MARIST COLLEGE

INSTITUTIONAL REVIEW BOARD

POLICY AND PROCEDURES
FOR RESEARCH INVOLVING
HUMAN SUBJECTS

Revised July 2006*

CONTENTS

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 Institutional Review Board (IRB) tries to be as flexible as possible and reviews each project as a separate case rather than imposing rigid requirements. 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 AND SHOULD NOT BE TAKEN TO INDICATE COLLEGE APPROVAL TO CONDUCT THE RESEARCH.

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 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.
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. 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 current (July 2006) IRB members include:

- **Elizabeth Quinn, Ph.D., Chair**
- **Kavous Ardalan, Ph.D.**
- **Erik Moody, Ph.D.**
- **Andrew Ryder, Ph.D.**
- **Benjamin Hayden, Ph.D.**

In addition, Michael Tannenbaum, Ph.D., Dean of the School of Science, serves as Human Subjects Administrator and is an *ex officio* member of the IRB. The Academic Vice-President/Dean of Faculty (currently Dr. Artin Arslanian, Ph.D.) serves as the Institutional Signatory Official.

11. Questions may be addressed to the current Chairperson of the Marist College Institutional Review Board:
Elizabeth Quinn, PhD.
Chair, Institutional Review Board
Elizabeth.Quinn@Marist.edu
845-575-3000 ext. 2458
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PROCEDURES

Planning a Research Project:

When 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.

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 should be made by the investigator. Final authority for making this determination rests with the IRB or its designee.

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:

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 two categories: Category I is eligible for "expedited review" and Category II requires" full review." The review procedures for each of these are described below in accordance with 45 CFR 46.110. Each researcher should 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 (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 II (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 on special populations; e.g. minors, prisoners, and the mentally incompetent

- 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. Human Subjects Review Form is available at www.marist.edu/academics/irb/.

Review Procedures

Under expedited review, only ONE (1) COPY of the review form must be submitted and the review is carried out by the 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 ORIGINAL PLUS EIGHT (8) COPIES of the proposal 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 middle of the week prior to the scheduled IRB meeting to be included on the agenda for that 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 must 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 decisionally 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.

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 should 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 <u>SAMPLE</u> 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. <u>PLEASE NOTE</u> 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 for projects is valid for one calendar year only. Investigators must request a continuation for the approval yearly if the activity lasts more than one year. Only two (2) continuations will be granted for a given project. After three years, the project must be resubmitted.

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 "expedited review" (Category I). In this way, approval for the projects will take very little time. Students are not, however, prohibited from conducting research in Category II, 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.

To further expedite the approval of class projects, the instructor can obtain approval before the semester begins under two circumstances: 1) if all of the students are using the same procedures, e.g., a class survey) and the instructor has established the procedures before the class starts, or 2) the instructor submits a list of alternative procedures for approval and the students are to choose one from the list.

Projects conducted as instructional demonstrations where subjects are not solicited from outside the classroom generally do not need to be reviewed. Care should be taken, however, to protect the rights and welfare of students who act as subjects.

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, should be reported immediately to the IRB Chairperson and the Human Subjects 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 Subjects 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.