Cardinal Stritch University

Standards for the Protection of

Human Participants of Research

Institutional Review Board
Cardinal Stritch University
Milwaukee, WI 53217

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PREFACE

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. The literature cites various incidents where investigators as well as universities have been fined, and/or their research activities have been jeopardized because of violation of the rights of human participants*. The Ethical Issues Committee, the precursor of the Institutional Review Board (IRB) at Cardinal Stritch University, was formed in 1985. The Committee was formed to address issues related to research conducted by faculty, staff, and students at the University, with Asuncion Miteria Austria, Ph.D serving as its Chair. The first task of the Committee was to develop guidelines to be followed in conducting research involving human participants. In 1987 the Institutional Review Board was formed and the policies implemented in Spring, 1988. Since then, there have been revisions and new policies promulgated all aimed to protect both research participants and investigators.

The IRB and its College Advisory Committees have oversight functions and ensure that the research conducted by the University community complies with Federal guidelines concerning the protection of human participants. The IRB and the College Advisory Committees are responsible for assessing the scientific value and validity of the research proposals. A proposal that poses even minimal risk will not be approved if the IRB has evidence that it has no scientific merit and the proposal's design is capricious and lacks scientific validity. The IRB and its Advisory Committees are not responsible for evaluating the research methodology unless the methodology presents research risks to the participants and ethical principles are comprised.

It is important to remember the three principles that will assist investigators in understanding the ethical issues inherent in research involving human participants.
They are:

Respect for Persons. This principle demands that participants enter into research voluntarily and with adequate information. Investigators need to obtain informed consent from the participants.

Beneficence means that participants need to be treated in an ethical manner, not only by respecting their decisions and protecting them from harm, but also by making efforts to secure well being.

Justice ensures the fair selection of participants such that no group is systematically selected simply because of its easy availability, manipulability, or a compromised situation (e.g., minors, prisoners, older persons, persons with developmental disabilities, etc.)

*The term "participant" is used here to replace the older term "subject". Although generally synonymous, the term "participant" emphasizes the voluntary nature of research involvement. The term "subject" (frequently used by the federal government) often refers to animals whose involvement is not necessarily voluntary.

This volume represents a major revision in terms of restructuring the IRB and the inclusion of all policies and guidelines that have been developed over the past years.

I want to thank the following members of the IRB who worked tirelessly in making this revised volume possible:

Sharon Garrett, MSN, College of Nursing
Sheila Isakson, MA, College of Business and Management
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Joan Kramer, MS, College of Business and Management
Don McCarty, Ph.D, College of Education
Debra Meuler, Ph.D, College of Arts and Sciences
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Most of all, I want to thank the advisors, investigators, and the entire University community for their support and patience throughout the duration of the revision.

Asuncion Miteria Austria, PhD
Chair, IRB, 1987-2001
College of Arts and Sciences

General Objective of Cardinal Stritch University

Cardinal Stritch University has continued, over the years, to reflect as a community on its ultimate purposes and goals. Those purposes and goals find their roots in the Mission Statement of the University.

A. Mission Statement

Cardinal Stritch University is an independent Catholic institution of higher education by the Sisters of St. Francis of Assisi. The University, rooted in the liberal arts, provides graduate and undergraduate programs to prepare students for life and for professional careers.

The University assists women and men in pursuing lifelong learning. It provides both traditional and non-traditional approaches to meet the educational needs of a diverse student body. The University strives to be a caring community. Its faculty and staff regard superior instruction and personal attention to each student as keys to quality education. In addition, faculty members model and promote meaningful integration of theory and practice.

Faculty, staff, administration, and trustees cooperate actively to anticipate and address the emerging needs of students, the Stritch community and society. The vitality of educational life is enhanced by the commitment of the University to programs of direct service to people who might not otherwise be served.

In keeping with Franciscan values and guided by the Judeo-Christian tradition, the University fosters the moral, spiritual, intellectual, cultural, emotional, social and physical development of each person. Finally, the University promotes the development of men and women who are committed to religious principles, who possess moral and aesthetic values, and who take their places as responsible persons, serving the local and global communities.

