St. Mary's University

Policy: Research Involving Human Subjects

Approver(s):	Academic Council
Authorizes release:	Provost and Vice President for Academic Affairs
Responsible office:	Academic Affairs Office
Update cycle:	Annually or as required
Next update:	June 2016
Last update:	July 30, 2013 to Feb. 7, 2014 – Revised Institutional Review Board
Adopted:	Oct. 6, 2009 – Approved by Institutional Review Board
Related policies:	
Additional references:	

RESEARCH INVOLVING HUMAN SUBJECTS
TABLE OF CONTENTS

Human Subjects final approved 10/6/2009
Human Subjects revisions approved 7/30/2013-2/7/2014

I. HUMAN SUBJECTS RESEARCH POLICY

from Faculty Handbook

2.12.2 Human Subjects Research Policy (Revised and Approved by the Board of Trustees Nov. 4, 2005)

2.12.2.1 Statement of Policy

The St. Mary's University policy on Human Subjects Research is founded upon basic ethical principles, embodied in the Marianist values and philosophy, that should guide research with human subjects. These principles are articulated in The Belmont Report (1978) and form the basis for the Federal Guidelines for Human Subjects Research. Briefly, these requirements for the ethical conduct of research involving human subjects concern respect for persons, beneficence, and justice.

Respect for Persons: Researchers who are employees or students of St. Mary's University will protect the rights of "persons involved in human research by recognizing the personal dignity and autonomy of individuals, and [by providing] special protection of those persons with diminished autonomy" (The Belmont Report in OPRR Guidelines, p. xxi). Researchers who are not employees or students of St. Mary's University must adhere to this policy when their subjects are employees or students of St. Mary's University. This principle speaks expressly to obtaining informed consent.

Beneficence: "Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm" (OPRR Guidelines, p. xxi). Safeguards must be followed to ensure that psychological, social, physical, legal, ethical, or moral harm to research participants are avoided or minimized. The foundation for evaluating ethical and moral harm lies within the University mission, its Roman Catholic tradition, and Marianist values and philosophy.

Justice: "Justice requires that the benefits and burdens of research be distributed fairly" (OPRR Guidelines p. xxi). No amount of institutional investigation and policing can prevent the abuse of human subjects if the investigator acts irresponsibly or does not ensure the fair selection of participants.

Thus the purpose of the Human Subjects Policy is to ensure that the three principles of ethical conduct in research are evident in all research involving human subjects and to provide guidelines for the conduct of such research as follows:

- ***a. to assist the investigator in developing specific procedures for the protection of human subjects and***
- ***b. to ensure institutional compliance with all applicable laws and regulations.***

2.12.2.2 Human Subjects Committee

Criteria for Membership:

Federal Policy Requirements for Internal Review Boards for Human Subjects Research are as follows (taken from OPRR manual, p.1-3):

The Federal Policy provides that IRB's must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB must therefore include persons

knowledgeable in these areas. No IRB, however, may consist entirely of members of one profession.

If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB must consider the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. It must also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

The IRB must make every nondiscriminatory effort to ensure that it does not consist entirely of men or entirely of women. Selections must not, however, be made on the basis of gender.

Membership: The Human Subjects Committee (IRB-HS) at St. Mary's University shall consist of the following members:

There will be at least one member from each school of the university except for two from the school of Humanities and Social Sciences as follows: one from Science, Engineering, and Technology, one from Business, one from Humanities, one from Social Sciences, one from Graduate, one from Law.

- ***a. A faculty member with a background in the Roman Catholic ethical tradition.***
- ***b. A staff professional, preferably from a non-academic area.***
- ***c. A member of the community who is not an employee or related to an employee of the university.***

Appointment: The Provost and Vice President for Academic Affairs, in consultation with the appropriate Deans, shall appoint the chair and members of the Human Subjects Committee. The membership of the IRB – HS shall be reviewed annually; therefore, membership should be considered a one year appointment, unless specified otherwise in the letter of appointment. If a member resigns, the Provost and Vice President for Academic Affairs shall appoint a replacement to complete the term. In those instances in which the representative has a vested interest in the research, the remaining members of the IRB-HS will review the proposal.

Meetings: The Human Subjects Committee will meet periodically, at a time and date convenient to the members. The frequency of meetings is to be determined by the number of research requests to be considered. All faculty or professional staff conducting or supervising research in this area are advised to obtain a copy of the most recent Guidebook from the Office of Human Research Protections (OHRP) and adhere to it. IRB – HS representatives in each school are available to assist with any questions.

II. THE HISTORY OF THE HUMAN SUBJECTS PROTECTION SYSTEM

Approved IRB 10/6/2009

§ 2.01 The modern story of human subjects protection begins with the Nüremberg Code, developed for the Nuremberg Military Tribunal as standards by which to judge the human experimentation conducted by the Nazis. The Code captures many of what are now taken to be the basic principles governing the ethical conduct of research involving human subjects. The first provision of the Code states that "the voluntary consent of the human subject is absolutely essential." Freely given consent to participate in research is thus the cornerstone of ethical experimentation involving human subjects. The Code goes on to provide the details implied by such a requirement: capacity to consent, freedom from coercion, and comprehension of the risks and benefits involved. Other provisions require the minimization of risk and harm, a favorable risk/benefit ratio, qualified investigators using appropriate research designs, and freedom for the subject to withdraw at any time. Similar recommendations were made by the World Medical Association in its Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects, first adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and subsequently revised by the 29th World Medical Assembly, Tokyo, Japan, 1975, and by the 41st World Medical Assembly, Hong Kong, 1989. The Declaration of Helsinki further distinguishes therapeutic from nontherapeutic research.

§ 2.02 In the United States, regulations protecting human subjects first became effective on May 30,1974. Promulgated by the Department of Health, Education and Welfare (DHEW), those regulations raised to regulatory status NIH's Policies for the Protection of Human Subjects, which were first issued in 1966. The regulations established the IRB as one mechanism through which human subjects would be protected.

§ 2.03 In July of 1974, the passage of the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission met from 1974 to 1978. In keeping with its charge, the Commission issued reports and recommendations identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and recommending guidelines to ensure that research is conducted in accordance with those principles. The Commission also recommended DHEW administrative action to require that the guidelines apply to research conducted or supported by DHEW. The Commission's report setting forth the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects is titled The Belmont Report.

§ 2.04 In 1981, in response to the Commission's reports and recommendations, both the Department of Health and Human Services (DHHS, formerly DHEW) and the FDA promulgated significant revisions of their human subjects regulations. As Robert J. Levine (1986) points out, these significant revisions "do not alter the general principles of IRB review as they had evolved over the preceding three decades. Rather, they are concerned with some of the details of what the IRB is expected to accomplish and some of the procedures it must follow" [p. 324].

§ 2.05 The DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. Those "basic" regulations became final on January 16, 1981, and were revised effective March 4, 1983, and June 18, 1991. The June 18, 1991, revision involved the adoption of the Federal Policy for the Protection of Human Subjects. The Federal Policy (or "Common Rule," as it is sometimes called) was promulgated by the sixteen federal agencies that conduct, support, or otherwise regulate human subjects research; the FDA also adopted certain of its provisions. As is implied by its title, the Federal Policy is designed to make uniform the human subjects protection system in all relevant federal agencies and departments.

§ 2.06 Additional protections for various vulnerable populations have been adopted by DHHS, as follows:

> Subpart B, "Additional Protections Pertaining to Research, Development and Related Activities Involving Fetuses, Pregnant Women and Human in Vitro Fertilization" became final on August 8, 1975, and was revised effective January 11, 1978, and November 3, 1978.
>
> Subpart C, "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects" became final on November 16, 1978.
>
> Subpart D, "Additional Protections for Children Involved as Subjects in Research" became final on March 8, 1983, and was revised for a technical amendment on June 18, 1991.
>
> The Revitalization Act of 1993 requires applicants to the National Institutes of Health to give special attention to the inclusion of women and minorities in study populations. If women and minorities are not included in the study population, a specific justification for this exclusion must be provided.
>
> FDA regulations on the protection of human subjects are codified at Title 21 Parts 50 and 56 of the Code of Federal Regulations. Part 50, which sets forth the requirements for informed consent, became final on May 30, 1980, and was revised effective January 27, 1981, March 3, 1989, and June 18, 1991. Subpart C, which provides special protections for prisoners, was adopted on July 7, 1981; the effective date of Subpart C has been stayed until further notice. Part 56, which sets forth the provisions for institutional review boards, was adopted on January 27, 1981, with revisions to some sections effective February 27, 1981, March 3, 1989, and June 18, 1991.
>
> The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, which met from 1980 to 1983, produced numerous reports on

various aspects of medical ethics and biomedical and behavioral research. Its mandate with respect to the protection of human subjects was, first, to review the federal rules and policies governing human subjects research, and second, to determine how well those rules were being implemented or enforced.

III. STATEMENT OF PRINCIPLES

Approved IRB 10/6/2009

§ 3.01 St. Mary's University is committed to the pursuit of excellence in teaching, research, and public service. Concomitantly, the University seeks to protect the welfare of every person who may be involved in research and training projects. Members of the University community, while upholding the highest standards of freedom of inquiry and communication, accept the responsibility this freedom offers: for competence, for objectivity, for consideration of the best interests of the University and society, and for the welfare of every participant in a project. The University gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended). Additionally, this institution will comply with the requirements set forth in 45 CFR 46 Subpart D which provides additional protections for children involved in research. Thus, the following principles are affirmed and should be interpreted in the broad context provided by the code of medical and general ethics promulgated by the World Medical Association as the Declaration of Helsinki and by the Ethical Principles in the Conduct of Research with Human Participants of the American Psychological Association.

