MARIST

INSTITUTIONAL REVIEW BOARD

POLICY AND PROCEDURES
FOR RESEARCH INVOLVING HUMAN SUBJECTS

Revised January 2022

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INTRODUCTION

The purpose of this manual is to assist investigators planning to conduct research involving human subjects in designing their research and submitting it for approval. Investigators are urged to read this manual carefully in order to avoid unnecessary delay in obtaining approval for their research. The review of human subjects research at the College is a collaborative process intended to result in mutually acceptable research procedures which accomplish the investigator's scientific objectives while protecting the rights and welfare of the subjects. The researcher must identify the proposed research to be in one of three categories; exempt, expedited, or full. Details on research project classification can be found on pages 7 and 8 of this document. The Institutional Review Board (IRB) will be flexible and review each project as a separate case rather than imposing rigid requirements on all projects. Every attempt is made to take into account all factors in determining the outcome of the review. While the IRB maintains ultimate authority to approve research proposals, it sees its role as educational and encourages consultation at all stages of the research process.

NOTE: APPROVAL OF A PROJECT BY THE IRB ONLY SIGNIFIES THAT THE PROCEDURES ADEQUATELY PROTECT THE RIGHTS AND WELFARE OF THE SUBJECTS.

COLLEGE POLICY

Marist College assures in its adherence to Federal Wide Assurance of Protection for Human Subjects (FWA) that all requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) will be met for all federally-sponsored research and **all other human subject research regardless of sponsorship,** except as otherwise noted in this policy. In accordance with these state and federal regulations and professional standards of ethical conduct, it is the responsibility of the College to reasonably ensure that, in research conducted under its auspices, the rights and welfare of human subjects are adequately protected. All of the Institution's human subjects research activities, regardless of whether the research is subject to federal regulations, will be guided by the Code of Federal Regulations.

In order for the College to fulfill its responsibility, the IRB is authorized to review and approve **ALL** research involving human subjects conducted under the auspices of the College, **regardless of the source of funding.** Except for those categories specifically exempted or waived under Section 46.101(b)(1-6) or 46.101 (i), all research covered by its FWA will be reviewed and approved by the IRB that has been established under the FWA with the Office of Human Research Protections (OHRP) or as may be otherwise agreed to by OHRP. The involvement of human subjects in research covered by the FWA will not be permitted until an appropriate IRB has reviewed and approved the research and written informed consent has been obtained from the subject or the subject's legal representative, unless properly waived by the IRB under Section 46.116(c), (d) or by any applicable waiver under Section 46.101(i). Student research involving human subjects from outside the class is also subject to the above provisions.

Functions and Responsibilities of the IRB

1. The Marist College IRB fulfills a two-fold purpose. First, it was established by law to protect human subjects of research from all reasonable harm, whether physical or psychological. Second, the IRB was established to alert researchers of possible risks to their subjects.

2. Any human subjects research proposed by any member of the Marist community, including faculty, staff and students, under the auspices of Marist College, is subject to review. All human research at Marist is reviewed to ensure protection of subjects of research.

3. The IRB is guided by respect for persons, beneficence, and justice. The IRB will ensure that legally effective informed consent is obtained and documented. The IRB has the authority to observe or have a third party observe the consent process.

4. The IRB must follow the written policies and procedures of Marist College for the protection of human participants in research. These policies and procedures are in compliance with federal regulations and state law.

5. Except when an expedited or exempt review procedure is applicable, the IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present. In order for the research to be approved, it must receive unanimous approval of those members present at the meeting.

6. The IRB will review and has the authority to approve, require modifications (to secure approval), or disapprove research activities that come under its review, including changes in previously approved human participants research. For approved research, the IRB will determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.

7. IRB approvals denote approval **within** the institution (Marist College). Further approval from other entities may be required. Human subjects research conducted outside the United States must comply with all regulations required by that country or territory.

8. IRB approval or disapproval decisions and requirements for modifications will be promptly conveyed to investigators in writing. Written notification of decisions to disapprove will be accompanied by reasons for the decision with provision of an opportunity for reply by the investigator.