B. Historical Perspectives

Cardinal Stritch University is a four-year, co-educational institution chartered in 1937. The University, which is operated by both religious and lay personnel, is fully accredited by the North Central Association of Schools and Colleges. The University has been and remains committed to excellence in teaching. It is recognized that research is one of many channels through which excellence in teaching is maintained. Further, the University recognizes that to be true to its Mission it must protect the rights and welfare of human participants participating in research and related experiments. Concern for establishing and maintaining the appropriate safeguards takes precedence over the completion of scholarly research projects.

On July 12, 1974, the National Research Act (Pub.L. 93-348) was signed into law. The passage of this law created the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research. One of the primary tasks of the Commission was to identify the basic ethical principles regarding the conduct of biomedical and behavioral research involving human participants and to develop guidelines to be followed, thus assuring that research is conducted according to these ethical principles. The deliberations of this Commission have come to be known as the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Participants of Research.* The *Belmont Report* sets forth the basic ethical principles and guidelines regarding the conduct of research and human participants.

The Department of Health and Human Services (HHS) on March 8, 1983, published regulations to be followed by Institutional Review Boards (IRB) in reviewing research where human participants are involved.

The safeguards in place at Cardinal Stritch University are grounded and specified in the University Mission Statement. The Board bases its activities and recommendations on the following documents, as they are presently constituted and as they may be revised. Other sources of guidance may be consulted by the Board at its discretion to clarify questions of the interpretation or implementation of the documents.

The Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Research, promulgated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

Protection of Human Subjects, Title 45 Code of Federal Regulations Part 46, revised as of June 18, 1991. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

American Psychological Association. (2002). Ethical principles of psychologists and code of conduct. *American Psychologist* 57(12), 1060-1073. http://www.apa.org/ethics/

C. Assurances

Although the Department of Health and Humans (HHS) regulations exempt some types of research from IRB review and allow institutions some flexibility in reviewing research, each institution is required to develop a statement of principles to be followed in the discharge of its responsibilities for protecting the rights and welfare of human participants of research conducted at or sponsored by the institution. In its conduct of research and related scholarly activity, Cardinal Stritch University remains steadfast in its dedication to protect the rights and welfare of human participants. Such a dedication flows from the institutional commitment to Christian values and a Franciscan tradition. Cardinal Stritch University adopts the Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," the Code of Federal Regulations 45 CFR 46, and the APA (1981) Ethical Principles of Psychologists as guides.

To ensure compliance with these ethical standards, the University's IRB is registered with the Federal Government's *Office for Human Research Protections* and has filed *Federalwide Assurances* (http://www.hhs.gov/ohrp/).

D. Authority

The Cardinal Stritch University policy for the protection of human participants shall apply to all research involving human participants regardless of the source of projects funds, if any. This scope applies to faculty, staff, and students alike.

Cardinal Stritch University Institutional Review Board

With the exception of the College Research Advisory Committees, the following policies are required by the Federal Government's Department of Health and Human Services, Office for Human Research Protections.

A. Structure

Cardinal Stritch University has a two-tiered committee structure to protect human participants from research risks. There is a Central committee (IRB) and four separate advisory committees, each representing a college within the University. The Advisory committees are 1) the College of Arts and Sciences Committee, 2) the College of Business and Management Committee, 3) the College of Education and Leadership Committee, and 4) the College of Nursing Committee.

Each advisory committee shall consist of at least three members with experience and expertise in the general subject matter of the committee. The Chair of each advisory committee serves as a full voting member of the Central IRB. The Advisory Committee may recruit members from other colleges. Each Advisory Committee shall submit minutes, including proposals reviewed, to the IRB.

B. IRB Membership

The IRB shall have at least six members with varying backgrounds, and preferably with at least one year of IRB experience, to promote complete and adequate review of research activities commonly conducted by the institution. To promote respect for its advice and counsel in safeguarding the rights and welfare of human participants, the IRB members shall be sufficiently qualified through experience, expertise, and diversity. This diversity should include consideration of race, gender, cultural background, and sensitivity to community attitudes. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall include members who are able to ascertain the acceptability of proposed research consistent with institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both genders, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

There must be at least one member whose primary concerns are in non-scientific areas, for example, lawyers, ethicists, and members of the clergy. One member, at least, is not to be affiliated with the institution. No IRB may have a member participating in the IRB's initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB. The IRB may, at its discretion, invite an individual with competence in special areas to assist in the review of complex issues, which requires expertise beyond or in addition to that available on the IRB.