(a) Since the participation of humans in research and training projects may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other University employees, on-campus or off-campus.

(b) All activities involving humans as participants must provide for the safety, health and welfare of every individual. Rights, including the right of privacy, must not be infringed.

(c) The direct or potential benefits to the participant, or the importance of the knowledge to be gained, must outweigh the inherent risks to the individual.

(d) Participation in projects must be voluntary and informed consent must be obtained from all participants, unless this requirement is specifically waived by the Institutional Review Board - Human Subjects (IRB-HS) as provided in 45 CFR 46.116(c). Methods that are in accordance with the requirements of 45 CFR 46.116 and 45 CFR 46.117 and adequate and appropriate to the risks of the project must be used to obtain the participant's informed consent.

(e) Consent should be obtained whenever possible from the participants themselves. If a participant is not legally or physically capable of giving informed consent, a legally authorized representative may do so. Careful consideration shall be given to the representative's depth of interest and concern with the participant's rights and welfare. Parents, for example, may not expose their child to risk except for the child's benefit.

(f) An individual does not abdicate any rights by consenting to be a research participant. A participant has the right to withdraw from a research project at any time or can refuse to participate, in either case, without loss of benefits to which the participant would otherwise be entitled. Further, a participant has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue embarrassment, discomfort, anxiety, and harassment.

(g) Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator. When the investigator is a student, responsibility for the conduct of the research and the supervision of human participants lies with the faculty sponsor. Such information shall not be communicated to others unless the following conditions are met:

i. Explicit permission for the release of identifying data is given by the individual.

ii. Information about individuals may be discussed only for professional purposes and only with persons clearly concerned with the project. Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid invasion of privacy.

iii. Provisions must also be made for the maintenance of confidentiality in the preservation and ultimate disposition of any data collected. Adequate security measures must be described to the IRB-HS and carried out by the principal investigator until the records are destroyed. Records which contain personal information shall be destroyed as soon as possible in keeping with the long-range goals of the project.

(h) Projects will be given initial and continuing review by the IRB-HS as set forth in Section IV, Paragraph 4. All members of the University community involved in investigation and training are responsible for continual monitoring to assure compliance of their research with these principles.

(i) No individual involved in the conduct and/or supervision of a specific project shall participate in IRB-HS review, except to provide information.

(j) A second review may be required if (a) a long interval has elapsed between IRB-HS review and project initiation; (b) if the proposed effort is in a rapidly changing scientific area; or (c) if the principal investigator wishes to change procedures after the proposed project has been reviewed by the IRB-HS. In no case will work take place without at least an annual review.

(k) In all cases, the investigator should show practical regard for St. Mary's University community, recognizing that violations of the ethical and legal standards incorporated in this statement of principles (for example, concerning confidentiality, informed consent, debriefing, and regard for the health, safety and welfare of all human participants) could impugn the investigator's own name and the reputation of the University. The investigator does not abdicate ethical and legal responsibility merely by complying with this protocol. **It is always the responsibility of the investigator to obtain clearance from the IRB-HS prior to the initiation of any research activity involving the use of human participants**. Failure to do so may result in personal restrictions on the research activities of such individuals, as well as potentially endanger all federal funding to the University.

IV. IRB-HS MEMBERSHIP AND INSTITUTIONAL RESPONSIBILITIES

§ 4.01 Approved IRB 10/6/2009

§ 4.02 The Institutional Review Board - Human Subjects shall have direct jurisdiction over St. Mary's University campuses. The Vice-President for Academic Affairs shall appoint the chair and members of the Institutional Review Board - Human Subjects. The membership of the Institutional Review Board - Human Subjects shall be reviewed annually. If a member resigns, the Vice-President for Academic Affairs shall appoint a replacement. In those instances in which the representative has a vested interest in the research, the remaining members of the Institutional Review Board - Human Subjects shall review the proposal the IRB-HS may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the Board. These individuals shall have no voting rights.

§ 4.03 All research projects involving the use of human participants must be submitted to the IRB-HS for approval. If it is unclear whether the proposed research involves human participants, the investigator should seek assistance from the Director of Academic Grants (DAC). IRB applications that support proposals for external funding shall be submitted to DAC well in advance of the agency deadline. If external funding is being sought, one copy of the research methodology section must be submitted along with the IRB-HS application. The IRB- HS Area Representative Committee member will review the complete proposal prior to its consideration by the Full Committee in an attempt to identify any items that need clarification or modification in order for the IRB-HS to act on the application at its next scheduled meeting. All applications, along with the comments/recommendations of the Committee Member, will be distributed to the Full Committee for review at least two weeks prior to the next scheduled meeting. Committee Member and IRB-HS Committee review normally takes **one month** from the initial submission to the Committee Member from that area, except for June through August and December through January.

§ 4.04 The IRB-HS will meet as needed with due regard for a thorough but speedy assessment of applications. Therefore, to assure consideration of an application by the IRB-HS in any given month, the Principal Investigator must initially submit a completed application ~~and the appropriate number of copies~~ (**~~the original and copies for Full Committee meetings,~~** plus a copy of the dissertation proposal, if applicable) to the IRB-HS in accordance with the published Schedule for Submission of Proposals deadline. This will allow sufficient time for the screening process prior to the monthly IRB-HS meeting.

> Applications are due by the first of the month. Applications for IRB proposal review must use a digital submission form and submit application form with digitally validated signatures through the Blackboard IRB Portal. Applicants must request enrollment in the Blackboard IRB Portal prior to submission. *Modification Approved by IRB, 2/7/2-14*

§ 4.05 An expedited review procedure is possible for those applications that involve no more than minimal risk to participants and that also fall under one of the research categories eligible for expedited review (refer to Section VII for a complete list of these categories) or fall under the categories exempted by federal regulations (refer to Section VI for a complete list of exempt research categories.) For information as to whether or not your research project falls under either of these category definitions contact the IRB-HS Chair.

§ 4.06 The Department Chair, by signing the application, indicates that he/she is aware of the research being done by individuals in the department (faculty, students or employees). In the case of student applications, the faculty sponsor certifies that the protocol has been checked for content and that research is conducted according to human participant guidelines. Thus, Department Chairs should critically evaluate applications before signing them. The college or department may set up any internal screening procedures that are determined to be necessary to assure adequate internal review. Upon request by the IRB-HS the College Dean and/or Department Chair may be asked to supply additional expertise or information to aid the Committee in its review process.

§ 4.07 The IRB-HS will proceed to weigh the following primary factors:

(a) That the rights and welfare of the participants will be adequately protected. Each project will be scrutinized with the interests of the participants foremost in consideration. No procedures shall be followed that would result in unnecessary or unacceptable risks to the participants. Appropriate safeguards and emergency measures must be provided. The IRB-HS is concerned with the maintenance of proper records and the protection of anonymity and/or confidentiality of all data collected. Furthermore, the IRB-HS will attempt to minimize personal embarrassment, mental anguish, and questions of conscience resulting from participation in a study. In short, the IRB-HS shall make every effort to ascertain that both the mental and physical well-being of the participants are adequately protected.

(b) b. That the risks to the participants and the researchers are reasonable in relation to anticipated benefits. The project protocol will be evaluated to determine if the risks to participants and the researchers are reasonable in relation to the anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. The IRB-HS expects that human participants will not be utilized in poorly designed projects. **HOWEVER, THE RESPONSIBILITY FOR MONITORING RESEARCH DESIGN QUALITY LIES PRIMARILY WITH THE DEPARTMENT CHAIR OR FACULTY SPONSOR.**

(c) That the informed consent of participants will be obtained by adequate and appropriate methods (described in Section V). All participants will be fully informed by the investigator of the procedures to be followed, including discomforts, risks, and possible benefits. Risks must be well defined in terms understandable by the participants. Informed consent must be obtained from all participants, unless specifically waived by the IRB-HS in accordance with 45 CFR 46.117 (c) (1) or (2).

(d) A majority of the members of the IRB-HS, including at least one member whose primary concerns are in non-scientific areas, must be present at a meeting in order to conduct business. Final approval by the IRB-HS shall then require a majority vote by members present. If the IRB-HS is agreed that the proposed research protects human participants in accordance with established standards, its conclusion shall constitute certification of approval. The IRB Chair will send a written letter of approval to the Investigator or Faculty Sponsor, the Human Subjects, Administrator, and other institutional officials as appropriate.

(e) In the case of a proposal being submitted to an external funding agency, certification of approval of the protocol, if required, will be made at the time the proposal is submitted in the form required by the agency.

§ 4.08 The following summarizes the actions the IRB may take when reviewing research:

(a) **Approval**: the determination of the IRB that the research has been reviewed and may be conducted at the institution. If the IRB cannot make one or more determinations required for approval by the HHS regulations (45 CFR 46.111, and if applicable subparts B, C, or D of 45 CFR 46), the IRB must not approve the research project.

(b) **Conditional Approval**: The IRB may approve research with conditions if the IRB is able, based on the assumption that certain conditions are satisfied, to make all of the determinations required for approval by the HHS regulations (45 CFR 46.111, and if applicable subparts B, C, or D of 45 CFR 46). This authority applies to IRB review of research at a convened meeting or under an expedited review procedure. The IRB may require the following as conditions of approval of research:

iv. Confirmation of specific assumptions on the part of the IRB regarding how the research will be conducted;

v. Submission of additional documentation (e.g. certificate of ethics training; letters of permission from cooperating institutions)

vi. Precise language changes to protocol or informed consent documents; or

vii. Substantive changes to protocol or informed consent documents, along with clearly stated parameters that the changes must satisfy.

