IRB Mission

The responsibility of the Marist Institutional Review Board (IRB) works with the College research community to help insure that human subjects engaged in research are treated with dignity adequately protected from risk of harm; and voluntarily give informed consent to participate in research.

For the purpose of this policy "human subject research" means any activity that meets the Office of Human Research Protections (OHRP) definition of "research" and involves "human subjects" as defined by OHRP. The IRB follows the ethical principals found in the Belmont Report and codified in CFR 45 Part 46.

Before any work may begin on a research protocol, the IRB must review and approve the research.

In addition, the *IRB* reviews all changes to research protocols *before* implementation. In accordance with federal regulations, the IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions, and requirements, or that has been associated with unexpected serious harm to subjects.

The IRB must conduct some form of risk-benefit analysis of all human subject research in an attempt to determine whether or not research should be done.

The Marist College IRB also reviews research conducted by outside investigators involving Marist College students, personnel, records, or facilities. Researchers not affiliated with Marist College, who wish to come onto the Marist College campus, or use Marist records to identify potential subjects, must either provide the IRB with a previously approved application from an IRB at an institution with an FWA or submit a new application to the Marist College IRB. The outside researchers must have approval from the Marist College IRB before they access Marist College records or contact Marist College students or personnel.

Regulation

The National Research Act of 1974 lead to the development of the Belmont Report, which outlines the primary ethical principles in human subjects review; these include "respect for persons", "beneficence", and "justice".

IRBs are themselves regulated by the OHRP within the Department of Health and Human Services (HHS). Additional requirements apply to IRBs that oversee clinical trials of drugs involved in new drug applications, or to studies that are supported by the United States Department of Defense.

IRBs are governed by Title 45 Code of Federal Regulations Part 46. These regulations define the rules and responsibilities for institutional review, which is required for all research that receives support, directly or indirectly, from the United States federal government.

Research

Belmont Report describes research as "an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective."

The OHRP provides the following definition:

"Research means a ***systematic investigation***, including research development, testing and evaluation, designed to develop or contribute to ***generalizable knowledge***. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." CFR 45 Part 46.102

This statement hinges on the definition of ***generalizable knowledge.***

For the purposes of the Marist College IRB, ***Generalizable Knowledge*** means that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied. This may include one or more of

the following:

- Presentation of the data at meetings, conferences, seminars, poster presentations, etc.
- The knowledge contributes to an already established body of knowledge
- Other investigators, scholars, and practitioners may benefit from this knowledge
- Publications including journals, papers, dissertations, and master's theses

If the project does not meet the definition of research (i.e. is not a systematic investigation or does not contribute to generalizable knowledge), as described above, then the project does not require IRB review and an IRB application is not required.

Examples of activities that typically are ***not generalizable knowledge*** include:

- Biographies
- Oral histories that are designed solely to create a record of specific historical events
- Service or course evaluations, unless they can be generalized to other individuals
- Services, or concepts where it is **not** the intention to share the results beyond Marist College
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is **not** the intention to share the results beyond the Marist community

For the purposes of this policy, a "**systematic investigation"** is an activity that involves a prospective study plan that incorporates data collection (quantitative and/or qualitative; new data or existing) and data analysis to answer a research question.

Human Research Subjects

A **Human Subject i**s defined by OHRP as - a living individual about whom an investigator (whether professional or student) conducting research obtains:

- Data derived through intervention or interaction with the individual, or
- Identifiable private information.

Identifiable information as defined by OHRP - means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Protected Populations
Some research may involve protected population groups. Research involving these populations who for various reasons cannot freely grant informed consent, must generally go through a Full Review.

Protected population includes these groups:

- prisoners
- minors (younger than 18)
- experiencing diminished capacity
- mentally or physically challenged
- pregnant (particularly for those projects where physical procedures, exercises, etc., will be performed).

All research involving protected populations must undergo a Full Review. The IRB must ensure these research involving these population groups is ethical and legal.

Informed Consent

No research involving 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 minimize 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.

Basic elements of informed consent:

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 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 (45 CFR 46.116).