If an IRB regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women, persons with mental disability or older people, consideration shall be given to the inclusion of one of more individuals who are knowledgeable about and experienced in working with these participants.

Membership on the Central IRB shall include:

1. Chair, IRB (from one of the areas listed below)
2. College of Arts and Sciences Committee Chair
3. College of Business and Management Committee Chair
4. College of Education Committee Chair
5. College of Nursing Committee Chair
6. "Non-scientific" representative
7. "Non-institutional" representative

Cardinal Stritch University faculty on the College Research Advisory Committees (RACs) and the Central IRB shall be appointed by the Faculty Council. The four RACs will determine the chairs of their respective committees. Those chairs will automatically become members of the Central IRB. The chair of the Central IRB will be appointed by majority approval of the Central IRB faculty members. In case of a tie, the Central IRB chair will be appointed by the chair of the Faculty Council. Non-institutional members will be determined by the Central IRB.

C. Procedures for Reviewing and Approving Research

The faculty researcher or the student investigator (with the assistance of the faculty advisor) prepares all the necessary documents. A Human Participants Research Protocol will be submitted in every case. Other documentation that may be needed is described in IRB Instructions. The documents are submitted to the appropriate College Research Advisory Committee Chair who will review and classify the proposal as either exempt, expedited, or one that requires Central IRB review (see Definitions in Appendix A).

1. The College Research Advisory Committee reviews the proposal and takes one of the following actions:

a. Approve
If the Advisory Committee determines that the research falls within the exempt category, the Advisory Committee approves the research and notifies the principal investigator and the advisor that the research can proceed without further review.

b. Request additional information
If more information is required, the research proposal is returned to the principal investigator or research advisor for clarification of specific areas. The proposal is resubmitted to the Chair of the Advisory Committee, who may approve the protocol without convening the full committee.

c. Approve Conditionally with Recommended Changes
If the Advisory Committee recommends changes, the research proposal is conditionally approved and returned to the principal investigator and/or research advisor. The principal investigator submits the revised proposal to the Chair of the Advisory Committee.

d. Send to the Central IRB
For all research involving human participants that does not qualify under the criteria for exempt or expedited research proposals, the Advisory committee forwards the proposal to the Central IRB for review.

2. Central IRB Review

All research which is funded, not exempt and/or which involves protected populations, more than minimal risks, illegal behavior, or sensitive topics are reviewed by the Central IRB. The Central IRB takes one of the following actions:

a. Approve the project.
The IRB will inform the principal investigator or research advisor to proceed with the project.

b. Request additional information
If more information is required the research proposal is returned to the principal investigator or research advisor for clarification of specific areas. The proposal is resubmitted to the Chair of the Central Committee, who may approve the protocol without convening the full committee.

c. Approve conditionally with recommended changes
If changes are required, the proposal is returned to the principal investigator and/or research advisor for revision. The modified proposal is then resubmitted directly to the Central IRB Chair or designated person.

d. Disapprove

3. Meeting minutes

Minutes of RAC and Central IRB meetings, which list protocol decisions, are sent to the Dean of Academic Affairs and the President of Faculty Council.

D. Revision of Previously Approved Research

Research must be conducted in the manner in which it was approved by the IRB. If a researcher wishes to change or modify the research that has been approved, a request for approval of such change or modification must be filed with the appropriate College Advisory Committee Chair. Minor changes may, at the discretion of the chair, be reviewed through the expedited review process (see Expedited Review Procedures). Major changes must be reviewed using the procedures through which original approval was granted. The IRB RAC Chair determines whether proposed changes are major or minor.