For research with conditions, the IRB must verify that the changes meet the required determinations. One IRB reviewer and the Chair will review response materials to determine whether the conditions have been satisfied. Once the determinations have been satisfied, the IRB Chair will issue a letter of approval and report the action to the IRB at the next convened meeting. The effective date of the approval is the date on which the IRB chair and the designated reviewer has accepted as satisfactory any revised protocol, informed consent documents, or other responsive materials required by the IRB and will be reflected in the approval letter.

If the designated IRB reviewer and IRB Chair are unable to make the necessary determinations, the IRB can either table the research for future consideration (Revise and Resubmit) or refer the proposal for full board review at a convened meeting. Research may not be disapproved without full board review. The determination will be reported to the IRB at the next convened meeting.

§408(b) Approved by IRB, June 20, 2014. Further information is available at OHRP Guidance Document, "Guidance on IRB Approval of Research with Conditions," http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html#section-b

(c) **Revise and Resubmit**: Any time the IRB reviewing a research project cannot make one or more of the required determinations, the IRB must not approve the research project. For example, the IRB must not approve a proposed research project when the IRB is unable to make the required determinations about research risks and benefits, the adequacy of privacy and confidentiality protections, or the adequacy of the informed consent process because the research proposal provides insufficient information related to these aspects of the research and the IRB is unable to specify changes to the research proposal that, if made, would allow the IRB to make the required determinations.

In this case, the IRB tables the proposal in order for the investigator to make changes to the protocol or informed consent documents or submit clarifications or additional documents prior to the next scheduled review. The review will be scheduled for two meetings after the proposal is returned. The IRB can require the investigator to make changes to the protocol or informed consent documents or submit clarifications or additional documents prior to the scheduled review.

Resubmission of the revised research shall follow the procedures for initial review of proposals.

(d) **Disapprove**: If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

V. CRITERIA FOR APPROVAL

Approved IRB 10/6/2009

§ 5.01 The preliminary review determines that the research proposal is covered by the federal regulations and/or by St. Mary's IRB policies and procedures. The research is covered by federal regulations [45 CFR part 46] if the following criteria are met:

(a) **The activity is research:** The activity is a systematic investigation designed to develop or contribute to generalizable knowledge [45 CFR 46.102(d)];

(b) **The activity involves human subjects:** The research involves obtaining individually identifiable, private information about living individuals or involves intervention or interaction with living individuals [45 CFR 46.102(f)];
   - Individually Identifiable: the identity of the subject is or may readily be ascertained by the researcher or may readily be associated with the information [45 CFR 46.102(f)(2)]
   - Private: behavior occurs in context in which an individual can reasonably expect that no observation or recording is taking place, or information was provided for specific purposes which the individual can reasonably expect will not be made public [45 CFR 46.102(f)(2)]

§ 5.02 For data collection activity that involves human subjects that are not from a vulnerable population, but does not meet the criteria for generalizable research, the IRB shall determine that the activity is consistent with the Marianist ideals for human dignity, specifically voluntary consent, privacy protection, and minimal risk (see section IX. NOT GENERALIZABLE RESEARCH).

§ 5.03 For all research involving human subjects, the IRB shall determine that all of the following requirements are satisfied:

(a) Risks to participants are minimized by using procedures consistent with sound research design.

(b) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and to the importance of the knowledge that may reasonably be expected to result.

(c) Selection of participants is equitable considering the purposes of the research, the research context, and any special-groups participation.

(d) Informed consent will be obtained as required in 45 CFR 46.116.
   - Statement that the study involves research
   - Explanation of the purpose, duration & procedures of the research
   - Description of risks, benefits, alternative procedures

- Extent to which confidentiality is maintained
- If more than minimal risk, compensation or medical treatment
- Whom to contact for information
- IRB contact information
  If you have any questions about your rights as a research subject or concerns about this research study please contact the Chair, Institutional Review Board, St. Mary's University at 210-436-3736 or email at IRBCommitteeChair@stmarytx.edu.
- Participation is voluntary

When appropriate:

- Additional risks are unforeseen
- Anticipated circumstances which may warrant termination of participation
- Any additional costs
- Consequences for subject's withdrawal; orderly termination
- Significant new findings will be provided to subject
- Approximate number of subjects

May waive consent or alter consent elements if:

- The research meets all of the following four criteria:
- The research involves less than minimal risk,
- is not practicable to conduct the research without a waiver or alteration of consent,
- waiving or altering the informed consent will not adversely affect the subjects' rights and welfare,
- and pertinent information will be provided to subjects later.

OR

- The research is conducted by or subject to approval of state or local government AND designed to examine public benefit or service programs, procedures for obtaining benefits or services, possible changes in programs, or possible changes in methods or levels of payment for benefits under those programs.

(e) Informed consent is appropriately documented as required in 45 CFR 46.117.
  - Signed written consent form
  - IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if:
    - The consent document would be the only record linking the subject and the research, and the principal risk is potential harm resulting from a breach of confidentiality [45 CFR 46.117(c)(1)]
    - In this case, investigators shall provide subjects with a written summary of the purpose and duration of the research, investigator contact information, and IRB contact information.

AND

- Investigator will ask each subject if he or she wants documentation linking the subject with the research, and subject's wishes will govern whether informed consent will be documented. If subject's informed consent is documented, investigator will need a privacy protection plan for such documentation.

OR

- The research presents no more than minimal risk;

AND

- The research involves no procedures for which written consent is normally required outside the research context [45 CFR 46.117(c)(2)]

(f) An adequate research plan is provided for monitoring data collection.

(g) A clear process to protect the privacy of participants and the confidentiality of data is provided.

(h) Adequate safeguards are in place to protect the rights and welfare of vulnerable populations included in this research:

- Pregnant women, human fetuses, and neonates [see 45 CFR Subpart B]
- Prisoners [see 45 CFR Subpart C]
- Children [see 45 CFR Subpart D]

(i) The research is determined to place participants at *minimal risk* (as defined in 45 CFR 46.102), and risks are not unreasonable in relation to the anticipated benefits;

(j) OR The research is determined to place participants at *greater than minimal risk* and provides precautions, safeguards, or alternative approaches to protocols to reduce the probability of harm or to limit its severity or duration.

(k) The researcher is competent in the planned area of research.

(l) The researcher does not have dual roles that might produce a conflict of interest.

(m) The intent of the proposed research is to yield useful data that will benefit the research participants and/or similar groups in the future.

§ 5.04 IRB Review Determination

(a) The proposed project is exempt from IRB review because it meets the requirements in one of the six **exempt categories** as determined by Federal regulations (45 CFR 46.101).

(b) The proposed research or change in approved research qualifies for **expedited review** as defined in university policies and Federal regulations.

(c) The proposed research or change in approved research must have a **full board review** and must receive approval by a majority of the voting members of the IRB board.

(d) Another certified IRB-HS has approved this protocol. IRB name _____ and date of approval _____. (Please attach the approval form.)

VI. REVIEW PROCEDURES

Approved IRB 10/6/2009

§ 6.01 The Principal Investigator may be asked to meet with the IRB-HS should it be apparent that clarification or modification of statements in the application are required. **No individual involved in the conduct and/or supervision of the research project shall participate in its review, except to provide information to the IRB-HS.** Even if the consensus of the IRB-HS is favorable, it may elect to impose some additional restrictions or recommendations under which the project shall be conducted.

§ 6.02 If the IRB-HS action is to disapprove the application, reasons for this negative decision will be provided in writing to the Principal Investigator or Project Director. If the researcher decides to modify the proposed research in such a way as to meet the objections of the IRB-HS, the investigator may resubmit the application for consideration at a subsequent IRB-HS meeting.

§ 6.03 The Principal Investigator may request a personal hearing before the IRB-HS Committee, but that request should be made in observation of the published deadline dates so that the request has adequate time to be entered on the agenda.

§ 6.04 Any substantial changes in the protocol, emergence of problems or development of hazardous conditions for the participant must be reported immediately to the IRB-HS by the responsible investigator. An amended protocol must then be approved by the IRB-HS before the research may continue. (See "Procedures for Managing Critical Events") For changes or problems, please refer to IRB-HS Forms "Changes to Approved Human Subjects Protocols" and "Incident Report," which is used for unanticipated problems involving risk to human research participants. The appropriate form should be forwarded as soon as possible to the Area Representative or the Chair, IRB-HS.

§ 6.05 When initial approval of a protocol is given, the IRB-HS will indicate the minimum interval between re-evaluation of the project so that continued acceptance of the protocol is assured. Routine projects will be reviewed at yearly intervals; more complex and potentially dangerous projects will be reviewed at a frequency commensurate with the related risks. Projects that are determined to be exempt will not require yearly review; however, a renewal will be required every five (5) years for exempt projects. Renewal projects should include a progress report as well as a description of any anticipated design changes. Projects may also be re-evaluated if participants involved in the research lodge a complaint with the IRB-HS, or the Principal Investigator reports problems with the research. In the latter case, the IRB-HS may elect to review the data accumulated by the Investigator and may interview both the investigational staff and persons under risk.

§ 6.06 Ongoing projects modified to include humans as participants must submit proposals to the IRB-HS for review and written approval **prior to the use of human participants**. In the case of an externally funded project, the granting agency will be notified of the IRB-HS action **prior to the appropriation cycle** for a budget period during which human participant involvement is proposed.

