardians, a copy of the fully signed form must be given to the subject/parent/ guardian and a copy must be retained by the researcher for a minimum of three years after completion of the project. For the convenience of researchers, a model format may be found in this packet.

Researchers must give participants the following information in an informed consent form:

1. Information on the purpose(s) of the research and a description of the method(s) and procedure(s) to be followed, including the intention to publish or disseminate, and the amount of time the participant will spend in the actual project,
2. A description of any reasonably foreseeable risks or discomforts to the participant; if disguised or deceptive procedures are used, debriefing plan must be explained to the IRB,
3. A description of any benefits to the participant or to others as a result of the information obtained from the research,
4. A disclosure of appropriate alternative procedures that may be advantageous to the participant in making an informed decision whether or not to participate in the research (this pertains primarily to medical research and drug trails),
5. A description of the measures to be taken to insure the confidentiality of data and the anonymity of individual participants, if applicable,
6. The name and phone number of a contact person(s) who will be available to answer any questions the participant or his/her legally authorized representative may have regarding the research (student investigators **must** include the name, address, and phone number of his/her faculty research advisor), and “Questions regarding the protection of human subjects may be addressed to: Dr. Richard Kyte, Director, D. B. Reinhart Institute for Ethics in Leadership.”
7. A clear explanation that participation is voluntary and that neither the refusal to participate nor the decision to discontinue participation (at any time) will involve penalty or loss of benefits to which the participant is otherwise entitled.

*For survey research projects, informed consent is obtained by providing the potential participants/respondents a detailed explanation of the purpose for and the protocol of the research project. Completion of the survey instrument by the participant shall constitute informed consent, but this should be stated in the cover letter or survey instructions.

8. Disclosure of costs to the participant, if any, because of his/her participation in the research; disclosure of compensation to the participant, if any, for his/her participation in the research.
9. For projects of **MORE** than minimal risk to participants, a statement that the costs of medical care or other therapies required as a result of injury or mishap incurred while participating in the research, must be borne by the participant or his/her insurance carrier. The Consent form should also include information about the availability and extent of on-site medical treatment should an injury occur.
10. The consent form must **NOT** include a statement releasing the investigator, sponsor, institution or its agents from liability or negligence.
11. The consent form must be written to the level of comprehension of the research participant or guardian.

MODEL INFORMED CONSENT FORM

TITLE OF PROJECT: _____

NAME OF INVESTIGATOR: _____

PHONE: _____

[1. Statement of Purpose]

You are invited to participate in a study of (state what is being studied.) We hope to learn (state what the study is designed to discover or establish). You were selected as a possible participant in this study because (state why and how the participant was selected).

[2. Description, Including Risks and Benefits]

If you decide to participate, we (or and associates) will (describe the procedures to be followed, including their purposes, how long they will take, and their frequency. Describe the discomforts and inconveniences reasonably to be expected, and estimate the total time required. Describe the risks reasonably to be expected, and any benefits reasonably to be expected.)

[3. Alternative Procedures]

(If applicable, describe appropriate alternative procedures that might be advantageous to the participant, if any. Any standard treatment that is being withheld must be disclosed.)

[4. Confidentiality]

Any information obtained in connection with this study that can be identified with you will remain confidential and will be disclosed only with your permission. In any written reports or publications, no one will be identified or identifiable and only group data will be presented. (If you will be releasing information to anyone for any reason, you must state the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure). This consent form, with your signature, will be stored separately from the data collected so that your responses will not be identifiable. (Note: If the study meets the criteria for exempt status, it is permissible to give the subject the only copy of the consent form when it is the only form that identifies the subject and when retaining it would only create a possible loss of anonymity.)

[5. Compensation]

(If the participant will receive compensation, describe the amount or nature. If there is a possibility of additional costs to the participant because of participation, describe them. If there is a possibility of a research-related physical injury, information as to the medical treatment and compensation available should be included.)

**VITERBO UNIVERSITY
REQUEST FOR CHANGE IN PROTOCOL FOR
RESEARCH INVOLVING HUMAN PARTICIPANTS**

Name of primary researcher: _____ Dept/Program: _____
(contact)

Campus address: _____ Phone: _____

Project title: _____

Project dates: from ____/____/____ to ____/____/____

Description of proposed changes (attach additional pages and revised consent forms if needed.)

Justification for proposed changes (attach additional pages if needed.)