If the principal investigator, student advisor, or any individual involved in data collection or interaction with participants determines a procedural change is required to eliminate apparent or immediate hazards to the participants, these changes should be made in a timely fashion and then reported, within five working days, to the chair of the Central IRB. This includes unanticipated problems involving risks to the participants or others, noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB, or any suspension or termination of IRB approval. In such cases, the President of Academic Affairs and, if appropriate, OHRP will be contacted by the chair of the Central IRB.

In cases where changes are made without IRB approval, details of the incident will be forwarded by the IRB to the student’s advisor (if applicable), the Dean of the College, and the Dean for Academic Affairs. The Deans will determine if disciplinary action is warranted. Note that random audits of research records may be made to ensure IRB compliance.

E. Extended or Additional Protocol Review

Under certain circumstances the principal investigator may be asked to submit a progress report prior to the termination of data collection. This could include, but is not limited to

- Studies in which participants are expected to be exposed to unusual levels or types of physical, psychological, reputation or legal risks.
- Research in which participants have voiced concerns about their treatment.
- Projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB.

Depending on the type and level of risks, adjustments in the study's procedures may be required. The IRB will determine and inform the principal investigator which projects require on-going review either prior to data collection or, if warranted, during data collection.

Projects may also require verification from sources other than the investigator to ensure no material changes have occurred since the original IRB review. This could include, but is not limited to,

- Studies in which participant contact and data collection are performed by a cooperating institution or individuals other than the principal investigator.
- Studies in which participants are expected to be exposed to unusual levels or types of physical, psychological, reputation or legal risks.
- Research in which participants have voiced concerns about their treatment.
- Projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB.

The IRB will determine and inform the principal investigator which sources must verify approved procedures either prior to data collection or, if warranted, during data collection.

F. Training

To ensure principal investigators and faculty advisors understand their responsibilities toward their participants, each investigator (faculty, staff, student and advisor) must complete on-line training. Those completing training will be certified to submit a research protocol to the IRB. Training must be completed every three years. Certain training programs may be substituted for the one recommended by the IRB. However, the IRB must review and approve the program before research may begin.

Types of Research

Research involving human participants may fall into one of three categories: exempt, expedited, or that which requires Central IRB review.

Exempt Research

Research is exempt from Central IRB review if it is included in one of the five categories listed below and involves no more than minimal risk to participants. Research which is, or is thought by the faculty researcher or faculty advisor to be, exempt must, however, receive a preliminary review by the advisory committee appropriate to the specific discipline. Exempt research should also meet the requirements of minimal risks, non-protected population, and be non-funded.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practice, i.e., (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 test (cognitive, diagnostic, aptitude achievement), if information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to participants.

3. Research involving survey or interview procedures, except where one or more of the following conditions exist: (a) responses are recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the subjects, (b) the participant's responses, if they became known outside of the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (c) the research deals with sensitive aspects of the participants own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

4. Research involving the observation, including observation by participants, of public behavior, except where one or more of the following conditions exist: (a) observations are recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the participants: (b) the observations recorded about the individual, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability; or (c) the research deals with sensitive aspects of the participant's own behavior such as illegal drug use, sexual behavior, or use of alcohol.

5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Expedited Review

Research in the categories listed below which involve no more than minimal risk may, at the discretion of the IRB chairperson, be reviewed using expedited review procedures (45 CFR 46.110). The expedited review procedures may also be used to review minor changes in previously approved research during the period for which approval has been authorized. Under the review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with Central IRB procedures.

The IRB Chair, or the person designated to conduct expedited reviews, should report on all reviews conducted through expedited procedures at regularly scheduled meetings of the IRB. The categories of research involving no more than minimal risk, which may be reviewed by the expedited procedures, are:

1. Collection of hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

2. Collection 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.

3. 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 subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencepthalography, thermography, and detection of natural occurring radioactivity, diagnostic echography, and electroetinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and more often than tow times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

5. 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.

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

7. Moderate exercise by healthy volunteers.

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

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

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

11. Other similar types of research, as announced in the *Federal Register* or as necessitated by future research projects.

Research that Requires Central IRB Review

All research which is funded and/or which involves protected population (e.g., minors, persons with mental retardation, or psychiatric disability), deception, sensitive topics (e.g., illegal behavior, sexual behavior), or more than minimal risks are reviewed by the Central. IRB.