VII. INFORMED CONSENT

Approved IRB 10/6/2009
Informed consent procedures are modified by the following sections:

for activity meeting the definitions of human subjects research in CFR § 46.102 (d) and (f):

§ 5.03 (d)
§ 5.03 (e)

for research of limited scope that does not meet the definitions of human subjects research in CFR § 46.102 (d) and (f):

§ 9.04
§ 9.08

§ 7.01 Informed consent is a process, not just a piece of paper. A written informed consent documents this process, but cannot serve as a substitute for it. No participant may be involved in research without the **legally effective informed consent** of the participant or the participant's legally authorized representative. This consent shall be sought under circumstances that provide sufficient opportunities for the participant to freely consider whether or not to participate. Particular attention should be paid towards the minimization of the possibility of coercion or undue influence. Negative consent, or requiring a participant to decline to participate, is not an acceptable procedure.

§ 7.02 The information given to the participant or the participant's legally authorized representative must be in simple, easily understood language. If the participant population is not English-speaking, the informed consent must be presented in whatever language is appropriate.

§ 7.03 Written documentation of the consent process (i.e. a cover letter or cover sheet) is always required unless specifically waived by the IRB-HS. While a cover letter can be used as a means of introducing a project, all required elements must be included in the informed consent document. The consent document should be signed by the participant or the participant's legally authorized representative unless this requirement is waived by the IRB-HS.

§ 7.04 If the participant is a minor (less than 18 years of age), written parental consent is required unless this requirement is waived by the IRB-HS. A waiver of the written informed consent requirement in accordance with 45 CFR 46.116(c) will be granted only if the investigator can provide adequate justification for the request. In addition to obtaining parental consent, the investigator must obtain the assent of the child unless the child is too young or incapable of giving assent and the IRB-HS has waived the requirement. In order to minimize any undue influence, parental consent and child assent should be obtained through separate processes.

§ 7.05 If the only record linking the participant to the research or data is the written, signed informed consent, its use may be waived by the IRB-HS. However, a statement describing the procedures and objectives of the research shall still be supplied to the participants in a written format. An example of such a project would be the analysis of a questionnaire that is distributed and returned anonymously through the mail. A cover letter should include all the elements of informed consent listed in this section. If informed consent is to be obtained orally (i.e. prior to a telephone interview) a written summary of what the participant will be told must be provided to the IRB-HS for review and approval.

§ 7.06 If the only record linking the participant to the research or data is the written, signed informed consent, its use may be waived by the IRB-HS. However, a statement describing the procedures and objectives of the research shall still be supplied to the participants in a written format. An example of such a project would be the analysis of a questionnaire that is distributed and returned anonymously through the mail. A cover letter should include all the elements of informed consent listed in this section. If informed consent is to be obtained orally (i.e. prior to a telephone interview) a written summary of what the participant will be told must be provided to the IRB-HS for review and approval

§ 7.07 No informed consent, whether oral or written, may waive or limit in appearance or in fact, the participant's legal rights, including any release of the institution or its agents from liability for negligence.

§ 7.08 The following information is required by the Federal government to be included in ALL consent material and shall be in language that is understandable and appropriate to the participant or participant's representative:

(a) A statement that the project is research and an explanation of the scope, aims and purposes of the research, and the experimental procedures to be followed, including the expected duration of the participant's participation.

(b) The following statement will be included in ALL written informed consents (including cover letters). It is suggested that this statement be inserted at the bottom margin of the form, letter or portion of the form that is to be retained by the participant.

*If you have any questions about your rights as a research subject or concerns about this research study please contact the Chair, Institutional Review Board, St. Mary's University at 210-436-3736 or email at IRBCommitteeChair@stmarytx.edu. ALL RESEARCH PROJECTS THAT ARE CARRIED OUT BY INVESTIGATORS AT ST. MARY'S UNIVERSITY ARE GOVERNED BY THE REQUIREMENTS OF THE UNIVERSITY AND THE FEDERAL GOVERNMENT***.**

(c) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.

(d) A description of any reasonably foreseeable risks or discomforts to the participant.

(e) A description of any benefits to the participant or to others that may reasonably be expected from the research.

(f) A statement regarding the availability of compensation and/or medical treatment if injury occurs will be required for research that involves more than minimal risk. If compensation or medical treatment will be provided, information about how it may be obtained or where further information may be secured will be required.

(g) An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant.

(h) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.

(i) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

(j) A statement detailing the approximate number of participants involved in the study. Additionally, the investigator should remember the following items relevant to the consent documents:

*A copy of the informed consent shall be supplied to the participant or the participant's legally authorized representative.

* Federal law mandates that copies of all informed consents be retained for a minimum of three years after the completion of the research; however, for audit purposes, the University requires that all copies of consents must be kept for five (5) years after the project is completed or the final report is accepted. The principal investigator is responsible for the maintenance and retention of such records. If the principal investigator is a student, the faculty sponsor is responsible for the maintenance of these records.

Important Notes:

1. ~~All required elements have been included in the samples provided although some elements may not be appropriate to the type of research projects described.~~

2. In order to allow adequate approval for the application and review procedure, investigators should be aware that the St. Mary's University IRB-HS requires school district approval for any research being conducted in that setting. This approval must come from the superintendent or a properly appointed designate. Approval from a classroom teacher or a principal (unless the district has given authority to the principal) is not sufficient. Some school districts have more complicated application and review processes than others.

3. The St. Mary's University IRB-HS requires approval from cooperating institutions, organizations, companies, and/or an IRB-HS. If the cooperating organization is an institution of higher education, approval must be from the appropriate human participants institutional review board.

~~Examples of cover letters and informed consent forms are available in Appendix 1.~~

VIII. OVERVIEW OF IRB INVOLVEMENT

Approved IRB 12/13/2013

Operating definitions: a) Research: a systematic investigation designed to develop or contribute to generalizable knowledge; b) an activity involving intervention or interaction with a human subject that would only occur given the research purposes.

	Not Generalizable Research			*Generalizable Research*		
	No IRB action	*IRB as needed*	*Review*	*Review and Approve*		
	Administrative Assessment Activities	Class-Based Learning Activities	Research of Limited Scope	Exempt from Annual Review	Expedited Review	Full Review
DESCRIPTION	Data collection within the scope of duty of an office, academic unit or recognized student organization of the university.	Data collection serves the purposes of student learning objectives of a course. Minimal risk. Private.	Sensitive topics: Class research, non-StMU program evaluations, quality improvement activities, or pilot studies	Minimal risk; 5 categories, such as de-identified survey, interviews, or existing data; normal educational practices	Minimal risk 10 categories, such as modifications, existing data, voice recordings, moderate exercise	Greater than minimal risk; Vulnerable population
EVAL	Activity consistent with Marianist ideals for human dignity, specifically informed consent, voluntary participation, and minimal risk.			Proposals must meet 11 federally regulated criteria for approval.		
INFORMED CONSENT	Provide a brief oral or written informed consent to include the purpose and duration of the activity, the responsible person to answer informational questions, and the supervising office (Dean or Vice President) to direct any complaints.		Oral or written statement of the purpose and duration, researcher's contact information, and IRB contact information	Full written informed consent, original signature. ○ May request a waiver for original signature. ○ May request a waiver for elements of informed consent Voluntary participation may be compromised through dual roles (i.e. instructor/ researcher; counselor/ researcher) or undue incentives (linking participation to grade; excessive compensation).		
MINIMAL RISK	Minimal risk means that the potential for discomfort or harm encountered in the research is not greater than that experienced in daily activities. Social and behavioral research may involve various types of harm or discomfort, ranging from economic, legal, physical, to psychological, social or moral. Personal disclosures about possibly illegal activity, stigmatized behavior, or embarrassing information are greater than minimal risk. (National Science Foundation, What is Minimal Risk?)					Examples of greater than minimal risk: criminal acts, stigmatized behavior
IRB INVOLVEMENT	IRB not involved	IRB only involved if: a) greater than minimal risk; b) concerns from participants	IRB approval will be granted if proposal meets limited criteria; report to next IRB meeting.	IRB approval granted if proposal meets 11 criteria; report to next IRB meeting.	IRB approval granted if proposal meets 11 criteria; report to next IRB meeting.	IRB approval will be granted upon review by all members and majority vote.
TIME	IRB not involved	Undefined	Deadline: 1st of month; IRB response by the end of the month	Deadline: 1st of month; IRB Response by the end of the month		Deadline: 1st of month; Time to review: 2 months.

IX. NOT GENERALIZABLE RESEARCH

(Approved by IRB Nov. 22, 2013)

§ 9.01 The Federal IRB guidelines define research as "a systematic investigation designed to develop or contribute to generalizable knowledge" (45 CFR 46.102(d)). A second operating definition of research activities is "The intervention or interaction with a human subject would not ordinarily take place, but for the research purposes." Several types of data collection conducted at the university are for other purposes, such as student learning activities, program evaluation, and outcome assessment.

§ 9.02 Consistent with the Catholic mission of the university, all research data collection activities must uphold fundamental ideals of human rights, specifically the rights of voluntary participation, informed consent, privacy, and minimal risk. This policy is to specify under what conditions data collection falls within the scope of authority of IRB-HS to protect human subjects.