Ethics and CITI Training

Any researcher using human subjects in a project affiliated with Marist College must treat their research participates ethically and conform to all state and federal regulations concerning research with human subjects. It is importation that all those involved with human subjects or their data be fully informed about ethical concerns and requirement when using human research participants. Federal policy requires that certain rights of human subjects be maintained and specific responsibilities of researchers be upheld and documented. An unfortunate history of violating basic human rights in the name of research has necessitated an act of Congress to insure that human research subjects are treated ethically. In order to insure that all researchers at Marist are aware of their responsibilities they must complete specific relevant CITI courses and submit their completion certificates with their proposal. The CITI course draw heavily from the Belmont Report and other resources which congress used to craft the Health and Human Services regulations that govern research with human subjects and the IRB.

The Collaborative IRB Training Initiative Program (CITI) is a leading online training program maintained by the Biomedical Research Alliance of New York (BRANY). It offers curricula in human subjects research, animal research, and the responsible conduct of research. The training requirement applies to anyone conducting human subjects research activities at Marist College. This means anyone working directly with human subjects or with identifiable data or biological specimens for research purposes under Marist College auspices. Investigators, research nurses, coordinators, students, technicians working with identifiable data, and faculty advisors would all need to obtain CITI certification. CITI contains modules on topics like informed consent, vulnerable populations, ethical principles and IRB regulations. Each module has a short quiz at the end to assess understanding. Over 1300 institutions are using CITI for their mandatory training.

All researchers who either, come in direct contact with participants or who have access to privately identified data must complete the required CITI training. Maris the completion of CITI training Basic Course in Social and Behavioral Research and the Responsible Conduct in Research Course (RCR) in Social and Behavioral Research. All researcher must attach the completion certificates for both courses to the IRB submission.

Review Process

All Marist College human subject research projects must undergo review and approval by the IRB prior to initiating research activities. The Federal Regulations for Protection of Human Research Subjects (CFR 45 Part 46) specify three categories of review (exempt, expedited, and full board) that an IRB can use to make a determination regarding human subjects research.

Exempt:

Under federal regulations, certain types of research may be exempt from further IRB review if the study involves no more than "minimal risk" and falls into one or more of six exempt categories. Minimal risk is defined by the federal regulations as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. The determination of exemption **may not** be made by the investigator. Exempt reviews are conducted by at least one member of the IRB. In order to qualify for review via exempt procedures, the research must not be greater than minimal risk and must fall into at least one of the exempt categories defined by federal regulations.

Summary of Exempt Categories:

1. Education research
2. Surveys, interviews, educational tests, public observations (that do not involve children)
3. Studies of public officials
4. Analysis of previously-collected, anonymous data
5. Public benefit or service program
6. Consumer acceptance, taste, and food quality studies

Expedited Review:

The IRB may use an expedited review procedure when the research involves no more than "minimal risk" to the subjects and where the only involvement of human subjects will be in one or more of the expedited category. For example: blood draws; non-invasive specimen samples; data collected from running on a treadmill; sensitive identified interviews; and secondary data analysis from non-public sources.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Full Review:

A full board review is required for research that is not eligible for exempt or expedited review. In short, research that is judged to involve more than minimal risk, or involves protected populations such as children, prisoners, or disabled individuals, must undergo a full board review. Individuals intending to conduct research that requires a full board review should allow ample time to complete the review process.

The following categories of research require full IRB approval:

- Projects for which the level of risk is determined by the IRB Chair to be greater than minimal.
- Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
- Projects that involve sensitive or protected populations (such as children or cognitively disabled individuals).
- Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

Extension of Previously Approved Research

To request re-approval, the researcher must complete and submit the IRB Extension Review form along with any required material as described in the instructions. This form is to be used in cases in which a researcher would like to extend the deadline of a previously approved and currently active study. No other changes to the proposal regarding procedure or personnel is allowed.

The Chairperson can approve both Expedited and Full Reviews, however, the chair may direct review to the entire committee. For full review, the outcomes of review of amendments by the convened board are the same as the options outlined under Initial Review by the Full Board.

Amendments to Previously Approved Research

A researcher may amend his/her approved protocol by submitting an IRB Amendment Review form. Minor changes can be approved by expedited review. All other changes will be reviewed by the full board.