9. Where appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children, as required by Subparts B, C, and D of 45 CFR 46. The IRB will notify OHRP promptly when IRB membership(s) is modified to satisfy requirements of 45 CFR 46.304 and when the IRB fulfills its duties under 45 CFR 46.305(c).

10. The members of the IRB are appointed by the Academic Vice President/Dean of Faculty in consultation with the Chair of the Faculty Affairs Committee. In accordance with the FWA, the College will provide the IRB with resources including professional and support staff sufficient to carry out their responsibilities effectively. In addition to other requirements of state and federal regulations, the membership of the IRB shall be composed of individuals of varying backgrounds who are qualified through maturity, experience, expertise and the diversity of the members' racial and cultural backgrounds to assure complete and adequate review of activities commonly conducted under the College's auspices, and to ensure respect for its advice and counsel for safeguarding the rights and welfare of human subjects.

11. The IRB shall possess the professional competence necessary to ascertain the acceptability of proposals in terms of institutional commitment and regulations, applicable law, standards of professional conduct and practice, and community attitudes.

The Dean of the School of Social and Behavioral Sciences serves as the Human Protections Administrator and is an *ex officio* member of the IRB.

The Vice President for Academic Affairs serves as the Institutional Signatory Official.

Questions may be addressed to the Chairperson of the Marist College Institutional Review Board at irb@marist.edu .

Definition of Human Subjects Research

Human Subject: a living individual about whom an investigator conducting research obtains:

i. information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
ii. uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

A project that fits within both of these definitions qualifies as human subjects research and must be reviewed by the IRB.

PROCEDURES

Planning a Research Project

All researchers must undergo assurance training prior to conducting any research under the auspices of Marist College. The College has arranged for such training to be provided by the CITI course in The Protection of Human Research Subjects. The Marist Office of Institutional Research & Planning will track faculty, student, and staff completion of this training. Certification of training completion must be submitted with the IRB Human Subjects Research Review Form.

Determining Human Subjects Involvement

The initial determination as to whether a research project should be considered human subjects research shall be made by the investigator. Final authority for making this determination rests with the IRB or its designee.

When student investigators plan to conduct research involving human subjects, they are advised to consult with their research supervisor on all aspects of their study in an effort to develop a research proposal that meets the standards for approval. If a research supervisor has questions, he or she may contact an IRB member for advice regarding appropriate design and methodology of the study.

In general, research which involves data gathered solely for internal, on-campus use (e.g., course evaluation or institutional research), or informal studies with no documentation of data would not need to be reviewed. If however, the results of this research will be disseminated in any way, then the research must receive prior approval. If no dissemination is planned at the time the data are gathered, but the possibility of future dissemination exists, the project director is advised to submit the project for approval prior to initiating the research.

Project Categories

All human subjects research projects must undergo review and approval by an IRB prior to initiation of research activities. There are 3 categories of review (exempt, expedited, and full board) defined by the Federal Regulations for Protection of Human Research Subjects (45 CFR 46).

Certain categories of research involving little or no risk to subjects need not be reviewed and approved by the full IRB, but maybe eligible for less intensive review procedures. The IRB shall develop and promulgate appropriate categories of research eligible for these procedures. Once it has been determined that an activity is to be considered human subjects research, it will be reviewed under one of three categories: Category I is eligible for "exempt review", Category II requires an “expedited review” and Category III requires "full review." The review procedures for each of these are described below in accordance with 45 CFR 46.110. Each researcher shall make the initial determination regarding the appropriate category of review, although the IRB or its designee may require review under another category. The researcher can always request a higher level of review than that required.