Student Research

A research project is considered to be **student research** if one or more students are acting as the principal or co-investigators. Such research will normally be conducted on an independent study basis, which fulfills graduation requirements **(**e.g., **Master's Thesis, Doctoral Dissertation, or Undergraduate Senior Thesis),** or as **a course requirement**. In both cases, the research is under the direction of the faculty member who is the advisor to the project. Research in which a faculty member is the principal investigator and one or more students are acting as research or laboratory assistants is **NOT** considered student research.

The Institutional Review Board has the same responsibility for ensuring the welfare of human participants in student research as in any other research. Therefore, there may be **NO** recruitment of participants and **NO** data may be collected without an approval letter from the IRB.

The following are the procedures in obtaining IRB approval for student research:

1. **Thesis research (and other independent projects):**

   For independent student research projects, the requirements and procedures for obtaining IRB approval are exactly the same as for faculty research, with one exception. Briefly, this means that the student (with the assistance of his/her faculty advisor) prepares all the necessary documents. These documents are then submitted to the appropriate College Advisory Committee Chair. Although the student will be listed as the principal investigator in all documents, the faculty advisor acts as principal investigator in interacting with the College Advisory Committee or with the Central IRB, and is ultimately responsible for the welfare of human participants.

2. **Class projects (several students):**

   The course instructor is responsible for determining the level of risk and classification of the research type for all of the students' projects, and preparing all the necessary documents. If all (or several) of the individual projects require either "exempt " or "expedited" review, then a "blanket" approval may be given.

   The faculty member should submit a Human Participants Research Protocol (HPRP), with a general description of all projects. Such approval is **valid for 12 months.** The course instructor's name should appear as the faculty advisor and "Students enrolled in _____ (course name and number)" should appear as the principal investigator.

   In the event that any of the projects require Central IRB approval, such projects must be considered separately, with all of the appropriate documents. Again, the course instructor is responsible for making sure that the documents are prepared by the student in accordance with the requirements described elsewhere in this manual. On these documents, the student will be listed as the principal investigator, with the course instructor as faculty advisor. The course instructor submits the documents to the appropriate College Advisory Committee Chair, acts as principal investigator in interacting with the College Advisory Committee, and is ultimately responsible for the research and welfare of human participants.

   Note: If a student does not want personal contact information to be available to participants, arrangements should be made with his or her advisor or department to have <u>institutional</u> contact information placed on the HPRP form instead.

Investigator Responsibility in the Conduct of Research

Investigators must recognize the boundaries of their competence and the limitations of their techniques. The maintenance of high standards of competence is a responsibility shared by all investigators. They also use techniques only for which they are qualified by training and experience. In those areas in which recognized standards do not yet exist, investigators must take whatever precautions are necessary to protect the welfare of their human participants. They must maintain knowledge of current scientific and professional information related to their research activity.

The decision to undertake research rests upon a considered judgment by the individual investigator about how best to contribute to science and human welfare. Having made the decision to conduct research, the investigator considers alternative direction in which research energies and resources must be invested. On the basis of this consideration, the investigator must carry out the investigation with respect and concern for the dignity and welfare of the people who participate and with cognizance of federal and state regulation and professional standards governing the conduct of research with human participants.

In conducting research the following must be considered:

a. In planning a study, the investigator has the responsibility to make a careful evaluation of its ethical acceptability to the extent that if the weighing of scientific and human values suggests a compromise of any principle, the investigator incurs a correspondingly serious obligation to seek ethical advice and to observe stringent safeguards to protect the rights of human participants.

b. The study must be properly designed, scientifically sound and likely to yield valid results. Risks to participants are minimized by using procedures consistent with sound research design that will yield useful data and that do not unnecessarily expose participants to risk.

c. Considering whether a participant in a planned study will be a “participant at risk” or a “participant at minimal risk,” according to recognized standards, is of primary ethical concern to the investigator. (See definition of minimal risks in Appendix A).

d. The investigator always retains the responsibility for ensuring ethical practice in the research. The investigator is also responsible for the ethical treatment of research participants by collaborators, assistants, students, and employees, all of whom incur similar obligations.

