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**Institutional Review Board**

**Policy & Procedure Manual**

**Edited to reflect the Revised Common Rule**

**Approved by Marymount University Provost**

**January 15, 2020**

**Marymount University Institutional Review Board**

**Policy & Procedure Manual**

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#  Institutional Review BoardPolicy & Procedure Manual

# 1.0 INTRODUCTION

The *Marymount University Institutional Review Board (IRB) Policy & Procedure Manual* is periodically updated. The most up-to-date version is available on the IRB website at <https://my.marymount.edu/Offices-Resources/Institutional-Review-Board> . You must be logged in to your Marymount account to access the IRB Website. All researchers are responsible for reviewing and making themselves familiar with the latest version of the manual.

The MU IRB Website provides information about and access via links to:

* **Collaborative Institutional Training Initiative (CITI):** This is an online system for education of researchers related to research ethics. Marymount faculty and student researchers are required to be current in CITI training prior to submission of IRB applications (please see <https://my.marymount.edu/Offices-Resources/Institutional-Review-Board/CITI>).
* **Mentor:** This is the online system used by Marymount University for management of and communication related to all IRB applications and documents (please see <https://my.marymount.edu/Offices-Resources/Institutional-Review-Board/Mentor>).

# 1.1 HISTORY OF THE INSTITUTIONAL REVIEW BOARD (IRB)

The United States Department of Health & Human Services (DHHS) codified the regulation of human subjects’ research in the Code of Federal Regulations Title 45 Public Welfare, Part 46 Protection of Human Subjects (found here: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>). References to the regulations throughout this document will be identified as 45 CFR 46. Subpart A of 45 CFR 46 requires that every institution performing federally funded human subjects’ research file an assurance of protection for human subjects. In addition, three ethical principles contained in the Nuremberg Code and the Declaration of Helsinki guide such research, as described in the Belmont Report:

* **Respect for persons** is the first principle of the Nuremberg Code and the Belmont Report, meaning that voluntary consent of the human subject is absolutely essential. This principle is applied by a process of informed consent, considering the subject’s right to privacy, keeping research results confidential, and using additional protections when the research involves vulnerable populations.
* **Beneficence** is the second principle outlined in the Belmont Report and is evaluated by comparing the risks of conducting research against the potential benefits that could be realized from that research.
* **Justice** is the third principle and requires that the researcher ensure subjects are selected equitably based on being an appropriate population for the study rather than merely a convenient group of study subjects. Attention to justice means avoiding disproportionately representing racial and ethnic minorities or those who are disadvantaged in the research.

Marymount researchers are encouraged to be familiar with the full text of The Code of Federal Regulations, Title 45 (Public Welfare: Department of Health and Human Service), Part 46 (Protection of Human Subjects), “45 CFR 46,” including the index of all that it covers. Applicable specific citations are included throughout this document for ready reference to the federal guidelines.

# 1.2 DEFINITION OF TERMS

The IRB provides review and oversight of all research involving human subjects at Marymount University. **Research** is defined by federal guidelines as “a **systematic** **investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable** **knowledge**” with **human subjects** (45 CFR 46.102(D)).

* A **human subject** is “a living individual about whom an investigator (whether professional or student) conducting research:
	+ obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens OR
	+ obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.” (45 CRF 46.102(E))

At Marymount University, these terms are defined to provide additional guidance:

* **Systematic** **investigation** means an activity involving a plan that incorporates quantitative or qualitative data collection and analysis to answer a research question.
* Investigations designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions, inform policy, or apply findings beyond a single individual, an instructional setting, or an internal program. Note that research results do not have to be published or presented to qualify as research according to federal guidelines.

Researchers should determine the extent to which their projects contain **all three components** set forth in 45 CFR 46 (i.e., human subjects, systematic investigation, generalizable knowledge). For example, if a project involves interacting or intervening with people, the project involves human subjects according to federal guidelines. If the project involves accessing existing records (i.e., a data set) that contain information about the subject’s identity and this information would be considered “private,” that project involves human subjects as federally defined.

The purpose of gathering information from human subjects is critical to determining whether IRB approval is necessary. Some projects involving human subjects are systematic, but the findings from these investigations are not designed to develop or contribute to generalizable knowledge. For example, the findings may be intended to be shared with a single client or used for internal improvement by an organization. In these cases, the project does not require IRB review because it does not meet the federal definition of research. A list of non-research activities is available on the IRB website: <https://my.marymount.edu/Offices-Resources/Institutional-Review-Board/Is-it-Research> .