Below are listed the project categories, along with examples of the types of projects included in each category:

Project Category I (Exempt Review)

Exempt reviews are conducted by at least one reviewer. To qualify for review at the exempt level, the research must not be greater than minimal risk and must fall into one or more of the exempt categories described below. See Appendix A for additional explanations about exempt categories

- Education research: Surveys, interviews, educational tests
- Public observations (that do not involve children)
- Benign behavioral interventions
- Analysis of previously-collected, identifiable info/specimens
- Federal research/demonstration projects (listed as such)
- Taste and food evaluation studies

Project Category II (Expedited Review)

- Anonymous, mail or telephone surveys on innocuous topics
- Anonymous, non-interactive, non-participating observation of public behavior
- Secondary analysis of existing data
- Research involving the use of records if information taken from these sources is provided to the researcher in such a manner that subjects cannot be identified
- Research on individual or group behavior of normal adults where there are no interviews and interactive surveys on non-sensitive topics

This research generally does not require written documentation of informed consent, but oral consent is required for all research involving direct interaction with subjects. All research in schools requires written permission of the school district administrator who has authority to grant such permission.

Project Category III (Full Review)

- Research which might put subjects at risk
- Research involving psychological or physiological intervention
- Non-curricular, interactive research, e.g., in schools, prisons, social service agencies
- Research involving deception
- Interviews or surveys on sensitive topics
- Research conducted outside the United States, regardless of the procedures involved

For all research involving subjects who have been determined to be "at risk," written documentation of legally effective informed consent is required. Research with minors or subjects incompetent to give consent requires written consent by a parent or legal guardian. Deception research will only be approved if it meets certain conditions (e.g., debriefing)
The IRB may require full review of any research submitted or approved under expedited review.

Review Forms

The IRB has developed a unified Human Subjects Research Review Form which is used in submitting research proposals in both project categories. The form is designed so that only the information required for the appropriate project category need be included in the proposal. The Human Subjects Review Form is available at https://www.marist.edu/academic-resources/institutional-review-board.

Review Procedures

Under expedited review, the review form must be submitted and the review is carried out by an authorized designee of the IRB. The designee may approve the project, request additional information, or submit the proposal to the IRB for review and approval. The IRB may require a full review to reconsider any proposal approved under expedited review. The investigator is notified in advance of this review. If the investigator questions any determination made under expedited review, he/she has the option of requesting a full review by the IRB, which will make the final determination.

Under full review, the review form must be submitted. The review is generally conducted at the next convened meeting of the IRB. The IRB meets regularly (at least monthly) during the academic year and as needed during the summer. A proposal should be received by the 15th of the month to be included on the agenda for that month's meeting.

Investigators are welcome to attend the meeting and answer questions or provide additional information regarding their projects.

Conditions of Approval

The following requirements are the minimal necessary for IRB review, discussion, and documentation in the meeting minutes in accordance with 45 CFR 46.111:

1. The proposed research design shall be scientifically sound and present a clear hypothesis. The study must be designed in a manner appropriate to examine the stated hypothesis.

2. The proposed research design will not expose subjects to unnecessary risks. Any risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. All possible identified risks must be minimized.

3. The proposed research design must allow for additional safeguards required to protect the rights of subjects likely to be vulnerable to coercion or undue influence including but not limited to: children, pregnant women, fetuses, those who are socially- or economically-disadvantaged, or those who are cognitively impaired.

4. Informed consent must be obtained from research subjects or their legally authorized representative(s).

    a. Consent documents must be understandable to subjects.

    b. If appropriate, a child's assent must be obtained.

    c. Documentation must include the following required elements:

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

        ii. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

        iii. For research involving more than minimal risk, an explanation of whether any compensation and any medical treatments are available if an injury occurs and, if so, what they consist of, or where further information may be obtained. Note: In general, the College does not have a formal plan or program to provide medical treatment or compensation for any injury which occurs as a result of the subject's participation (the participant should also be informed that this does not waive any of his/her legal rights);

iv. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact if a subject suffers a research-related injury. Typically, the person responsible for the study (either the principal investigator or his/her supervisor) should be identified as the person to contact if any such issues arise.

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

vi. A description of any reasonably foreseeable risks or discomforts to the subject.

vii. A description of any benefits to the subject or to others that may reasonably be expected from the research.

viii. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5. Subject privacy and confidentiality must be maximized. Any personally identifiable material must be protected from access or use. See Appendix B regarding anonymity and confidentiality.