e. The investigator must establish a clear and fair agreement with research participants prior to their participation, which clarifies the obligations and responsibilities of each. The investigator has the obligation to honor all promises and responsibilities of each. The investigator must inform the participants of all aspects of the research that might reasonably be expected to influence willingness to participate and explain all other aspects of the research about which the participants inquire. Failure to make full disclosure prior to obtaining the informed consent requires additional safeguards to protect the welfare and dignity of the research participants.

f. The participant must be competent to understand the ramifications of his or her involvement in the study. Research with children, participants who have impairments that would limit understanding and/or communication, or individuals who speak a different language requires special safeguarding procedures. Thus, if the participant is not competent because of age, illness, incapacity, or any other reason, the

participant may not be included in the research unless authorized by a parent, guardian or legal representative. With few exceptions, the potential participant must also give consent.

g. Methodological requirements of a study may make the use of concealment of information or deception necessary. Before conducting such a study, the investigator has a special responsibility to 1) determine whether the use of such techniques is justified by the study's prospective scientific, educational, or applied value; 2) determine whether alternative procedures are available that do not use concealment or deception; and 3) ensure that participants are provided with sufficient explanation as soon as possible.

h. The investigator must respect the individual's freedom to decline to participate in or to withdraw from the research at any time. The obligation to protect the freedom requires careful thought and consideration when the investigator is in a position of authority or influence over the participant. Such positions of authority include, but are not limited to situations in which research participation is required as part of employment or in which the participant is a student, client, or employee of the investigator.

i. The investigator must protect the participant from physical and mental discomfort, harm, and danger that may arise from research procedures. If risks of such consequences exist, the investigator must inform the participants of that fact. Research procedures likely to cause serious or lasting harm to a participant are not to be used unless the failure to use these procedures might expose the participant to risk of greater harm, or unless the research has great potential benefit and fully informed of procedures for contacting the investigator within a reasonable time period following participation should stress, potential harm, or related questions of concern arise.

j. After the data are collected, the investigator must provide the participants with information about the nature of the study and attempt to remove any misconceptions that may have arise. Where scientific or human values justify delaying or with holding this information, the investigator incurs a special responsibility to monitor the research and to ensure that there are no damaging consequences for the participants including long-term effects.

k. Where research procedures result in undesirable consequences for the individual participant, the investigator has the responsibility to detect and remove or correct these consequences including long-term effects.

l. Information obtained about a research participant during the course of an investigation is confidential unless otherwise agreed upon in advance. When the possibility exists that others may obtain access to such information, this possibility, together with plans for protecting confidentiality, must be explained to the participant as part of the procedure for obtaining informed consent.

Adapted from: American Psychological Association. (2002). Ethical principles of psychologists and code of conduct. *American Psychologist* 57(12), 1060-1073. http://www.apa.org/ethics/

Rules and Procedures on Disapproved Proposals

Disapproved Proposals Submitted by Student Investigators

1. The IRB Chair will notify the student investigator and the advisor or course instructor in writing of the non-approval of the submitted protocol. The notification memo will specify the IRB concerns and its reasons for the disapproval.

2. The student investigator must respond in writing, addressing the IRB concerns within four weeks from the date of the notification.

3. If the IRB does not receive a response from the student investigator after four week, the IRB chair will notify the student and the advisor or course instructor in writing that no response has been received. Copies of this memo will be sent to the Department Chair and the College Dean.

4. The advisor or course instructor, who has the responsibility to ensure the student's compliance with IRB guidelines, is then required to advise the IRB in writing how compliance with IRB guidelines will be achieved.

5. If the proposed research project is nevertheless completed in a manner which fails to comply with Federal guidelines as outlined by the IRB, the student must be given an "F" grade for the research project as it is a violation of the rights of human participants and Federal guidelines and places the entire University in jeopardy.

Disapproved Proposals Submitted by Faculty Investigators

1. The IRB Chair will notify the faculty investigator in writing of the non-approval of the submitted protocol. The notification memo will specify the IRB concerns and its reasons for the disapproval.