The Chairperson can approve both Expedited and Full Reviews, however, the chair may direct review to the entire committee. For full review, the outcomes of review of amendments by the convened board are the same as the options outlined under Initial Review by the Full Board.

Review Outcomes & Approvals

Following the Review of either an Expedited or Full review the reviewer(s) can return on of three decisions; Approved, Approval Pending or Disapproved. Discussion on a full review may be deferred or tabled prior to the committee reaching a decision.

Approval: For studies which meet Federal and Institutional criteria for approval as laid out in 45 CFR 46.111, including:

- Risks to subjects are minimized
- There is an appropriate risk-to-benefit ratio
- The selection of subjects is equitable
- Appropriate procedures are followed for obtaining and documenting informed consent, or waiving or altering informed consent documentation or procedures
- The research plan has adequate provisions for monitoring the data collected in order to ensure subject safety
- Additional safeguards are included to protect the rights and welfare of any vulnerable populations involved in the research

Approval Pending: For studies which otherwise meet the above criteria for approval, but for which minor changes are required before approval may be granted. These changes can include anything from minor alterations to the study design to requests for the Investigator to re-write or re-word certain study documents, the consent form, for example. If the Board agrees, review of the Investigator's response to these requested changes may be undertaken by a Designated Reviewer, expediting the process.

Deferred: For research proposals which require substantive or complex changes, or additional information, before they meet approval criteria. The Board may vote to defer a final decision of approval or disapproval until the Investigators have had time to adequate respond the Board's concerns. Once the Investigator has responded, the study will again be reviewed by a fully convened IRB.

Disapproval: If a study does not meet approval criteria, and the Board cannot see that a deferral would change the situation, the Board may vote to disapprove a proposed study. If disapproved, no proposed study procedures may take place, and the study may not be re-submitted for review.

Tabled: If, due to a loss of quorum, or lack of time or expertise, the Board is unable to provide adequate review of a study, then the review may be postponed until another meeting.

For the IRB to pass any of these motions, a majority of the voting members must agree.

Approval Timeline

The timeline for expedited submissions will differ depending on the complexity of the submission and the number of submissions under review at that time. The committee does their best to process submissions as quickly as possible. Typical turnaround from submission date, to notification of approval, is two weeks, however the process can take as long as four weeks. Researchers should expect receive a letter from the committee four weeks after submission. If the review is taking longer than four weeks the researcher should contact the IRB.

A Full Review requires a meeting of the IRB committee. A quorum must be present for any vote. The IRB chairperson assigns submissions to a primary and secondary IRB reviewer for presentation at the full board meeting. Investigators may be invited to attend the meeting to answer questions from the board. At the conclusion of the meeting, the board votes and issues a determination. Full meeting of the committee are scheduled on an as needed basis. It can take as long as one month after submission for the committee to make

a decision so plan accordingly.

Collaborative Research

Whether additional IRB requirements apply to multisite /collaborative research often depends on whether an external site or personnel are engaged in human subjects research. Marist College relies on the federal guidance on engagement in research to determine whether IRB oversight for external sites or personnel is required and, if so, what IRB reliance mechanism to use to ensure oversight is in place. Researchers are encouraged to review the resources below to help determine what additional requirements may apply to their study and to contact the IRB Chairperson with any questions.

Marist IRB of Record

In some cases, Marist College may agree to serve as the IRB of record for an external site or individual engaged in human subjects research as part of a study reviewed by a Marist College IRB. Please review the guidance below for information on when the IRB may agree to serve as the IRB of record.

Relying on an Outside IRB

In some cases, the Marist College may cede IRB oversight to a non-Marist College IRB, particularly when the involvement of Marist College personnel is limited (e.g., data analysis). Studies eligible for review through an existing IRB reliance partnership also may qualify for review by a non- Marist College IRB. Please see the guidelines and FAQ below for additional information on when the IRBs will consider ceding IRB review as well as how to request review by a non-Marist College IRB.

What is a multisite study?

From an IRB perspective, multisite research includes projects or studies that involve collaboration with sites or individuals with not a Marist employee or student. Some examples of multisite and collaborative research include:

- An investigator with a Marist appointment is conducting a study involving other VA locations.
- UW-Madison investigator conducting a study at a community-based site with a community partners.
- UW-Madison investigator sharing identifiable or coded data/images/specimens collected for a study with researchers at another university or institution.