§ 9.03 OHRP Guidance indicates that an intent to publish is not a sufficient criteria for determining whether a data collection activity involves research. Planning to publish a project of limited scope, such as a program evaluation, customer satisfaction, or quality improvement study, does not necessarily mean that the project fits the definition of research. People seek to publish descriptions of nonresearch activities for a variety of reasons if they believe others may be interested in learning about those activities. Conversely, program evaluation or quality improvement studies that use a systematic methods to increase the generalizability of the study may involve research. Please consult the IRB if you have any questions about a planned data collection activity.
(OHRP Guidance: http://answers.hhs.gov/ohrp/categories/1569)

A. ADMINISTRATIVE ASSESSMENT ACTIVITIES

(Approved by IRB Nov. 22, 2013)

§ 9.04 When the data collection is within the scope of responsibility of a professional or an office on campus, it is not subject to IRB review under 45 CFR 46.102(d). This includes program evaluation or needs assessment activities of university offices, academic programs or departments, and recognized student organizations. The university employee conducting the data collection and his or her supervisor will be responsible for the administrative assessment activity within the structure of the appropriate Vice President supervising the office. In the case of student organizations, the President of the organization and the faculty sponsor will be the responsible parties within the structure of the Dean of Students and the Vice President for Student Development. Examples of Administrative Assessment Activities are assessment of program activities, outcomes assessment of student learning activities or student evaluations of teaching effectiveness.

§ 9.05 Assuring Voluntary Consent

Data collection should be anonymous, or if not feasible, should protect participants' privacy, and should be consistent with FERPA requirements. Participation should be voluntary, and non-participation should not disadvantage anyone in any way. The project should have a brief informed consent, to include the purpose of the assessment, the duration of the activity, the university office and person responsible for the data collection activity, and how to contact the responsible person's university supervisor. The informed consent may be in writing or oral.

An example of written information:

> Turner Luce in the Office of University Animal Control wants to know how much you like the cats on campus. This survey should take you about 2 minutes. If you have questions about this assessment activity, please contact Dr. Lois Steem, Director of University Animal Control at lsteem@stmarytx.edu or 436-1234.

An example of oral information:

> Hi. Would you like to take our survey on the cats on campus? I'm Turner Luce from the Office of University Animal Control. The survey should take you about 2 minutes. If you have any questions about this survey, you can contact Dr. Lois Steem, Director of University Animal Control at lsteen@stmarytx.edu or 436-1234.

§ 9.06 Assuring Minimal Risk

Information obtained in the data collection activity should be minimal risk. Minimal risk means that the probability for harm or discomfort—that is the potential for negative effects—is no greater than those ordinarily encountered in daily life. Harm or discomfort

may be physical, psychological, or social; other harms may be economic, legal, or moral. Administrative Assessment Activities should not need to address behaviors that participants consider private, sensitive topics, stigmatized behavior, or illegal behavior. These topics include private behavior in which an individual can reasonably expect that no observation or recording is taking place; personal behavior such as sexual identity or sexual practices; protected information such as health, disability status, or mental health diagnosis; violence, criminal activity, illegal behavior; personal history that may elicit embarrassment or shame. If the Administrative Assessment Activity has a need to know these types of information about human participants, then the data collection needs to minimize risks through sound research methods and needs to be reviewed and approved by the IRB.

§ 9.07 IRB Review

Review of Administrative Assessment Activities does not fall under the scope of the St. Mary's University IRB, rather falls within the scope of the Vice President under which the organization or staff member resides. For example, academic assessment activities fall under the appropriate Dean and the Vice President for Academic Affairs, program assessment activities of university offices fall under the Vice President for Business and Finance, and program assessment activities of student organizations fall under the Vice President for Student Affairs.

All Administrative Assessment Activities should indicate, orally or in writing, the purpose of the assessment, the duration of the activity, the university office and person responsible for the data collection activity, and how to contact the responsible person's university supervisor.

University staff may obtain an opinion from the IRB that the proposed data collection activity is minimal risk, but IRB will not review and approve the activity (email IRBCommitteeChair@stmarytx.edu). If results of the administrative assessment are later submitted for professional publication, it is possible that the publisher asks for an IRB approval letter. In this case, the IRB can only provide a statement that this activity does not meet the definition of generalizable research, therefore 45 CFR part 46 does not apply.

If participants have complaints about the administrative assessment activity, the supervisor should report the complaint to the St. Mary's University IRB-HS within 48 hours. The complaint will be reviewed in light of criteria for informed consent and minimal risk with human subjects, and the appropriate university administrator will be informed of the IRB determination.

B. STUDENT LEARNING ACTIVITIES (CLASS PROJECTS)

(Approved by IRB Nov. 22, 2013)

§ 9.08 When the data collection serves the purposes of student learning objectives, the activity is pedagogy, not generalizable research (45 CFR 46.102(d)). This includes class assignments designed to engage students with people and problems outside the classroom, such as research activities, service learning assignments, and audio or video interviews.

The class instructor who makes the assignment will be responsible within the structure of the Academic Department, Dean, and Vice President for Academic Affairs for the conduct of the student learning activities. This is consistent with the Marianist principle of Subsidiarity (Faculty Handbook, 1.6.9) in which "Every effort is made to locate the decision-making process as close as possible to those who will be required to carry out or act on the decision." Toward that end, this policy statement is to provide classroom instructors the information they need to decide what class projects may proceed without IRB review. However, if instructors have questions about how to apply the guidelines, they can contact the IRB Chair at IRBCommitteeChair@stmarytx.edu.

Data collection activities for purposes of student learning objectives must uphold fundamental ideals of human dignity, specifically the rights of informed consent, voluntary participation, privacy, and informed consent. Data collection in student learning activities cannot utilize any vulnerable population, such as children or adolescents (under 18), prisoners or probationers, or pregnant women.

The class instructor must make a determination that each student learning project meets the following criteria:

1. minimal risk;
2. anonymous data collection;
3. voluntary participation;
4. oral or written informed consent;
5. has no vulnerable population (children, prisoners, or pregnant women);
6. and is not intended for publication outside the university.

If the Student Learning Project meets these criteria, explained in more detail below, the instructor may supervise the activity without IRB involvement. Any Student Learning Project that does not meet these criteria must be reviewed by IRB as a Project of Limited Scope.

§ 9.09 Assuring Informed Consent

The project should have a brief informed consent to include the purpose of the data collection, the duration, the class title and instructor responsible for the assignment, and how to contact the instructor's Dean. The informed consent may be in writing or oral.

An example of written information:

> Dr. Marge Innovera's class, Statistics for Life Applications, wishes to survey people about their irrational fears of statistics and spiders. The survey will take about 5 minutes. Don't worry, you won't be exposed to statistics or spiders during the survey. If you have any questions about this study, please contact Dr. Marge Innovera, College of Arts and Sciences at minnovera@stmarytx.edu or (210) 436-1234.

An example of oral information:

> Hi. We're doing a survey to learn more about irrational fears of statistics and spiders. We are in Dr. Marge Innovera's class, Statistics for Life Applications. The survey will take about 5 minutes. Don't worry, you won't be exposed to statistics or spiders during the survey. If you have any questions about this study, please contact Dr. Marge Innovera, College of Arts and Sciences at minnovera@stmarytx.edu or (210) 436-1234.

If the purpose of the research activity may bias the participant's responses, then the students can provide a partial information, oral or written, before the data collection AND a complete written explanation after completion of the data collection.

An example of partial oral presentation:

> Hi. We're doing a survey to learn more about people's reactions to controversial topics. We are in Dr. Dr. Marge Innovera's class, Statistics for Life Applications. The survey will take about 5 minutes. If you have any questions about this study, please contact Dr. Marge Innovera, College of Arts and Sciences at minnovera@stmarytx.edu or (210) 436-1234.

Written information with full information provided after study:

> Thank you for participating in our survey about reactions to controversial topics. This project is an assignment of Dr. Marge Innovera's class, Statistics for Life Applications. The purpose of this project is to compare people's irrational fears of statistics and spiders. If you have any questions about this study, please contact Dr. Marge Innovera, College of Arts and Sciences at minnovera@stmarytx.edu or (210) 436-1234.

§ 9.10 Assuring Voluntary Participation

Participants should be free to decline participation without loss of benefits outside the research activity. Linking participation in data collection activities with grades, attendance, or an alteration of course assignments violates this criteria of voluntary participation.

Voluntary participation in the data collection activities may be compromised by undue inducement to participate or by a dual role of the researcher. Instructors must insure that the solicitation to participate in the data collection activity does not compromise the potential participants' ability to agree or disagree to participate.

Undue Inducement. Inducements are offers that get people to do things they may not otherwise do. The data collection activity should not have monetary inducements or product inducements of a value greater than $3.00 (or equivalent to a cup of coffee) per participant. Random drawings for products or services of a value greater than $3.00 requires IRB review as "Research Activity of Limited Scope."

If the data collection activity uses an inducement, the research activity must assure that participants may withdraw from participation and still receive the incentive. Participants who start the study, by agreeing to the informed consent (oral or written) and starting the data collection, then quit the data collection activities for whatever reason, must still receive the incentive.

Dual Role. If the data collection occurs in a social service treatment context, including medical care, mental health care or provision of social services, the person asking for participation and consent in the data collection cannot be involved in the patient's treatment.

§ 9.11 Assuring Privacy

A range of information is considered private or personally identifiable: name, ID number (school- or government-issued), date of birth, mother's maiden name; HIPAA protects health-related information and FERPA protects educational records. Use of any of these types of information in the data collection creates a need to protect private information and must be reviewed by IRB.

Inadvertent disclosure: In classroom based surveys, care should be taken to avoid "inadvertent disclosure" based on demographic information. Given St. Mary's demographics, a classroom survey that includes 7 categories of demographics can easily identify the one or two minority subjects:

Demographic	St. Mary's %	Est. Class of 30	
Hispanic	55.8%	17	
White, non-Hispanic	25.9%	8	
International	6.9%	2	
African-American	3.7%	1	
Asian/Pacific Islander	2.6%	1	
American Indian/ AK Native	0.4%	1	
Other	3.7%	1	

Source: 2013 St. Mary's University Profile

Better to collect demographic categories of Hispanic; White, non-Hispanic; and Other. If the classroom based project has a need to know other demographic categories, the proposal

must be reviewed by IRB as a Project of Limited Scope. Internet surveys access a different population, and do not have the same concerns for inadvertent disclosure.