2. The faculty investigator must respond in writing, addressing the IRB concerns within four weeks from the date of the notification.

3. If the IRB does not receive a response from the faculty investigator after four weeks, the IRB Chair will notify the faculty investigator and the Department Chair in writing that no response has been received.

4. The Department Chair has the responsibility to ensure the faculty member's compliance with IRB guidelines.

5. If the proposed research project is nevertheless completed in a manner that fails to comply with Federal guidelines as outlined by IRB, the faculty member will be informed that the research project is a violation of the rights of human participants and Federal guidelines and places the entire University in jeopardy.

Informed Consent

Requirements for Informed Consent

The investigator has the responsibility to obtain the legally effective (signed), informed consent of the participant (or participant's legally representative) involved in research, experiment, or other activity, regardless of the agency or other sponsoring funding.

The investigator has a serious obligation to maintain ethical standards of competence and to observe safeguards that will ensure the rights and respect the dignity and welfare of the human participants. The investigator shall at all times minimize the possibility of coercion or undue influence and provide sufficient opportunity to the participant or the participant's representative to consider whether or not to participate in the study.

The following information, which constitutes the basic elements of informed consent as defined by the Code of Federal Regulations 45 CFR 46, Protection of Human Subjects (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm), shall be provided to each prospective participant:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the participant;

3. A description of any benefits to the participant or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be expected from the research;

5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of research-related injury to the participant; and

8. 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.

Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each participant:

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;

2. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent;

3. Any additional costs to the participant that may result from participation in the research;

4. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;

5. A statement that significant new findings developed during the course of research which may relate to the participant's willingness to continue participation will be provided to the participant; and

6. The approximate number of participants involved in the study.

In addition, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive such requirements provided the IRB funds and documents that:

1. The research involves no more than minimal risk.

2. The waiver or alteration will not adversely affect the rights and welfare of the participants.

3. The research could not practically be carried out without the waiver or alteration.

4. The participants will be provided with additional information after participation, whenever appropriate.

Documentation of Informed Consent

Informed consent involves the use of a written consent form approved by the IRB and signed informed consent shall be given to the participant.

All information given shall be in a language understandable to the participant or his/her authorized representative. The informed consent must not include any exculpatory language through which the investigator, the sponsor, or the institution forms liability for negligence.

The consent form should contain some of the following elements:

1. Title of research project
2. Description of the project
3. Description of the procedures
4. Alternative procedures if there are any
5. Possible risk to the participant
6. Assurance of confidentiality
7. Benefits to be derived from the research by the participant or by society in general
8. Statement of voluntary participation on the part of the participant and the freedom to withdraw from the study without suffering any penalty
9. Contact for inquiries regarding the research (address and telephone number of Principal Investigator or major advisor)
10. Person to whom complaints about treatment may be referred (the IRB chair)
11. Statement asserting that the participant or a legally authorized representative has received adequate explanation of the research project and agrees to participate in the study
12. Signature of the participant and the date of the agreement (signature is not necessary in certain cases where the signature would link the participant to responses that might be detrimental to the participant).
13. In the case of a minor child or dependent, the name of that person and the signature of the legally authorized representative
14. Statement of approval of the project proposal by the Cardinal Stritch University Institutional Review Board for the Protection of Human Participants

Research Agreement Forms

If the research project involves institutions other than Cardinal Stritch University, the principal investigator needs to submit one of the following:

1. **Affiliation Agreement Form –** A signed Agreement Form on the institution's letterhead is needed if the principal investigator from Cardinal Stritch University is conducting research at their facility, conducting research with their students or personnel, or accessing their research/data records.

2. **Cooperative Research Agreement Form –** A signed Cooperative Agreement Form on the institution's letterhead is needed if the project is collaboration between Cardinal Stritch University and another institution. Cooperative Research includes instances in which professors, staff, or students conduct studies in collaboration with another institution, agency, corporation, or facility other than Cardinal Stritch University. In such instances, regardless of funding sources the lead or prime contracting institution or agency is responsible for safeguarding the rights and welfare of the human participants. Also, each cooperating institution or agency shall comply with the Department of Health and Human Services regulations. Each institution shall conduct its own review and submit a signed copy of the research proposal to the other institution. However, to avoid duplication of effort, a cooperating institution may rely on the review of the prime or lead institution. Alternatively, the institutions may use a joint review of some similar arrangements.