Are any IRB requirements different for multisite or collaborative research studies?

Yes. Although multisite studies undergo the same type of IRB review as single site studies, the IRB also must determine whether external sites or personnel need IRB approval in order to participate in study activities. This may include requiring a IRB reliance agreement such as an IRB authorization agreement or independent investigator agreement. In addition, the HS-IRBs require that all collaborative research studies have a protocol, regardless of the study's risk level.**When is IRB approval required for an external site or personnel?**

Whether IRB approval is required depends on whether the external site or personnel are engaged in human subjects research as defined by federal guidance. It also can depend on whether a study qualifies for exemption. Determining whether an external site or external personnel are engaged in research can be difficult and researchers are encouraged to consult with the IRB Chairperson.

Will the HS-IRBs consider serving as the IRB for an external site or personnel?

Yes. Depending on the nature of the study and the activities that will be conducted by the external sites or personnel, the IRB may consider serving as their IRB of record. Anyone for whom the IRBs serves as IRB of record must be listed as a study team member and must complete human subjects research training. For more information about when the IRBs may consider serving as IRB of record.

If the Marist College is serving as one of the sites for a multisite study, will the HS-IRBs consider ceding

IRB oversight to another IRB?

Yes, although it depends on the nature of the study and the study activities to be conducted at Marist College.

Does the IRB review process take longer for collaborative research studies?

Depending on the complexity of the study, the need for IRB reliance agreements, and the quality of the study materials, the IRB review process may take additional time. A well-prepared application and study protocol can help ensure that the IRB review process goes as smoothly as possible. The IRB Chairperson is available to assist researchers with addressing IRB requirements for collaborative research projects.

International Research

Introduction

When conducting international research, additional review and documentation is required from both the international site and the Marist College IRB. It is imperative that you start the process early and request a consultation with the IRB staff during the initial planning stages. If the PI is a student, we highly recommend that both the faculty mentor and student PI meet with the IRB staff consultant.

Email IRB@marist.edu to request an IRB consultation

When is IRB review required?

All human subject research conducted by Marist College faculty, staff, or students, regardless of funding source or the ***location*** at which the research will be conducted, requires submission to the Marist IRB.

What additional regulatory reviews are needed?

When research is conducted outside the United States, investigators must comply both with the U.S. regulations and with the local policies and regulations governing the international research sites. It is important to do your homework early and, if possible, enlist a local collaborator to help you address that site's requirements and assist in identifying who to contact and what is required to obtain ethics reviews and permissions to conduct research at that international site.

Definitions

Minimal risk: the probability and magnitude of physical or psychological harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life, or in routine medical, dental, or psychological examinations.

Greater than minimal risk: the research involves more than minimal risk to subjects.

Cultural appropriateness: Sensitivity and awareness of how other ethnic, racial, and/or linguistic groups differ from one's own. Sensitivity can be manifested through knowledge of different languages or manners of speech, norms, and mores, religious beliefs and practices, family structures and dynamics, community decision-making patterns, and class consciousness and socioeconomic realities.

Federal Wide Assurance (FWA): an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the U.S. Department of Health and Human Services (HHS).

Ethics committee: a committee that has been formally designated to approve, monitor and review biomedical and behavioral research involving humans. May also be referred to as an Institutional Review Board (IRB), an Independent Ethics Committee (IEC), an Ethical Review Board ERB) or Research Ethics Board (REB).

What is required for Minimal Risk studies?

Depending on the international site, local ethics committee review may not be required. It is the responsibility of the PI to contact the appropriate entity who will make that determination and obtain written documentation that

review is not required. However, even if local ethics committee review is not required, additional documentation will be required to assess the cultural appropriateness of the proposed research and activities to be performed.