In projects where subjects are determined to be at risk, the actual procedure utilized in obtaining "legally effective informed consent" must be fully documented. This is accomplished by using a written consent form embodying all of the elements of information required for the project. The consent form must be read by or to the subject or his/her legally authorized representative and signed by the person giving consent. A copy of the consent form shall be given to the person signing the form and the signed form must be maintained in the investigator's files for an indefinite period of time following completion of the study.

The IRB has designated a SAMPLE form that can be used as a guide in preparing the consent form that will actually be used in the investigators research project or activity. PLEASE NOTE the final form administered must be approved by the IRB before it can be legally administered.

In rare cases, where these procedures will surely invalidate important objectives of the project, IRB approval of modified consent procedures may be sought. In projects where risk to subjects has been determined to be no more than minimal, provision may be made for oral or written presentation and consent. Under this procedure, the subject is informed of those basic elements of consent which are applicable to low risk procedures and no signed document is necessary on the part of the subject. However, a sample copy of the presentation must be approved by the IRB. A major exception to this policy occurs when research involves minors as

subjects, in which case, written parental consent is usually required. (See "Guide to Research Involving Minors.")

In some cases, the IRB may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent or may entirely waive the requirement to obtain written informed consent.

Approval of a project by the IRB applies only to the procedures submitted in the proposal. The investigator must secure prior approval from the IRB for any changes in the procedures that will affect the use of human subjects.

Approval of expedited projects with less than minimal risk, can be approved for up to five years. Full review projects are approved for one year only. Any requested changes to an approved proposal require approval through the submission of an addendum.

Single IRB-of-Record (sIRB)

IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB document. In human subjects research involving more than one institution, one collaborator shall be identified as the primary research institution. In an effort to maintain consistency, documentation used to gain approval at the primary institution shall be used at all other collaborating institutions.

The use of a Single IRB-of-Record (sIRB) is intended to streamline the human subject protection process by eliminating redundancy and duplication of efforts at each participating site. The sIRB has been required for all NIH-sponsored, multi-site, non-exempt, human research studies since 2018. Effective January 20, 2020, the sIRB review requirement applies to all multi-site human subjects research studies in the U.S. that are sponsored by the NIH and other federal Common Rule agencies. The Common Rule (45 CFR 46.114) requires the designation of one IRB to serve as the central point of project oversight for IRB functions (e.g. roles, authorities, management protocols, and communication plan among the sIRB and participant institutions). These functions are documented in a reliance agreement among the collaborating institutions or a contract with an accredited commercial IRB to provide IRB oversight for the research project. It is important to note that each institution, not the individual investigators, determine if a reliance agreement can be arranged and executed, and which IRB will be the sIRB-of-Record. Authorization of sIRB agreements for Marist College are negotiated and signed by the Vice President for Academic Affairs.

NIH multi-site research projects with human subjects must designate the sIRB at the time of application submission and include a plan for sIRB use. The IRB fees, if applicable, should be budgeted (See PHS G.300 – R&R Budget Form). Please see the NIH FAQ's on the Single IRB Policy for Multi-Site Research

To request Marist's IRB to serve as the sIRB, **request a consultation** and contact the IRB at least 2 months prior to the grant application submission date to allow time for IRB review and to determine if a reliance agreement can be executed. *To request that Marist grant IRB oversight to an external IRB*, contact the IRB at least one month prior to the submission date. The Marist IRB requires lead time to determine if Marist can serve as the sIRB on any given project and reserves the option to decline acting as the sIRB on any project. The following are a few of the considerations to be reviewed in determining if the Marist IRB can serve as the sIRB:

- Risk level to the human subjects
- Whether Marist College is a primary recipient of the federal grant
- Communication processes for sharing information across participating sites
- The number and location of collaborating institutions
- The activities to be undertaken at the various research sites
- The experience of the research team and available administrative resources available to the PIs

Note that exceptions to the sIRB requirement are granted in the following instances:

1. research that includes international site(s);
2. when individual IRB review is required by law (e.g. Alaskan or American Indian tribal law);
3. the federal agency documents the sIRB process to be inappropriate for the study.

