

Review Timeframes

Approximate timeframes for initial processing and review:

- Exempt Review: one-two weeks
- Expedited Review: three weeks
- Full Review: one month

These estimates do not include time needed for questions and revisions. Nor do they include holiday breaks and periods when faculty members are off contract. **IRB applications should be submitted well in advance of the start date for data collection.**

Informed Consent

More than just a form, Informed Consent is a process that ensures respect for people by offering them thoughtful consent to voluntarily participate. Informed consent is achieved when voluntary participants fully understand their rights and the expectations, risks and benefits of participating in a research project. The process is designed to provide potential participants sufficient information, in terms they can understand, so they can make an educated decision whether or not to participate in a research project.

Research Integrity Training

All researchers are required to complete a course in research integrity and human subjects' protection before they can conduct research involving human subjects. Madonna University offers UNV 3000 Research Integrity Training, an online course found in Blackboard. The researcher may self-register for this free course. Upon completion of the course, the three certificates of achievement are submitted for documentation and filing to the Center for Research.

Defining Research

"Any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"¹ is considered research. Human subject research encompasses questionnaires, surveys, interviews, tests, observations, and certain experimental procedures regardless of the content or routine nature of the study, even if it is preliminary in nature. Human subject research extends to any systematic collection of data from human subjects. If you plan to publish or share the results of your study in a public forum (anything outside of class), you meet the definition of contributing to "generalizable knowledge."

Human Subjects

All researchers who conduct or collaborate in a research activity are responsible for knowing whether or not their research involves human subjects. "A 'human subject' is a living individual about whom a researcher obtains either (1) data through interaction or intervention with the individual, or (2) identifiable private information."² In many cases, the determination of whether a particular research activity involves human subjects is not difficult, but in some cases, the researcher's judgment may be mistaken. When it is not clear to a researcher whether research activities involve human subjects, he or she is encouraged to seek advice from the Chair of the IRB or the Director of the Center for Research.

Submission of Faculty Research

Faculty projects such as Teaching Empowerment Team (TET) and Faculty Professional Development (FPD) fall under the same rules as other research. Many of these are exempt, but they must be reviewed to determine that status. A TET/FPD application form may be found on the Center for Research website.

¹ 45 CFR 46.102d, 2005

² 45 CFR 46.102f, 2005

You are invited to contact the IRB Chair or the Director of the Center for Research with any questions before or during completion of your application.

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LEARN MORE ABOUT MADONNA



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MISSION STATEMENT

The mission of Madonna University, a Catholic and Franciscan institution of higher learning, is to instill in its students Christian humanistic values, intellectual inquiry, a respect for diversity, and a commitment to serving others through a liberal arts education, integrated with career preparation and based on the truths and principles recognized within a Catholic tradition.

Madonna's mission receives its spirit from these Franciscan Values:

- Respect for the dignity of each person
- Peace and justice
- Reverence for creation
- Education for truth and service

THE CENTER FOR RESEARCH

HUMAN SUBJECTS RESEARCH REVIEW



PROCESS, PROCEDURES AND REQUIREMENTS

Purpose of the Institutional Review Board

Madonna University is committed to upholding Christian humanistic values in the conduct of all research that involves human subjects. This commitment is grounded firmly in its mission statement and core values that are inspired by Franciscan tradition. Therefore, in accordance with federal laws and standard university practices, all research projects involving human subjects require review and approval by the Madonna University Institutional Review Board (IRB) which has oversight responsibilities for subjects and researchers. (See *Determining When to Contact the IRB*)

Board Functions and Duties

The IRB reviews proposals for adherence to Federal regulations for the protection of human subjects involved in research activities conducted by students, faculty, staff, and external investigators at Madonna University. Research projects that involve students, faculty or staff as subjects, and research projects conducted by faculty, staff or students as part of their role at the University, are subject to Madonna University IRB review. Every effort is made to ensure that human subjects engaged in research are treated with dignity, adequately protected from risk of harm, and informed of their rights as research subjects.

The IRB must approve research protocols before any data collection begins. Approval is valid for one year. Research that is ongoing must be reviewed annually for continuing approval. Any changes in the protocol must be submitted for review prior to implementation. The IRB may withdraw approval and suspend research not being conducted according to approved protocol.

IRB Members

The IRB is comprised of faculty members elected by their colleges to serve a three-year term. The board chair appoints an individual who is not affiliated with the University to represent external constituents. The Director of the Center for Research serves as the University administrator.

When to Contact the IRB

You must contact the IRB if, in your role as a Madonna University student, faculty or staff member, you are conducting research with human subjects (regardless of source of subjects). Additionally, you must contact the IRB if you will be using Madonna University faculty, staff or students as subjects. Your research may be exempt from full review, requiring only minimal review, but you do not have the authority to make that determination. Even if your research has approval from another institution, you must apply to the Madonna University IRB. The IRB reserves the right to contact the other institution for clarification purposes.

Levels of Review

All projects require some review.

Exempt from Full Review – Research that involves less than minimal risk to the subjects; may include educational tests and methods, surveys, interviews where subjects are not identified. *Only the IRB, not the researcher, may determine if research is exempt.*

Expedited Review – Research that involves minimal risk to the subjects; i.e., recorded voices or images, use of names or codes to identify subjects, certain surveys, study interventions or observations of behavior.

Full Review – Research that involves greater than minimal risk or vulnerable populations; i.e., children or the incarcerated. The full IRB reviews the protocol and a quorum is needed for a decision.

If you are unsure about the level of review needed for your project, or whether it is considered human subjects research, contact the IRB Chair or the Director of the Center for Research.