Two documents are required for studies where international regulations *do not* require local ethics review

1) Memo of Cultural Appropriateness authored by an individual completely independent of your study who is highly familiar with the culture of the region where the research will be conducted

Required elements:

- Reference the title of the study displayed in the IRB application
- Describe the expertise of the individual preparing the letter to address the local cultural and social norms
- Confirm they understand the intent of the research and activities to be performed
- Confirm the planned study does not conflict with local and cultural norms
- Document is signed and dated
- Documentation that the local regulations do not require a local ethics review
- Providing direct references to the local regulations that state ethics review is not required

2) Acknowledgement of Unregulated Research Activities letter confirming that local ethics review is not required

Required elements:

- Provided on the official letterhead of the signatory
- Document is signed and dated
- Clearly state the planned research does not require local regulatory oversight
- Confirm the Regulatory Official understands the intent of the research and activities to be performed
- Reference the title of the study displayed in the IRB application

Required document for studies where international regulations *do* require local ethics review

Letter of Approval from an Ethics Committee

Required elements:

- Reference the title of the study displayed in the IRB application
- Clearly state the research study was designated Minimal Risk by the committee
- Clearly state the planned research was reviewed and approved
- Document is signed and dated
- Provided on the official letterhead of the signatory

What is required for Greater than Minimal Risk studies?

Studies that are designated as greater than minimal risk **require** a formal ethics review within the country where the research will be conducted. Not all countries have an ethics review committee and the oversight may be addressed by the Department of Ministries or other governmental entities. This is why it is important to collaborate with local individuals early in the planning process so they can assist you in identifying the proper mechanism to obtain the approval.

- Letter of Approval from an Ethics Committee
- Required elements:
- Reference the title of the study displayed in the IRB application
- Clearly state the planned research was reviewed and approved
- Document is signed and dated
- Provided on the official letterhead of the signatory

When are site permissions required?

When research is conducted at any site other than Marist College facilities, an authorized individual from the proposed research site must provide written permission that the research can be conducted.

Site permission letter from authorized individual

Required elements:

- Reference the title of the study displayed in the IRB application
- The document is signed and dated
- Confirm the authorized individual understands the intent of the research and activities to be performed

Why is it important to have a local collaborator and knowledge of the local culture?

Investigators are **strongly** encouraged to collaborate with an individual or organization with expertise in the region. This collaboration will greatly assist in identifying appropriate research sites, navigating the local regulations and policies, understanding culture, local infrastructure, overcoming language barriers & increasing community partnership.

Based upon study location and risk level, the IRB may **require** a local site collaborator.

What are the additional requirements for enrolling non-English speaking participants?

When enrolling non-English speaking research subjects, investigators must have a plan to manage communications with participants during ***all phases*** of study participation. Given that participants may have questions or concerns at any time, Investigators must be prepared to manage communication beyond the consent process and data collection.

The initial IRB submission should **only** include the English version of documents that will be used with research subjects, (recruitment materials, consent documents, data collection materials, etc.). Once the materials are approved both by the Marist College IRB **and** foreign Ethics Committee, the approved documents should be submitted to a translator. Once translated, a Modification must be submitted to and approved by the Marist IRB to provide the final English language documents, final translated documents, back translations (if required) and a signed translator certification form. The documents may not be used until this Modification is approved.

Why is it important to start the process early?

Now that you have a good understanding of the required review and documentation process, you can see that research in some areas of the world can require a significant timeline to accomplish. Investigators' most common mistake when implementing international research is not allowing a realistic amount of time for protocol development and regulatory reviews.

When developing project timelines, Investigators should consider issues such as the stability of local government and infrastructure, time differences between countries, availability of communication technology in the foreign location, responsiveness of foreign offices, cultural differences within professional organizations and how frequently regulatory bodies convene.

Specific travel plans and the purchasing of plane tickets should **not** occur until all of the required reviews and approvals have been obtained.

Collaborative Research

Review of IRB Requirements for Multisite and Collaborative Research

What is a multisite study?

From an IRB perspective, multisite research includes projects or studies that involve collaboration with sites or individuals with not a Marist employee or student. Some examples of multisite and collaborative research include:

- An investigator with a Marist appointment is conducting a study involving other VA locations.
- UW-Madison investigator conducting a study at a community-based site with a community partners.
- UW-Madison investigator sharing identifiable or coded data/images/specimens collected for a study with researchers at another university or institution.

Are any IRB requirements different for multisite or collaborative research studies?