To maintain consistency among participating institutions, if Marist serves as the sIRB, documentation used to gain approval at Marist shall be used at all collaborating institutions. Related local functions such as ancillary reviews, verification of human subjects training, conflict of interest, and other localized IRB responsibilities remain the responsibility of each participating institution.

Consent of Use of Secondary Data

For research that "involves the collection of identifiable private information or identifiable biospecimens":

i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Student Research

All student investigators must have a College supervisor who is responsible for ensuring all procedures of the approval are complied with by the investigator. The faculty supervisor is also responsible for ensuring the research methodology is appropriate for the study and adheres to ethical standards identified on pages 6 and 7 of this document. The faculty supervisor must sign the proposal review form certifying that the project is under his/her supervision.

Class projects may be reviewed as one proposal, at the discretion of the instructor. However, if the entire class is not using the same procedure, then each student or group of students must submit a separate proposal.

In general, it is advisable for students to select research projects which are eligible for "exempt and expedited review" (Categories I & II). In this way, approval for the projects will take very little time. Students are not, however, prohibited from conducting research in Category III, but additional time may be required to obtain approval from the full IRB. In all cases, it is the responsibility of the instructor to ensure that students use only approved procedures.

Projects conducted as instructional demonstrations where subjects are not solicited from outside the classroom generally do not need to be reviewed. Care shall be taken, however, to protect the rights and welfare of students who act as subjects. Students shall be informed their participation is voluntary. Procedures shall not expose students to more than minimal risk.

Reporting Unanticipated Risks, Misconduct, and Non-Compliance

Any instance of serious or continuing non-compliance with the IRB policies and procedures or the requirements or determinations of the IRB, including the development of hazardous conditions for subjects, shall be reported immediately to the IRB Chairperson and the Human Protections Administrator. Ordinarily, it is the responsibility of the investigator to report such unanticipated problems or adverse events. Once the IRB becomes aware of such problems, whether via the investigator or from other sources, it may request a meeting with the investigator and/or suspend the research until the problem can be resolved, in which case the IRB must approve an amended protocol before the research can continue.

As set forth in 45 CFR 46.113 Suspension or Termination of IRB Approval of Research, “an IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements, or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action, and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.”

The Human Protections Administrator, along with the Institutional Signatory Official, will report all cases of unanticipated risks or instances of non-compliance to the appropriate federal or state department or agency head.

Procedures for reporting scientific misconduct (including fabrication, falsification, plagiarism, unauthorized use of privileged information, violation of federal regulations, and retaliation against a person who has in good faith reported suspected or alleged misconduct) involving risk to human subjects are listed in the Marist College Policy for Responding to Allegations of Scientific Misconduct.

Appendix A - OHRP Exempt Categories

1. EDUCATION

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

2. TESTS, SURVEYS, INTERVIEWS

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. PUBLIC OFFICIALS

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. EXISTING DATA

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 subjects cannot be identified, directly or through identifiers linked to the subjects.

5. DEMONSTRATION PROJECTS

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are 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.

6. FOOD

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Appendix B - Anonymity and Confidentiality

Anonymity:

Providing anonymity of information collected from research participants means that either the project does not collect *Identifiable private information* (e.g., name, address, email address, social security number etc.), or the project cannot link individual responses with participants' identities. A study should not collect *Identifiable private information* of research participants unless it is essential to the study protocol. Anonymity cannot be guaranteed if any *Identifiable private information* will be collected.

Confidentiality:

Maintaining confidentiality of information collected from research participants means that only the investigator(s) can identify the responses of individual participants. Additionally, researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses. Researchers who collect *Identifiable private information* must inform participants how their data will be stored, and when it will be destroyed.

Identifiable private information:

Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Examples of Personally Identifiable Information (PII):

Name
Addresses
Employer's name or address
Relatives' names or addresses
Date (e.g., birthdate, date of death, etc.)
Phone
Email addresses
Social security numbers
Member / account numbers
Voiceprints
Fingerprints
Full face photos & comparable images