Most research that utilizes secondary (existing) data sets does not meet the definitional criteria for “human subjects” research and, therefore, does not require IRB approval. There is no need to apply for IRB approval if your data are:

(i) Publicly available (e.g., through a public website or publication or by subscription as long as a responsible use statement or other confidentiality agreement is included to protect human subjects) AND

(ii) De-identified so that it is impossible to link a record to a particular individual.

If your data do not meet either criteria (i) or (ii) above or if it is coded so that it would be possible to link a record to a particular individual if one possesses the key, you may need to apply for IRB approval and you should contact the IRB for clarification.

Non-research activities may become research activities if the nature, scope, or purpose of the project changes. The IRB does not give retrospective approval to projects, and the IRB cannot approve research involving data already collected without IRB approval. Therefore, it is very important that researchers determine in advance the actual and potential nature, scope, and purpose of their project. If a research idea evolves out of a classroom activity, Marymount does have an IRB policy related to using existing classroom data in research (see Section 5.3.1).

**1.2.1 Student Research**

Marymount students undertaking research, as defined above, must work with a faculty or staff member to secure IRB approval before beginning the research. All student work involving systematic investigations with human subjects that is intended to be shared as research in a forum outside the instructional setting of Marymount University is designated as research and, therefore, requires IRB approval. This includes presentations at conferences, and print and online publications. Individually supervised student work that meets the federal definition of research, such as a research-based Honors thesis, master’s thesis, or doctoral project, is designated as research even when there is no intention to share the project beyond the University. IRB approval for research cannot be conferred retroactively.

**1.2.2 Classroom Projects**

Course activities that involve students in systematic investigations with human subjects for instructional purposes only are designated as “classroom projects.” Classroom projects are distinguished from student research by the fact that they are not designed to develop or to contribute to generalizable knowledge (see Section 1.2). Classroom projects are not shared beyond the instructional setting of Marymount University. They may be shared in the classroom and the Marymount Student Research Conference, but classroom projects may not be presented at other conferences or published in print or online. Though classroom projects do not require IRB approval, all Marymount instructors who supervise classroom projects must complete the appropriate CITI course(s) (see 4.1) and submit a Faculty / Instructor Assurance Form (FAF) for Classroom Projects via Mentor before initiating the project (please see <https://my.marymount.edu/Offices-Resources/Institutional-Review-Board/Classroom-Projects>).

The FAF confirms that the instructor is taking responsibility for ensuring appropriate design and ethical conduct of student projects involving human subjects. The course instructor must make the following assurances:

* As a MU instructor, I am familiar with the current *Marymount University Institutional Review Board Policy & Procedure Manual*, as well as the guidelines for the ethical treatment of human participants associated with my discipline or field of inquiry.
* I will ensure that my students adhere to MU IRB Policies and Procedures and guidelines for the ethical treatment of human participants when completing classroom projects.
* I have completed a CITI basic course within the last three years. I will ensure that any and all information linking subjects with responses, including consent forms, audio or videotapes arising out of the project, will be destroyed upon completion of the course. I will review each student project before initiation and confirm that adequate safeguards to protect the welfare and privacy of the participants are in place.
* I am directly responsible for overseeing data collection activities.
* I will monitor human participant involvement during classroom projects and assure that subjects are fully protected.
* I will mentor students on how to present their classroom projects in ways that respect the privacy of human participants involved in the project (Section 1.2.3).
* I assume responsibility for ensuring that all student projects under my supervision that are beyond the scope of classroom projects and meet the definition of **student research** (see Section 1.2.1) are appropriately submitted to the IRB for review.
* I acknowledge that failure to meet these responsibilities may subject me to a charge of misconduct (see Section 7.2).

Faculty / Instructor Assurance Forms are kept on record through Mentor and are valid for one year from the date of submission. The IRB does not review specific classroom projects; however, the IRB Chair confirms that the classroom instructor has completed a CITI basic course within the last three years when he or she submits a Faculty Assurance Form.

Many Marymount courses involve activities with human subjects that do not meet the definition of research (see Section 1.2) or classroom projects. For example, clinical field experiences, student teaching, and course activities that involve non-systematic data gathering (e.g., informal interviews) do not meet the definition for research or classroom projects, so instructors do not need to submit an IRB application or a Faculty Assurance Form in these cases. Examples of these types of activities are listed on the IRB website.

**1.2.3 Marymount Student Research Conference**

The Student Research Conference (SRC) is considered an instructional forum within the Marymount institutional setting. Students may present research and classroom projects at the SRC. When applying to present their work at the SRC, students indicate whether they are presenting research or a classroom project. Presentations of student research, as defined in 1.2, are allowable only if the research was approved by the IRB. Presentations of classroom projects are allowable only if the course instructor submitted the Faculty Assurance Form for Classroom Projects before initiating the project.