Class projects can utilize a range of procedures to protect participant privacy:
Anonymous data: the most complete protection of participant privacy is an anonymous survey, in which the subject identity is not known at data collection. No identifying, information nor information subject to inadvertent disclosure is collected.

Anonymous Interview data: The students must assure the instructor that they will only interview people they do not previously know. Interviews may use note-taking or audio recording for the data collection; video recording permits identity disclosure.

De-identified data: the original data collection included some forms of identifiable information, but the source, not the researcher, stripped the data file of all identifiable information. An example of this is: non-profit service information is maintained on an Excel database; the non-profit representative saves no fields with identifying information. Class-projects can utilize "source de-identified" data without IRB review.

Researcher anonymized data: the original data has identifying information, but the researcher only records data that is not identifiable. An example of this is a review of paper records of a non-profit agency. Class projects that need to use this data must have a confidentiality protocol that is reviewed and approved by IRB.

§ 9.12 Assuring Minimal Risk

Information obtained in the data collection activity should be minimal risk. Minimal risk means that the probability for harm or discomfort—that is the potential for negative effects—is no greater than those ordinarily encountered in daily life. Harm or discomfort may be physical, psychological, or social; other harms may be economic, legal, or moral. Examples of each type of risk can assist the instructor in guiding student projects:

- physical harm: Will it bruise or draw blood?
- psychological harm: Will asking this information traumatize someone?
- social harm: Will this information embarrass someone?
- economic harm: Can someone lose money because of this information?
- legal harm: Can someone get arrested because of this information?
- moral harm: Can someone's reputation be damaged because of this information?

Classroom Learning Activities should not need to address behaviors that participants consider private, sensitive topics, stigmatized behavior, or illegal behavior. These topics include private behavior in which an individual can reasonably expect that no observation or recording is taking place; personal behavior such as sexual identity or sexual practices; protected information such as health, disability status, or mental health diagnosis; violence, criminal activity, illegal behavior; personal history that may elicit embarrassment or shame. If the Classroom Learning Activity has a need to know these types of

information about human participants, then the data collection needs to minimize risks through sound research methods and needs to be reviewed and approved by the IRB.

§ 9.13 IRB Consultation

University instructors may obtain an opinion from the IRB that the proposed student learning activity meets the four criteria of adequate informed consent, voluntary participation, anonymous, and minimal risk, but IRB will not provide an approval letter for Student Learning Projects. (email IRBCommitteeChair@stmarytx.edu). If the Student Learning Project does not meet the four criteria, then the student and instructor must apply for IRB Review as a Project of Limited Scope.

If results of the student learning activity are later submitted for professional publication, sometimes the publisher asks for an IRB approval letter. In this case, the IRB can only provide a statement that this activity does not meet the definition of research, therefore 45 CFR part 46 does not apply.

If student class assignments must address sensitive topics that are inherently higher risk or must maintain identifiable private information, then students will need to complete the IRB Application for Research of Limited Scope.

If student projects are in fulfillment of an Honor's/Master's thesis or Doctoral dissertation, then students will need to complete the IRB Application for Proposal Review.

IRB Class Projects Policy

Class assignments intended to engage students with people and problems outside the classroom do not require IRB review and approval if they meet all the following criteria:

1. minimal risk;
2. anonymous data collection;
3. voluntary participation;
4. oral or written informed consent;
5. has no vulnerable population (children, prisoners, or pregnant women);
6. and is not intended for publication outside the university.

Class projects that meet all these criteria may proceed under the supervision of the course instructor. The instructor may request a consultation in cases that are unclear if the class project meets the criteria (email IRBCommitteeChair@stmarytx.edu). Class projects that, due to the nature of the subject matter or procedures, do not meet one or more criteria should complete an IRB Application for Proposal Review.
This is a summary of the IRB policies and procedures for class projects; instructors and students should consult the full policy at § 2.08-- § 2.16 of the IRB Policies and Procedure Manual.

Minimal risk: The probability of harm or discomfort is no greater than those ordinarily encountered in daily life. Harm or discomfort may be physical, psychological, or social; other harms may be economic, legal, or moral. Examples of each type of risk can assist the instructor in guiding student projects:

- physical harm: Will it bruise or draw blood?
- psychological harm: Will this activity evoke distressing memories?
- social harm: Will this information embarrass someone?
- economic harm: Can someone lose money because of this information?
- legal harm: Can someone get arrested because of this information?
- moral harm: Can someone's reputation be damaged because of this information?

Informed consent: The project should have a brief informed consent, oral or in writing, to include the purpose of the data collection, the duration, the class title and instructor responsible for the assignment, and how to contact the instructor. Providing the instructor's business card in an interview or contact information on an internet survey is sufficient contact information.
Anonymous: The data collection activity will not collect any form of personally identifiable information, such as signature, name, phone number, email address, government or university issued ID number, or date of birth. Classroom-based surveys should avoid "inadvertent disclosure." Given St. Mary's demographics, a classroom survey that includes detailed demographics (more than Hispanic, Anglo, and Other) can easily identify the one or two African-American or Asian subjects in the class. Class projects that utilize existing data should consult the IRB Policy on Class Projects.
Voluntary participation: Participants should be free to decline participation without loss of benefits outside the research activity. Linking participation in data collection activities with grades, attendance, or an alteration of course assignments may compromise voluntary participation and will require IRB review. Inducements of a value greater than a cup of coffee will require IRB review.

C. OTHER RESEARCH OF LIMITED SCOPE

(Section approved by IRB, 2/7/2014)

§ 9.14 Research of limited scope is research activity that is not intended to be a systematic investigation to develop generalizable knowledge. Examples of research activity of limited scope are program evaluation or quality improvement studies or for non-St. Mary's entities, pilot studies, or student research projects that do not meet all criteria for approval as Student Learning Activities.

Research of limited scope must fulfill five criteria:

- class research assignments, program evaluation or quality improvement studies for non-St. Mary's entities, or pilot studies that are intended to develop limited knowledge about a specific group, not generalizable knowledge (45 CFR 46.102(d));
- involving intervention or interaction with individually identifiable individuals that would not occur except for the proposed research activity (45 CFR 46.102(f));
- May be more than minimal risk to human subjects, but includes protocol to reduce risks (45 CFR 46.102(i));
- Does not have subjects from a vulnerable population, as defined by Subpart B (Pregnant Women, Human Fetuses, and Neonates), Subpart C (Children), or Subpart D (Prisoners);
- Other Federal or State laws do not apply (i.e. HIPAA, FERPA, Texas Mental Health laws).

Applicants must use the Request for Proposal Review form approved by the IRB.
Upon validation of the criteria and supporting documents by the Area Representative and one other IRB member, the researcher(s) will be allowed to proceed with the research activity and the decision will be reported to the IRB at the next scheduled meeting.

X. EXEMPTIONS FROM ANNUAL REVIEW

Approved IRB 10/6/2009

§ 10.01 The University has adopted certain categories of research as exempt from continuing IRB-HS review based upon DHHS regulations published in the Federal Register on January 26, 1981 and March 4, 1983. In order to establish an individual research project as exempt from annual review, an investigator must complete and submit an IRB-HS application for review and approval. **Final determination as to whether a research project is exempt from annual review rests with the IRB-HS.**

§ 10.02 If a research project is certified as exempt from annual review by the IRB-HS, the investigator need not resubmit the project for annual IRB-HS review as long as there are no modifications in the exempted procedures; however, the investigator will be required to resubmit a renewal application every five (5) years. The investigator will be sent a reminder notification letter by the Academic Grants Office. Renewing these protocols allows the IRB-HS to assess the project in light of any developments that may have occurred during the previous five years. **The use of the term "exempt" refers to the requirement for annual IRB-HS review, but not the general requirements for informed consent and protection of participants. Thus, even if your project is determined to be exempt from annual review, you still must inform potential participants of the proposed procedures and their rights as participants.**

§ 10.03 Exemption Categories

The following categories of exemption from review by the IRB-HS have been adopted by St. Mary's University:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   (a) Research on regular and special education instructional strategies, or
   (b) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
   (a) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
   (b) Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be

damaging to the participants' financial standing, employability, or reputation; or
(c) The research involves the use of children as participants (legal age of consent in the State of Texas is 18 years old).

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

(a) The human participants are elected or appointed public officials or candidates for public office; or
(b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

(a) Public benefit or service programs;
(b) Procedures for obtaining benefits or services under those programs;
(c) Possible changes in or alternatives to those programs or procedures; or
(d) Possible changes in methods or levels of payment for benefits or services under those programs.

5. Taste and food quality evaluation and consumer acceptance studies:

(a) If wholesome foods without additives are consumed

or

(b) 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 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.

XI. EXPEDITED REVIEW

§ 11.01 DHHS regulations recognize that there are certain categories of research that involve procedures that pose no more than minimal risks to participants and for which clear standards can be set. Accordingly, research proposals that fall under one of the categories listed below can be reviewed by the Committee Member in that area for expedited review. A proposal determined to be eligible for expedited review will be forwarded to the chair of the IRB-HS. He/she will then review the proposal and, if in agreement, will expedite its review. If not, the proposal will be referred to the whole IRB-HS for review.