Yes. Although multisite studies undergo the same type of IRB review as single site studies, the IRB also must determine whether external sites or personnel need IRB approval in order to participate in study activities. This may include requiring a IRB reliance agreement such as an IRB authorization agreement or independent investigator agreement. In addition, the HS-IRBs require that all collaborative research studies have a protocol, regardless of the study's risk level.

When is IRB approval required for an external site or personnel?

Whether IRB approval is required depends on whether the external site or personnel are engaged in human subjects research as defined by federal guidance. It also can depend on whether a study qualifies for exemption. Determining whether an external site or external personnel are engaged in research can be difficult and researchers are encouraged to consult with the IRB Chairperson.

Will the HS-IRBs consider serving as the IRB for an external site or personnel?

Yes. Depending on the nature of the study and the activities that will be conducted by the external sites or personnel, the IRB may consider serving as their IRB of record. Anyone for whom the IRBs serves as IRB of record must be listed as a study team member and must complete human subjects research training. For more information about when the IRBs may consider serving as IRB of record.

If the Marist College is serving as one of the sites for a multisite study, will the HS-IRBs consider ceding IRB oversight to another IRB?

Yes, although it depends on the nature of the study and the study activities to be conducted at Marist College.

Does the IRB review process take longer for collaborative research studies?

Depending on the complexity of the study, the need for IRB reliance agreements, and the quality of the study materials, the IRB review process may take additional time. A well-prepared application and study protocol can help ensure that the IRB review process goes as smoothly as possible. The IRB Chairperson is available to assist researchers with addressing IRB requirements for collaborative research projects.

Forms

Marist IRB Submission Form

Signed consent form

Consent Statement

Debriefing Statement

IRB Amendment Review form

IRB Extension Review form

Determining if IRB approval is needed?

Before submitting an IRB application, first determine if IRB review is actually required for your project.

IRB review and approval is required for projects that:

- Meet the definition of research
- Involve human subjects and

- Include any interaction or intervention with human subjects or involve access to identifiable private information

IRB approval is required before you start your research.

Federal regulations require that research projects involving human subjects be reviewed by an Institutional Review Board (IRB). The IRB must approve or determine the project to be exempt prior to the start of any research activities. The IRB cannot provide approval or determinations for research that has already been concluded.

Does your project meet this definition of Research?

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to ***generalizable knowledge***.

A Systematic Investigation follows a predetermined plan for looking at a particular issue, testing a hypothesis or research question, or developing a new theory that may include:

- Collection of quantitative or qualitative data
- Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups
- Collection of data using experimental designs such as clinical trials
- Observation of individual or group behavior

Contribute to ***Generalizable Knowledge*** means that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied. This may include one or more of the following:

- Presentation of the data at meetings, conferences, seminars, poster presentations, etc.
- The knowledge contributes to an already established body of knowledge
- Other investigators, scholars, and practitioners may benefit from this knowledge
- Publications including journals, papers, dissertations, and master's theses

If the project does not meet the definition of research (i.e. is not a systematic investigation or does not contribute to ***generalizable knowledge***), as described above, then the project does not require IRB review and an IRB application is not required.

No, My Project is not considered Research, now what?

If your project does not meet the definition of research you do not need to gain IRB approval.

If you are uncertain about if your project is research, please contact the IRB Chairperson

Yes, My Project is Considered Research, Now What?

If the project meets the definitions of research (i.e. is a systematic investigation or does contribute to generalizable knowledge), as described above, the next set of questions apply.

Are Human Subjects Involved?

A Human Subject is a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

If the project does not meet the definition of research or the project does not include human subjects, as described above, then the project does not require IRB review.

No, My Project does not involve human subjects, now what?

No further action is needed. You do not need IRB approval for research that doesn't involve humans.

Yes, My Project Includes Human Subjects, Now What?

If the project does include a human subjects aspect, you need to determine if there is any interaction or intervention with subjects or if there is any access to identifiable information.

Interaction—Any communication or interpersonal contact between the investigator(s) and the subjects. This includes in-person, mail, telephone, etc. Online surveys (even if anonymous) involve interaction.

Intervention—Physical procedures or manipulations of the subject or his/her environment (e.g. taking blood samples, exercise studies, use of devices, cognitive tasks, etc.)