The faculty member supervising the student work is responsible for teaching students how to present their research or classroom project in ways that respect the human subjects involved in the investigation. For example, the identity of subjects must be kept confidential unless the intent to reveal their identity was clearly communicated to the subjects during the consent process.

# 2.0 THE INSTITUTIONAL REVIEW BOARD (IRB) AT MARYMOUNT UNIVERSITY

# 2.1 REGULATIONS GOVERNING THE IRB

The federal regulations are codified in 45 CFR 46. Researchers are encouraged to be familiar with the full text of these regulations. See: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html> .

**2.2 AUTHORITY**

The IRB reports to the Provost of the University through the Associate Vice-President of Research, who is the Authorized Organizational Representative for the University.

* Marymount’s Federal Wide Assurance (FWA) number (FWA00019383, expiration 10-02-2024) is used on all federal grant applications for projects in which human subjects will be involved.
* The Office of Human Research Protection (OHRP) in the DHHS has assigned MU, as the parent organization for MU IRB, an organizational ID number of IORG0003273.
* Marymount’s IRB has its own human subject registration assurance number, assigned by OHRP of 00003907 (expires 10-10-2022). Registration of the MU IRB must be renewed with OHRP (a) every three years; (b) within 90 days after a new Chair is appointed; or (c) when changes are made to the IRB membership.

**2.3 IRB DUTIES AND RESPONSIBILITIES**

The primary purpose of the IRB is to protect human subjects and assure University compliance with federal regulations. In addition, the goal of the Marymount IRB is to create an institutional culture where the responsible conduct of research is understood, supported, and followed by all Marymount students, faculty, staff, and administrators. The IRB is charged with providing review and oversight of all Marymount University research as defined by federal guidelines (see 1.2). Such protection ensures that:

* Risks to human subjects are minimized;
* Risks to human subjects are reasonable in relationship to anticipated benefits;
* Selection of human subjects is equitable;
* Informed consent is obtained and properly documented;
* Data are collected and retained in a way that protects human subjects; and
* Privacy of human subjects and confidentiality of data are maintained. (45 CFR 46.111)

The IRB has the responsibility and the authority to require modifications to research applications, approve research, disapprove research, conduct continuing reviews, observe and verify changes to research projects, and suspend or terminate approval of research.

The IRB is ultimately responsible for determining the appropriate level of review for all research proposals. Some research with human subjects may be eligible for Exempt status (i.e., exempt from federal regulations); however, the IRB Chair or his/her designee will make the determination of eligibility for Exempt status based on review of the submitted Application for Exempt Review Form. Research that presents no more than minimal risk to subjects and meets specific criteria may be eligible for Expedited review. The IRB Chair or his/her designee will make the determination whether or not the research falls into one of the categories for Expedited review. Research involving human subjects not eligible for exempt or expedited review requires Full review.

The IRB is also responsible for archiving the Faculty / Instructor Assurance Forms for Classroom Projects. These are uploaded into the Mentor System by faculty / staff.

In order to create an institutional culture where the responsible conduct of research is understood, supported, and followed by all Marymount students, faculty, staff, and administrators, the IRB will plan and conduct activities that:

* Raise the Marymount community’s awareness of opportunities and challenges relating to research involving human subjects;
* Provide the Marymount community with a clear overview of the process to promote appropriate decision making by human subject researchers; and
* Offer training opportunities for human subject researchers to navigate the IRB process.

While the role of the IRB is not to police research quality, the OHRP does identify the following IRB institutional responsibility: “Specification of quality standards in the conduct of research is an important function of the institutional leadership. Insistence upon well-conceived and -conducted research should be evident both in written policies and in actions of institutional officials. Research that is conducted so poorly as to be invalid exposes subjects and the institution to unnecessary risk. Approval procedures should be devised such that the institution supports only well-designed and properly executed research.” (http://archive.hhs.gov/ohrp/irb/irb\_chapter1.htm#c6)

**2.4 MEMBERSHIP AND COMPOSITION OF THE IRB**

Federal requirements state that the IRB shall consist of at least five members, including at least one non-scientist, one scientist, and one member not affiliated with the University. Federal guidelines encourage diverse representation (e.g., with regard to race, gender, and cultural backgrounds).

**2.4.1 Appointment of Members**

The Provost will appoint the Chair, faculty, and staff members to the IRB for staggered three-year terms. Members may be reappointed for additional three-year terms. In addition to faculty and staff members, the IRB also includes a Provost’s designee who serves as a liaison between the Board and the Provost. The member(s) not affiliated with the University are also appointed by the Provost.