§ 11.02 If the application is approved for expedited review, it will be reported to the IRB-HS at the next convened meeting. The IRB-HS has the option of requesting more information, requiring modification of the protocol or disapproving the project.

Investigators should be aware that even though applications for expedited review are less complicated to review, the expedited review process may be no faster than the full review procedure.

§ 11.03 Listed below are eleven categories subject to expedited review. Expedited review will be given only for research protocols that fall under one of these categories.

1. Minor modifications or additions to existing approved studies;

2. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate participants' behavior and the research will not involve stress to participants;

3. The study of existing data, documents, records, pathological specimens or diagnostic specimens;

4. Voice recordings made for research purposes such as investigations of speech defects;

5. Moderate exercise by healthy volunteers;

6. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from participants 18 years of age or older who are in good health and not pregnant;

7. Collection (in a non-disfiguring manner) of hair, nail clippings and deciduous teeth; and permanent teeth if patient care indicates a need for extraction;

8. Collection for analysis of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;

9. Recording of data from participants 18 years of age or older using noninvasive procedures routinely employed in clinical practice. 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 matter or significant amounts of energy into the participant or an invasion of the participant's privacy. (These procedures include weighing, testing sensory acuity, electrocardiogram, electroencephalogram, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range, i.e., x-rays, microwaves.);

10. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; and

11. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

XII. FULL REVIEW

§ 12.01 Proposals that are determined to be greater than minimal risk to human subjects OR proposals that contain vulnerable populations as research subjects, i.e. Children, Prisoners, or Pregnant Women or Fetuses, must have full convened review by the IRB. Proposal receiving full review must be distributed to all IRB members at least 2 weeks prior to a scheduled meeting and will be reviewed according to all criteria for approval noted in section V. Criteria for Approval. In addition, research with vulnerable populations will be evaluated by the following relevant criteria:

Subpart B, "Additional Protections Pertaining to Research, Development and Related Activities Involving Fetuses, Pregnant Women and Human in Vitro Fertilization"

Subpart C, "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects"

Subpart D, "Additional Protections for Children Involved as Subjects in Research"

XIII. EXTERNAL RESEARCHER GUIDELINES

(Approved by IRB Oct. 25, 2013)

§ 13.01 Applicability

These External Researcher Guidelines apply to all individuals not currently affiliated with the St. Mary's University (StMU) who are interested in conducting research involving StMU, its students, faculty, staff, or alumni.

§ 13.02 Purpose

The purpose of these guidelines is to establish a standard method of reviewing and approving any research conducted that involves StMU faculty, staff, students, or alumni as research participants and to balance a cooperative, collaborative research effort with existing research and data collection by researchers affiliated with StMU. Any and all external researchers (anyone currently unaffiliated with the University) are required to follow these guidelines.

§ 13.03 Background

The StMU Institutional Review Board (IRB) was established for the review of any research involving humans as subjects and is in compliance with Federal Regulations concerning experimentation involving human subjects (45 C.F.R. Part 46, Protection of Human Subjects). The purpose of this Board is to provide review of all research conducted by faculty, staff, and students to insure protection of human subjects and compliance with the federal regulations. All research conducted on the StMU campus involving StMU students, faculty, staff, alumni, or StMU resources is subject to compliance with all federal regulations regarding human subject research.

§ 13.04 Education

All individuals engaged in research involving human subjects must complete an educational program related to the responsible conduct of research prior to initiation of a research project. StMU requires its faculty take the NIH Protecting Human Research Participants Training and provide proof of completion (http://phrp.nihtraining.com/users/login.php). Others who wish to conduct research at StMU will be required to provide proof of this training or a similar training such as Collaborative Training Initiative (CITI). CITI is an on-line educational training course that provides relevant, up-to-date information on the protection of human research subjects in the format of instructional modules.

§ 13.05 Guiding Principle

It is the guiding principle of the Office of Academic Research and Sponsored Projects at StMU that all research, whether conducted by an internal or an external researcher, involving human subjects must be approved by the StMU IRB before any human subjects are recruited for the study. For all research activities, an external researcher must identify a StMU employee (regular, full-time) willing to serve as the local sponsor for the duration of the research project. The local sponsor should be able to answer questions about the project, serve as the campus contact for questions or concerns about the research, and has completed the required CITI or NIH educational program. Procedure

Researchers who are unaffiliated with StMU but wish to recruit participants on the StMU campus, must request permission from the IRB before recruiting alumni, students, or employees at StMU (via poster, flyer, email announcement, newspaper ad, or any other method of recruitment). Unaffiliated researchers must submit one copy of the full packet of materials submitted to the IRB at their own institution, including the letter of IRB approval for the project, to the StMU IRB Office. Researchers who do not have an IRB at their home institution should submit all required documents, using StMU application materials found a https://www.stmarytx.edu/academics/research-programs/institutional-review-board- irb/, to the StMU IRB. The packet should include, but may not be limited to, the IRB protocol application, consent form or information sheet, recruitment flyer or ad, instruments or measures to be used, and any supporting documentation.

For research activities that qualify as exempt from IRB review, evidence must be provided from the home institution that exempt status has been granted. The IRB Chair or his/her designee will review the request and issue a letter of permission to recruit on campus. The IRB reserves the right to have requests for permission to recruit on campus go to the full board for review and approval, should the Chair decide that the nature of the study requires the independent scrutiny of the IRB to protect its students and employees.

The StMU IRB only considers the protection of human subjects; it does not grant authority for the Researcher to conduct the research at StMU. Therefore, the authority to conduct research on the StMU campus must also be obtained from the appropriate university official relative to the research to be conducted. For assistance in obtaining this approval, contact the STMU Research Compliance Officer, Dr. Mark Roltsch (mroltsch@stmarytx.edu)in the Office of Academic Research and Sponsored Projects.

XIV. MANAGING CRITICAL INCIDENTS

Approved IRB 10/6/2009

§ 14.01 This section contains procedures for the following: (1) unanticipated problems and adverse events; (2) non-compliance with 45 CFR 46 or university policies; (3) suspension or termination of IRB approval.

§ 14.02 Unanticipated Problems/Adverse Events:

Because all research inherently contains unknown factors, the university is required to have procedures in place to manage unanticipated or serious problems associated with research involving human participants.

The Office of Human Research Protections (OHRP) provides guidance differentiating two key terms in human subjects research:

1. Unanticipated problems
2. Adverse events

You can access a full discussion of these key terms at http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm.

The guidance cites the regulatory background to 45 CFR 46.103(b)(5). The definitions provided here do not appear in 45 CFR 46, but OHRP has defined the two terms as follows: OHRP considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. Related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and Suggests that the
3. Research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Adverse Events are defined as: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding, extreme anxiety), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

§ 14.03 At St. Mary's University, researchers engaged in any research involving human participants must follow the procedures outlined below.

Emergency (life threatening)
1. Manage according to University emergency procedures if on campus (i.e. notify University police). If off-campus site, call 911.
2. Communicate the medical emergency to the Human Subjects Administrator, the VPAA, OR to the IRB--HS chair immediately.

Non-emergency
1. Communicate the nature of the problem to the IRB-HS chair or Area Representative as soon as the event or problem is identified **but no later than 72 hours** after knowledge of the problem.

In non-emergency incidents, the IRB chair will work with the investigator to identify the appropriate steps to address the problem in the best interests of the participant(s) using the guidance documents provided by OHRP and in accord with 45 CFR part 46. After due consultation with the investigator and university officials (Human Subjects Administrator, VPAA, others as appropriate), the IRB-HS chair will determine whether the IRB Committee will be convened to review the research protocol in light of the incident.

Depending on severity, such events routinely warrant consideration of changes to the research protocol or informed consent process/document or other corrective actions in order to protect human participants. For example, such an occurrence may warrant more frequent and/or detailed reports by the investigator. In any event, the following steps must be taken.

§ 14.04 Steps for resolving critical incidents: unanticipated problems/adverse events

1. Critical incidents will be reviewed by the IRB-HS unless they are determined to be anticipated problems, are non-emergency, and are managed within the research protocols approved by the IRB-HS.

2. The Investigator will complete Form HS7 promptly and forward the form with all explanatory documentation to the Area Representative or IRB-HS Chair.

3. The Chair will either convene a special Board meeting or will place the Critical Incident on the next regularly scheduled meeting agenda, as appropriate.

4. The Investigator will meet with the board to discuss the Critical Incident and determine whether changes to the research protocol are warranted, whether an outside expert should be consulted, or whether other steps should be taken based on the nature of the Critical Incident.

5. A decision by the Board to require protocol changes based on information provided by the investigator is final.

6. The investigator shall submit a proposal to the IRB-HS encompassing the new protocols prior to proceeding with further interventions or in the timeframe and conditions deemed appropriate by the Board.

7. The research may continue once the board reviews and approves the revised protocols.

§ 14.05 Steps for resolving critical incidents: non-compliance

University employees and students have an ethical obligation to report non-compliance with university policies and procedures. Individuals or groups conducting research with human subjects must abide by the policies and procedures in place in order to protect humans participating in research. Complainants are protected from retaliation by university policies generally and by the Research Integrity Policies specifically. Reports may be made directly to the VPAA, to the IRB-HS chair or any member of the IRB-HS committee.

In cases of serious or continuing non-compliance, the Chair of the IRB shall report the findings of the Board to the VPAA, the Human Protections Administrator, and other parties as appropriate for action. Human Subjects Policy provides guidance for disciplinary actions that may be required in Section II, (¶11). Misconduct in Scholarly Research policy may also be applicable.