Access to Identifiable Private Information

Private Information—Information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place (e.g. person's home, exam room, public restroom, etc.) OR has been provided for specific purposes with a reasonable expectation that it will not be made public (e.g. medical records, student records, employee file, etc.)

Identifiable Information—The identity of the individual is or may be readily ascertained by the investigator or others either directly or indirectly through the use of codes or a combination of data points.

If the project does not include any interaction or intervention with human subjects or include any access to identifiable private information, then the project does not require IRB review. If even one of the above categories are met (intervention, intervention, access to identifiable private information), an IRB application is required.

No research activities can be conducted without IRB approval. When in doubt, contact the IRB.

FAQ

Q. What is an Institutional Review Board?

A. An institutional review board (IRB) is a committee used in research in the United States that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. They often conduct some form of risk-benefit analysis in an attempt to determine whether or not research should be done. The purpose of the IRB is to assure that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study.

Q. What is "research"?

A. "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." (OPRR, CFR 45 Part 46.102).

Q. Who are "human subjects"?

A. Human subjects are defined as living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction or (2) identifiable private information. More simply put, a human subject is a person from whom or about whom information is collected.

Q. Whose research is reviewed?

A. Any human subjects research proposed by any member of the Marist community under the auspices of Marist College is subject to review. Staff, faculty, and student research is reviewed.

Q. Is all research subject to review?

A. Yes, at Marist, all human subjects research regardless of design type is subject to review.

Q. Why is all human research at Marist reviewed?

A. A review of all research insures protection of subjects of research as well as legal protection for the researcher. The IRB can help researchers identify potential risks. The Board ensures that researchers comply with federal regulations governing studies involving human subjects. Breaking federal laws regarding human subject research can have very serious consequences for both the researcher and the College. Consequences include jeopardizing all federal funding received by the College

Q. What ethical principles guide the work of the IRB?

A. The IRB is guided by respect for persons, beneficence, and justice. Voluntary consent of the subject is absolutely essential. If possible, the subject should benefit from the process and come to no harm. Vulnerable groups should not be "over studied" in comparison with more powerful segments of the population. These concepts are outlined in the documents the IRB uses to guide it operation such as the Belmont Report and CFR 45 Part 46.

Q. What is informed consent?

A. Human subjects of research have a right to be informed of the purpose and nature of the research, identity of the researcher and sponsoring agency, the procedures, any risks or benefits and confidentiality (who will have access to the data).

Q. How does the IRB work?

A. Review Forms completed by the researcher are evaluated by an committee member or IRB staff to decide whether the study is human subjects research and whether a full or expedited review is needed. If no review is necessary, as in the case of secondary data analysis, the researcher will be notified. In an expedited review, an IRB member completes the review where minimal risk is posed. Full review involves discussion by the IRB as a whole.

Q. Is the review process lengthy?

A. Expedited reviews usually take less than one week. Full reviews usually take less than four weeks.

IRB Member Resources

Proposal Review form

Contact Information

Preparing an Initial Submission

When preparing an initial submission, please complete the applicable steps below.

Note that not all of these steps are required for each project.

Step 1: Determine who will be the Principal Investigator (PI). To qualify as a Principal Investigator, individuals must have a Marist appointment and be working within the scope of that appointment in performing the research. In special circumstances the Marist IRB Chairperson will approve the review of research conducted by researchers not affiliated with College

Step 2: All study team members must complete the CITI online ethics training modules

Step 3: If you are collaborating with another institution, please see additional instructions

Step 4: Make the initial determination of the level of review for your study

Step 5: Download and complete the current versions of the initial application and protocol. If you need more space than the study team table provides, please complete and submit the additional study team members table.

Step 6: Create a signed consent and/or consent statement documents

Step 7: Additional documents typically required for review

1. Recruitment Materials
2. Test Instruments (e.g. questionnaires, surveys, interview guides, focus group guides, etc.)

Additional steps when applicable:

Step 8: Complete forms or requirements related to vulnerable populations and others requiring additional safe

Step 9: Complete forms related to Biological Materials or Radiation Safety

Step 10: If you are proposing research that involves a drug, biologic, dietary supplement, food, or medical device, please incorporate the relevant sections of the FDA supplement into the primary protocol template.

Read instructions carefully and complete all relevant sections of the Marist IRB submission Form