

Section One

Research Requirements for Madonna University

The process of research is one of discovery and problem solving. Research begins with defining a problem and considering the anticipated benefits of the study. A review of previous research helps to determine what others have learned about the problem. Further consideration is needed to specify the researcher's hypotheses about the relationship between the observations and theoretical constructs. Applied research looks at more practical constructs within specific institutions and organizations in relation to the observation. A research proposal creates a formal plan of actions and contract between the university, faculty, sponsors, and students. Development of this proposal incorporates standards for the ethical conduct of research. The mission of Madonna University is to instill in its students Christian humanistic values. Respect for the individual is valued and promoted in the application of ethical considerations to the conduct of research. Madonna University faculty operationalizes this by requiring all students involved in research education to receive training in research integrity and the protection of human subjects.

If the research involves human subjects, then the researcher must comply with ethical principles of human subject research described in this guide. This guidebook contains procedures for Human Subjects Review, Business, Nursing, Hospice, and Psychology research requirements, and procedures, and Graduate School procedures and forms. Faculty members conducting research are also required to comply with human subject protection requirements. Students need to discuss with their instructors and advisor the advantages and disadvantages of conducting a research thesis, practicum, or project.

Thesis Defined

The thesis is a formal, scholarly manuscript that describes all aspects of an independent investigation of a problem completed by the master's candidate under the guidance of a graduate faculty member. Typically, it contains chapters rather than sections. In addition to the [Madonna University Research Guide](#), the student should refer to the [Publication Manual of the American Psychological Association](#), Sixth Edition (2009) and other sources as directed by the faculty advisor.

The research thesis, project, or practicum may vary in length and comprehensiveness. The project or practicum typically takes a more informal format and may be formatted as a publishable manuscript. The student is encouraged to work with academic instructors and a faculty advisor to develop a plan of approach that can be effectively and efficiently executed. Development of a time table for completion of the thesis, project, or practicum may be helpful to the student. This time table should be developed in conjunction with the advisor to assure that the schedule is realistic considering the student's project and University resources.

Human Subjects Review Committee

The purpose of the Human Subjects Review Committee (HSRC) is to demonstrate the respect and value for human dignity held by Madonna University through ensuring that the rights and welfare of human subjects are protected in biomedical or behavioral research. The Committee follows Federal

Regulations set forth by the Department of Health & Human Services (Federal Register, 1981: Code of Federal Regulations 45 CFP 46, 1983) in response to the National Research Act (Public law 93-348, July 12, 1974).

The HSRC is a faculty standing committee. That is, the Faculty Affairs Committee appoints members of the HSRC on a rotating basis for 3-year terms at the beginning of each academic year. Committee representation includes faculty from the five academic divisions, the Dean of the Graduate School & Research, and one outside (non-university) member.

HSRC Objectives:

1. Review proposals for adherence to DHHS guidelines for the protection of human subjects involved in research activities conducted by students, faculty, and staff sponsored by Madonna University.
2. Assist in reducing Madonna University's exposure to legal liability that could arise if unethical practices were used in research projects involving human subjects.
3. Maintain protocol to allow for systematic review of applications for use of human subjects for research purposes (exempt, expedited, and full review.)

The HSRC will:

1. Review and have the authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy;
2. Monitor adherence to copyright laws and University policy with respect to instruments used in human research by investigators;
3. Develop and disseminate to students, faculty, and staff specific guidelines and materials to be used when making application;
4. Encourage students, faculty, and staff to increase their awareness of taking precautionary measures that will ensure the protection of the rights and welfare of human subjects.

Madonna University abides by professional and legal standards for ethical conduct, including the Nuremberg Code and the Ethical Principles of the American Psychological Association.

The excerpt below is from the United States Government Code of Federal Regulations, and should be followed when obtaining informed consent.

**FEDERAL POLICY
FOR PROTECTION OF HUMAN SUBJECTS
(Common Rule)
Effective Date: August 19, 1991.**

' 46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in

research covered by this policy, unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate, and that minimizes the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language, through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

- a. Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent, the following information shall be provided to each subject:
 1. A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject'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 subject;
 3. A description of any benefits to the subject 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 advantageous to the subject;
 5. A statement describing the extent, if any, to which confidentiality of records identifying the subject 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 subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

- b. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
 1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable;
 2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject;
 5. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject; and
 6. The approximate number of subjects involved in the study.
- c. An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the IRB finds and documents that:
1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in, or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
 2. The research could not practicably be carried out without the waiver or alteration.
- d. An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:
1. The research involves no more than minimal risk to the subjects;
 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 3. The research could not practicably be carried out without the waiver or alteration; and
 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- e. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws, which require additional information to be disclosed, in order for informed consent to be legally effective.
- f. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget, under Control Number 9999-0020.)