Research with Animals

If Cardinal Stritch University conducts research with animals, the institution is to establish an Institutional Animal Committee in accordance with the Improved Standards for Laboratory Animal Act passed November 23, 1985 (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm). The committee will conduct semiannual inspections, file reports with the facility and notify the proper federal agency of violations. The committee, which is to represent "society's concerns," must consist of at least three members, one of whom must be a veterinarian and one who is not associated with the institution.

Appendix A
IRB Definitions
Cardinal Stritch University

1. **Affiliation Agreement** is an agreement between the researcher and institution/agency where the researcher is employed and will conduct research with human subjects.

2. **Anonymity** is the inability of a researcher or any other individual to link a research participant with his or her data.

3. **Competence** involves the use of procedures and techniques used only by qualified and/or experienced researchers, with care being taken to protect the welfare of the participants.

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

5. **Cooperative Research Agreement** is an agreement between two or more different institutions/agencies to conduct research with human subjects.

6. **Dependent variable** means the variable, or event that is being measured; the variable that is affected by the manipulation of the independent variable (e.g., the number of correct answers on a test, the answers to a survey question).

7. **Deception** is involved when participants are not informed about the risks of research in order to gain cooperation from the subjects. (Note; care must be taken to identify research in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigator).

   An alternative definition of deception means that participants may not be fully aware that they are involved in the research. The deception by a researcher for the purpose of securing participant's cooperation and/or to prevent potentially biased reporting of data by the participant is allowable provided that all of the following conditions are met:

   1) Deception is necessary due to lack of alternative procedures for data collection not involving deception;
   2) The deceptive procedures will not place participants at significant financial, physical, psychological, or social risks;
   3) Careful debriefing whereby the participants are fully informed of the nature and purpose of the deception will follow the data collection/experiment.

8. **Exempt research** includes those activities in which there is minimal participation of human participants as defined in OPPR Report 455 CRF Section 46.101.

9. **Expedited research** is that which involves no more than minimal risk to the participant or for which a previously approved protocol requires minor changes. Approval is obtained from the IRB Chair or designated IRB member.

10. **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** protects against the misuse or disclosure of the participants health records and personal information.

11. **Human participant** means a living individual with whom an investigator (faculty, staff, or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46.102).

12. **Informed consent** is a statement of agreement to be signed by the participant and/or his/her parent or legally authorized representative in whom s/he expresses a willingness to participate in the experiment detailed in the document.

13. **Independent variable** means the variable, or treatment that is manipulated by the research (e.g., if the different tests are given to different groups of participants, the type of test would be the independent variable).

14. **Institution** means any public or private entity or agency including federal, state, and other agencies.

15. **Instrument(s)** is a measuring device for determining the present value of a quantity under observation. Examples of an instrument might be questionnaires or surveys.

16. **Interaction** includes communication or interpersonal contact between investigator and participant.

17. **Intervention** includes both physical procedures by which data are gathered (for example venipuncture) and manipulations of the participant or the subject's environment that are performed for research purposes.

18. **Legalized authorized representative** is an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to allow participation in the procedure(s) involved in the research.

19. **Minimal risk** means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

20. **Private information** includes information about the behavior of an individual that occurs in a situation and will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is available to the investigator or associated with the information) in order to obtain information to constitute research involving human participants.

21. **Protocol** is a plan for scientific experiment or treatment.

22. **Research** means a systematic investigation, including methodology development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of these regulations, whether or not they are supported or funded under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

23. **Research proposal** is a written plan for the proposed research investigation containing basic information related to the area being researched.

24. **Sensitive or protected population** includes minors (17 years of age or younger), persons with mental retardation, people with mental disabilities, persons with developmental disabilities, prisoners, pregnant women and fetuses, or any individual who might not be capable of making an informed decision concerning participation (e.g., persons with mental illness or psychiatric disability) as defined by the code of federal regulations 45.CFR.