§ 14.06 Steps for resolving critical incidents: suspension or termination of IRB-HS approval

Some problems or adverse events may be serious enough to warrant IRB-HS terminating approval of the research. Termination or suspension may also be the result of failure to follow approved research protocols. All suspension or termination decisions by the IRB-HS are final. Research must stop and may not be resumed. However, Researchers may choose to re-vision their research and submit new research proposals for IRB-HS approval if human participants are part of the research plan.

§ 14.07 Reporting Responsibilities

In all cases of problems/adverse events, non-compliance, or termination of IRB approval of research, the IRB Chair shall file a timely report with the VPAA, the HPA, and others as directed by the VPAA. As appropriate, the Human Protections Administrator shall file the appropriate required reports with the Office of Human Subjects Protection and the federal agency providing funding, where relevant, according to the conditions of award and federal regulation.

XV. APPROPRIATENESS OF RESEARCH TOPIC

Approved IRB 10/6/2009

§ 15.01 The IRB-HS is charged with evaluating the risks and benefits to human participants in proposed research and seeks to ensure that research methods provide adequate safeguards to all participants. The IRB-HS does not determine the appropriateness of the proposed research in terms of the mission of the university or its Marianist, Catholic values and traditions. Any questions about the appropriateness of proposed research topics should be referred to the Vice President for Academic Affairs for resolution.

XVI. GLOSSARY OF TERMS

Approved IRB 10/6/2009

ADVERSE EVENT: Any untoward or unfavorable medical occurrence in the human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporarily associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (OHRP Appendix A).

ASSENT: Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

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 [Federal Policy º___.103].

AUTONOMY Personal: Capacity to consider alternatives, make choices, and act without undue influence or interference of others.

BENEFICENCE: An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules:

(1) do not harm; and
(2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

BENEFIT: A valued or desired outcome; an advantage.

CASE-CONTROL STUDY: A study comparing persons with a given condition or disease (the cases) and persons without the condition or disease (the controls) with respect to antecedent factors. (See also: Retrospective Studies.)

CHILDREN: Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)]. (The St. Mary's University Legal Counsel defines anyone less than eighteen (18) years old as a child.)

CLINICAL TRIAL: A controlled study involving human participants, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

COGNITIVELY IMPAIRED: Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental

retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, may also be compromised in their ability to make decisions in their best interests.

COHORT: A group of participants initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.

COMPENSATION: Payment or medical care provided to participants injured in research; does not refer to payment (remuneration) for participation in research. (Compare: Remuneration.)

COMPETENCE: Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: Incompetence, Incapacity.)

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

CONTROL (PARTICIPANTS) or CONTROL Participant(s): Used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of participants is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.

CONTRAINDICATED: Disadvantageous, perhaps dangerous; a treatment that should not be used in certain individuals or conditions due to risks (e.g., a drug may be contraindicated for pregnant women and persons with high blood pressure).

CROSS-OVER DESIGN: A type of clinical trial in which each participant experiences, at different times, both the experimental and control therapy. For example, half of the participants might be randomly assigned first to the control group and then to the experimental intervention, while the other half would have the sequence reversed.

DEBRIEFING: Giving participants previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

DECLARATION OF HELSINKI: A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It

was revised in 1975 and 1989.

DESCRIPTIVE STUDY: Any study that is not truly experimental (e.g., quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies).

DHHS A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

DOUBLE-MASKED DESIGN: A study design in which neither the investigators nor the participants know the treatment group assignments of individual participants. Sometimes referred to as "double-blind."

EMANCIPATED MINOR: A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation. (See also: Mature Minor.)

EQUITABLE: Fair or just; used in the context of selection of participants to indicate that the benefits and burdens of research are fairly distributed [Federal Policy º____.111(a)(3)].

ETHNOGRAPHIC RESEARCH: Ethnography is the study of people and their culture. Ethnographic research, also called fieldwork, involves observation of and interaction with the persons or group being studied in the group's own environment, often for long periods of time. (See also: Fieldwork.)

EXPEDITED REVIEW: Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [Federal Policy º____.110].

EXPERIMENTAL STUDY: A true experimental study is one in which participants are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. (See also: Quasi-Experimental Study).

FIELDWORK: Behavioral, social, or anthropological research involving the study of persons or groups in their own environment and without manipulation for research purposes (distinguished from laboratory or controlled settings). (See also: Ethnographic Research.)

FULL BOARD REVIEW: Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting [Federal Policy º____.108].

GUARDIAN: An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care [45 CFR 46.402(3)].

HUMAN PARTICIPANTS: Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human participants are defined as: living individuals(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [Federal Policy º___.102(f)].

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. Often used as a synonym for incompetence. (See also: Incompetence.)

INCOMPETENCE Technically: A legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (See also: Incapacity.)

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. In giving informed consent, participants may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor the institution or agents thereof from liability for negligence [Federal Policy º116; 21 CFR 50.20 and 50.25].

INSTITUTIONAL REVIEW BOARD: A specially constituted review body established or designated by an entity to protect the welfare of human participants recruited to participate in biomedical or behavioral research [Federal Policy º____.102(g), º____.108, º____.109].

INSTITUTIONALIZED: Confined, either voluntarily or involuntarily (e.g., a hospital, prison or nursing home).

INVESTIGATOR: In clinical trials, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (e.g., drugs) involved in the study are administered to participants under the immediate direction of the investigator. (See also: Principal Investigator.)

JUSTICE: An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

LEGALLY AUTHORIZED REPRESENTATIVE: A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human participants research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedure(s) involved in the research {Federal Policy º____.102(c)].

LONGITUDINAL STUDY: A study designed to follow participants forward through time.

MASKED STUDY DESIGNS: Study designs comparing two or more interventions in which either the investigators, the participants, or some combination thereof do not know the treatment group assignments of individual participants. Sometimes called "blind" study designs. (See also: Double-Masked Design; Single-Masked Design.)

MATURE MINOR: Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care). Note that a mature minor is not necessarily an emancipated minor. (See also: Emancipated Minor.)

MEDICAL DEVICE: A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

MINIMAL RISK: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy º____.102(I)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.
NOTE: The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults. {See 45 CFR 46.303(d)].

NONTHERAPEUTIC RESEARCH: Research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the current participants, although it may benefit participants with a similar condition in the future.

NORMAL VOLUNTEERS: Volunteer participants used to study normal physiology and behavior or who do not have the condition under study in a particular protocol, used as comparisons with participants who do have the condition. "Normal" may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the "normals" in a study of diabetes complicated by heart disease.

NUREMBERG CODE: A code of research 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 human participants.

PATERNALISM: Making decisions for others against or apart from their wishes with the intent of doing them good.

PERMISSION: The agreement of parent(s) or guardian to the participation of their child or ward in research [45 CFR 46.402(c)].

PLACEBO: A chemically inert substance given in the guise of medicine for its psychologically suggestive effect; used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than actual power of a drug.

PRECLINICAL INVESTIGATIONS: Laboratory and animal studies designed to test the mechanisms, safety, and efficacy of an intervention prior to its applications to humans.

PRINCIPAL INVESTIGATOR: The scientist or scholar with primary responsibility for the design and conduct of a research project. (See also: Investigator.)

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

PROSPECTIVE STUDIES: Studies designed to observe outcomes or events that occur subsequent to the identification of the group of participants to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

PROTOCOL: The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective participants and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

QUASI-EXPERIMENTAL STUDY: A study that is similar to a true experimental study except that it lacks random assignments of participants to treatment groups. (See also: Experimental Study.)

RANDOM, RANDOM ASSIGNMENT, RANDOMIZATION, RANDOMIZED: Assignment of participants to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of participants to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between participant groups are the result of the experimental intervention.

REMUNERATION: Payment for participation in research. (NOTE: It is wise to confine use of the term "compensation" to payment or provision of care for research-related injuries.) (Compare: Compensation.)

RESEARCH: A systematic investigation (i.e., the gathering and analysis of information)

designed to develop or contribute to generalizable knowledge [Federal Policy º____.102(d)].

RESPECT FOR PERSONS: An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

RETROSPECTIVE STUDIES: Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

REVIEW (OF RESEARCH): The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis [Federal Policy º____.108(e)].

RISK: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

SERIOUS ADVERSE EVENT: Any event that:
(1) Results in death;
(2) Is life-threatening;
(3) Results in inpatient hospitalization or prolongation of existing hospitalization;
(4) Results in a persistent or significant disability/incapacity
(5) Results in a congenital anomaly/birth defect; or
(6) Based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed above.
(OHRP Adverse Event Guidance p. 9)

SINGLE-MASKED DESIGN: Typically, a study design in which the investigator, but not the participant, knows the identity of the treatment assignment. Occasionally the participant, but not the investigator, knows the assignment. Sometimes called "single-blind design."

SOCIAL EXPERIMENTATION: Systematic manipulation of, or experimentation in, social or economic systems; used in planning public policy.

SURVEYS: Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

UNANTICIPATED PROBLEM: Any incident, experience, or outcome that meets all of the following criteria:

(1) unexpected (in terms of nature, severity, or frequency) given

(a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and

(b) the characteristics of the subject population being studied;
(2) related or possibly related to a subject's participation in the research; and
(3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

UNEXPECTED ADVERSE EVENT: Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:
(1) The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in
(a) the protocol's related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and
(b) other relevant sources of information, such as product labeling and package inserts; or
(2) The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

VOLUNTARY: Free of coercion, duress, or undue inducement. Used in the research context to refer to a participant's decision to participate (or to continue to participate) in a research activity.

THIS PAGE IS INTENTIONALLY LEFT BLANK.