The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able

to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiments.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problem under study that the anticipated result (will) justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those that conduct or engage in the experiments.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Procedure for The Madonna University Human Subject Review Process

Procedure of the review process is summarized as:

1. The Human Subject Review Committee will accept completed applications for use of human subjects via the Madonna University Center for Research. Applications will contain all information and supplemental materials deemed necessary by HSRC to allow for sound decisions with respect to review outcomes. An application form is available in this guide. Applications requiring **full review** may be submitted September to May only. Proposals for exempt or expedited review will also be accepted in June and July; however, due to fewer faculty members available, reviews may take longer to process.
2. Applications that appear to meet criteria for exemption from review process will include a statement of rationale from the faculty advisor (or independent investigator) on the Application for Use of Human Subjects. The Chair of the HSRC will make the final decision regarding review status and respond to the investigator and advisor in writing.
3. Applications that appear to meet criteria for expedited review (to be carried out by a HSRC subcommittee composed of three committee members) include a statement of rationale from the faculty advisor (or independent investigator) directly on the Application for Use of Human Subjects. In expedited review, reviewers exercise complete authority of the total committee except that they may not disapprove the application. A full committee review is necessary to disapprove research. The Chair of the HSRC will respond to the investigator and advisor in writing. All members of HSRC will be informed of all outcomes of expedited reviews.
4. Applications that appear to need full committee review will be processed from the Center for Research to committee members at least five working days in advance of scheduled meeting. Investigators and advisors will be notified of committee decisions (approval; approval pending modification; disapproval) in writing by chair of HSRC.
5. Applications for use of human subjects that receive written approval allow the investigators to continue research activities as planned and to initiate human subject inquiry. Faculty and students must obtain written approval from the Chair of HSRC before moving ahead with human research. Applications that receive approval pending modification require the investigators to make specified changes and resubmit the application to the Center for Research for additional review. The research advisor should also receive a copy. Applications that receive disapproval require investigators to revise proposals in keeping with committee response and re-submit completed, new applications for HSRC review. The HSRC Chair or the Dean of the Graduate School and Research is available to clarify questions and concerns of investigators.
5. Records of all applications and corresponding decision outcomes will be maintained by the

Center for Research for a 3-year period.

HSRC Responsibilities

The HSRC maintains appropriate records for a 3-year period after research and project have been completed to include:

- Copies of all research applications for use of human subjects research proposals and sample consent forms.
- Minutes of HSRC meetings which are in sufficient detail to show attendance at the meetings, actions taken by the HSRC, the number of members voting for or against these actions, and the basis for requiring changes in or disapproving research, and a written summary of the discussion of controversial issues and their resolution.
- Records of continuing review activities.
- Copies of all correspondence between HSRC and the investigator.
- A list of HSRC members and their respective divisions.
- Written procedures for the HSRC.

Researcher Responsibilities

It is the responsibility of the investigator to:

- Complete the Research Integrity Training modules prior to proposing and conducting research.
- Understand the rationale underlying the protection of human subjects and become familiar with protocols adopted by Madonna University for review of applications for use of human subjects - exempt, expedited, and full review classifications.
- Seek direction as needed from faculty advisor and/or Center for Research during preparation of a detailed application for use of human subjects. The applicant should request this application be reviewed and co-signed by advisor, if applicable. Submit in a timely fashion a completed application for use of human subjects in accordance with HSRC guidelines.
- Comply with the decision of HSRC with respect to use of human subjects. If the HSRC calls for submission of additional materials or modification in the proposed use of human subjects, these requirements must be fulfilled. Written approval must be received from the Chair of the HSRC before the research with human subjects can be implemented.

- Keep faculty advisor informed of progress and any problem encountered regarding human subjects during research implementation phase. Should it become necessary to modify the data, collection instrument or procedure, the HSRC must be notified.

It is the responsibility of the faculty advisor to:

- Complete the Research Integrity Training modules prior to advising student research.
- Guide the student regarding the importance of protecting the rights and welfare of human subjects who are involved in research activities.
- Direct the student investigator in the design of an acceptable plan of action when including human subjects in research.
- Facilitate a systematic review of applications for use of human subjects by following HSRC protocol for exempt, expedited, and full review.
- Read and co-sign student investigator's application, making note of advisor's recommendation plus rationale if proposal qualifies for exempt or expedited review.
- Monitor student investigator's adherence to HSRC approved course of action involving human subjects.