Primary researcher's printed name Department/Program

Primary researcher's signature Date

For student research:

Faculty research advisor's printed name Department/Program

Faculty research advisor's signature Date

Committee use only:

Date received by IRB: _____ Date approved by IRB: _____

**VITERBO UNIVERSITY
END OF PROJECT REPORT FOR
RESEARCH INVOLVING HUMAN PARTICIPANTS
(NOT REQUIRED FOR EXEMPT PROJECTS)**

Complete the following information and submit one copy to the IRB.

Project title: _____

Name of primary researcher: _____ Dept/Program: _____
(contact)

Campus address: _____ Phone: _____

Project dates: from ___/___/___/ to ___/___/___/

This is to verify that the above named research involving human participants was performed according to the procedures approved by the IRB. The research project is now complete.

A total of _____ participants participated in this research project. _____ participants voluntarily withdrew from the research project. _____ participants experienced complications, adverse reactions, or injuries resulting from participation in the research project. All records for this project will be maintained for 3 years by the researcher or faculty research advisor and will be accessible if review of the data is necessary. If the faculty member is no longer at VU, the Department/Program will maintain the records.

Primary researcher's printed name

Department/Program

Primary researcher's signature

Date

For student research:

Faculty research advisor's printed name

Department/Program

Faculty research advisor's signature

Date

Committee use only:

Date received by IRB _____ IRB project number _____

SECTION IV

Glossary

ASSENT: Agreement by an individual not competent to give legally valid informed consent (e.g., child or cognitively impaired individual). Failure to object cannot be construed as assent.

ASSURANCE: A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human participants and stipulates the procedures through which compliance will be achieved.

CONFIDENTIALITY: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

DEBRIEFING: Giving participants previously undisclosed information about the research project following completion of their participation in research (This usage departs from standard English, in which debriefing is getting rather than imparting information.)

DECLARATION OF HELSINKI: A code of ethics approved by the World Medical Association and adopted by medical associations in many countries as guidelines for their clinical research.

GUARDIAN: See legally authorized representative.

HUMAN PARTICIPANT: A living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual; or 2) identifiable private information.

INFORMED CONSENT: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic therapeutic or preventive procedure.

LEGALLY AUTHORIZED REPRESENTATIVE: An individual or judicial or other body who is authorized under applicable state or local law to consent on behalf of a prospective participant in the procedure(s) involved in research.

MINIMAL RISK: The probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

MINOR: Any person under the age of 18 years.

NUREMBERG CODE: A code of ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting humans participants during research.

PARENT: A child's biological or adoptive parent.

PREGNANCY: The period of time from confirmation of implantation of a fertilized egg, through any of the presumptive signs of pregnancy, such as missed menses or by a medically acceptable pregnancy tests, until expulsion or extraction of the fetus.

PRINCIPAL INVESTIGATOR OR PRINCIPAL RESEARCHER: The scientist or scholar with primary responsibility for the design and conduct of a research project.

PRISONER: An individual involuntarily confined or detained in a penal institution or an alternative facility including those detained pending arraignment, trial, or sentencing.

PRIVACY: Control over the extent, timing, and circumstances of sharing oneself (intellectually, physically, behaviorally) with others.

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

RESEARCH PROTOCOL: The formal design or plan of an experiment or research activity; specifically, the plan submitted to the IRB or designated representative for review and to an agency for research support.

VOLUNTARY: A participant's decision to participate (or to continue to participate) in a research activity that is made free of coercion, duress, or undue inducement.

References

Federal Guidelines:

The Belmont Report: Ethical Principles and Guidelines for the Protection of human Subjects in Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, U. S. Department of Health, Education, and Welfare.

Protecting Human Research Subjects, Institutional Review Board Guidebook, National Institutes of Health, Office of Extramural Research, Office for Protection from Research Risks.

Protection of human Subjects, Title 45 Code of Federal Regulations Part 46, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks.

Information was taken from the following guidelines that were shared with us from the institutions indicated below:

Amended Policies and Procedures Pertaining to Research Involving the Use of human Subjects, Northern Illinois University, Institutional Review Board.

Guidelines for Proposal Development and Review, All-College Review Board for Human Subjects Research, Ithaca College.

Human Subjects in Research: Institutional Review Board Policies and Procedures, Office of Research and Sponsored Programs, Central Michigan University.

Policies and Procedures of the Institutional Review Board for the Protection of Human Subjects, University of Scranton

Texas Woman's University Application to Human Subjects Review Committee, Human Subjects Review Committee, Texas Woman's University.