Classification of Reviews

There are 3 classifications for review status: exempt, expedited, and full review. The committee using the guidelines below determines which classification to assign to a project.

Criteria for Exempt Status

Research is exempt that meets one or more of the following criteria:

(This classification is usually reserved for studies analyzing data that are public or collected for other reason i.e., classroom examinations used for course evaluation and research using documents such as medical records.) Only the HSRC may make the determination of exemption. The investigator may not self-determine.

1. Research conducted in established or commonly accepted educational settings involving normal educational practices such as research on regular and special education instruction strategies, or 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, or

achievement) if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

3. Research involving surveys or interviews procedures, EXCEPT where ANY of the following conditions exist:
 - a. Responses are recorded in such a way that human subjects can be identified, directly or through identifiers linked to subjects.
 - b. Subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.
 - c. Research deals with sensitive aspects of subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
4. Research involving the observation (including observation by participants) of public behavior, except where ANY of the following conditions exist:
 - a. Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to subjects.
 - b. Observations recorded about the individual, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability, or are damaging to the subject's financial standing or employability.
 - c. The research deals with sensitive aspects of the subject's own behavior such as illegal conduct, 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 subject cannot be identified, directly or through identifiers linked to the subject.

Criteria for Expedited Review

To qualify for expedited review, the research involves certain MINIMAL physical and/or psychosocial risk such as: (This classification is used for most survey and interview method protocols.)

1. Use of survey research instruments (interviews or questionnaires) and psychological tests, interviews, and procedures that are part of the standard battery of assessments used by psychologists in diagnostic studies and in the evaluation of judgmental, perceptual, learning, and psychomotor processes, provided that the subjects are volunteers and that the data will be gathered anonymously or such that confidentiality will be protected by procedures appropriate to the sensitivity of the data.
2. Program evaluation projects that entail no deviation for subjects from the normal requirements of their involvement in the program being evaluated or benefits related to their participation in such programs.

3. Research using standard protocols or noninvasive procedures generally accepted or presenting no more than minimal risk, even when done by students.

Criteria for Full Review

All other studies require full review for higher risk topics such as: (This classification includes any study involving venipuncture or other invasive procedures.)

1. Research that does use physically invasive procedures even when performed by fully qualified professionals.
2. Research that involves deception of the subject.
3. Any project that does not fit criteria for exempt or expedited review.

Typical Errors in the Application Process

There are several common errors that applicants make in the application process. If you have any questions, please consult your instructor, advisor, or the Dean of the Graduate School and Research for assistance. Follow the application instructions carefully.

Confusing anonymous and confidential. Anonymous means that any identifiable information about an individual is not collected. Confidential means that the subjects name or some other type of identifiable information is collected and the researcher promises to: 1) take precautions so that no one else ever sees the individual's data, and 2) the researcher destroys the confidential links when it is appropriate to do so.

Failure to fully inform subjects. The most common failure is to not tell the subjects that their participation is voluntary and that they may withdraw from the study at any time without any consequences. The researcher must also inform the subjects of both the potential risks and benefits of the study and whom they may contact if they have questions. For research at Madonna University, faculty and students may use the Dean of the Graduate School and Research or advisor as the contact. Other contacts such as the research advisor are preferable to the researcher in case the subject(s) may wish to indicate concerns about the research.

Failure to identify risks. Many applicants often make the statement: "As there is no risk of any kind in this study..." This statement cannot be true; there is always a risk associated with research.

Notification of Research Misconduct

If the conduct of any researcher is considered inappropriate, the person making this allegation must report it to the Dean of The Graduate School and Research. All misconduct matters will be investigated by the Dean of The Graduate School and Research and will be kept confidential until a formal report is written. The person who believes a misconduct investigation is needed should complete the **Report of Possible Research Misconduct**. See next page.

Madonna University
Report of Possible Research Misconduct

Note: This form is used to request the Dean of The Graduate School and Research to investigate the event that you believe was an incidence of misconduct. The Dean will investigate and report findings to the Academic Council of Madonna University and to the initiator of this form. The Dean's report will recommend appropriate actions following the policies in the Madonna University Faculty Handbook.

Your Name _____ Date _____

Your Address _____
Street City State Zip

Your Phone: Day _____ Evening _____

Name of Researcher _____

Title of Research Project (or subject nature)

Date of Incident _____ Place of Incident _____

Witnesses (if any) _____

Describe in detail the alleged incidence of misconduct:

(Signature)

(Date)

Send this report to:
Dean of The Graduate School and Research
Madonna University
36600 Schoolcraft Rd.
Livonia, MI 48150-1173