**2.4.2 Qualifications of Members**

The IRB members must collectively represent research experience in the arts, humanities, and international settings, as well as biomedical and social and behavioral research. Members should have experience in reviewing research proposals. All members must complete IRB training outlined in 4.0. While an effort will be made to secure equal representation of IRB members from each School, ultimately the membership will be selected based on the collective expertise in the types of research projects conducted within the Marymount institutional setting.

**2.4.3 Duties of IRB Members**

Every three years IRB members must complete the CITI training course as described in Section 4.1. Because they will be tasked with reviewing applications in many different fields, all members of the IRB must complete both the Biomedical Research and the Social and Behavioral Research courses in addition to the IRB Members course.

IRB members evaluate applications for Full review at convened meetings. They complete Expedited reviews on a rotating basis. Members are expected to attend all IRB meetings, which are scheduled monthly during the academic year, or more frequently if the need arises. IRB members may be compensated if summer meetings are necessary. IRB members also promote the educational goals of the IRB (see 2.3) and serve as liaisons with their respective departments, schools, and administrative units.

**Need to add a section for IRB Coordinator**

**responsibilities**

**2.4.4 IRB Chair – modify role of chair in light of IRB coordinator**

The IRB Chair is appointed by the Provost from the faculty and serves a three-year term, which may be renewed. The Chair is an experienced reviewer of research proposals. The Chair receives one course release in both the fall and spring semesters and may receive additional compensation for performing duties over the summer. The Chair’s duties include:

* Presiding at meetings of the IRB.
* Review of all Exempt proposals or designation of reviewer(s).
* Assuring that meeting Minutes are in order. Per federal guidelines, Minutes must include: persons in attendance; actions taken; a report of the vote on actions; basis for required changes in research proposals or for disapproving proposals; and written summary of any discussion of controversial issues and resolutions.
* Determining eligibility for proposals for review and designating IRB Board member(s) who will conduct the review.
* Notifying the IRB of all approved applications.
* Communicating IRB decisions to approve or disapprove proposed research activity to researchers and the Provost’s designee.
* Conducting continuing review of ongoing projects when needed.
* Serving in an outreach role to educate students, faculty, and staff about IRB policies and procedures and providing assistance to researchers as needed in submitting proposals to the IRB.

**2.5 IRB RECORD REQUIREMENTS**

The Academic Affairs office provides administrative support to the IRB Chair. Federal requirements stipulate that IRB records, including minutes, decisions, correspondence with researchers, and approved applications, be kept for at least three years.

**3.0 ROLES AND RESPONSIBILITIES OF THE RESEARCH COMMUNITY**

**3.1 PRINCIPAL INVESTIGATORS**

The Principal Investigator (PI) is the individual responsible for the implementation of research, and, as such, must personally conduct or supervise the research. The PI assures that the rights and welfare of human subjects are protected and that informed consent is obtained from subjects before research begins. The role of PI implies ultimate administrative and fiscal responsibility for the project, subject to University review and oversight. PIs owe it to their subjects, and the community at large, to be knowledgeable of the policies and procedures discussed in this manual. All PIs affiliated with Marymount University must agree to accept certain responsibilities:

* Conducting the research in accordance with ethical guidelines such that the rights of subjects are protected and risks are minimized.
* Keeping abreast of the policies and procedures of the Marymount University IRB, the published guidelines for the ethical conduct of research relevant to their field of inquiry, and state and federal regulations.
* Ensuring that the research is of good quality.
* Ensuring that the proposed research is not currently underway and will not begin until written approval from the IRB is obtained.
* Ensuring that the information provided in the IRB Application is accurate and complete.
* Maintaining the integrity of the project as it was originally approved by the IRB. Any proposed changes to a project must be submitted in writing to the IRB and approved before the changes are implemented.
* Submitting the annual report for projects approved under Full review,
* Promptly reporting to the IRB any unanticipated problems or serious adverse events involving risk to human subjects.
* Maintaining records for at least three years after completion of research (see Section 3.2.2) and having a clear plan for destruction of research records.
* Maintaining up-to-date CITI certification (within 3 years) and ensuring that all Marymount students and faculty and staff members on the research team have current CITI certification.
* Ensuring that all members of the research team comply with the findings, determinations, and requirements of the IRB.

The PI is always affiliated with Marymount University and can be a faculty or staff member. Adjunct faculty and part-time staff members may also serve as PIs if they secure approval of their respective dean or administrator of non-academic units. Faculty members from other institutions may serve as co-investigators with the Marymount PI (see 7.3). Marymount students may conduct research under the supervision of a faculty or staff member who assumes the role of the PI. When working with students, the PI takes on additional responsibilities beyond those listed above:

* Explaining any modifications requested from the IRB to the student; and
* Training students on how to present their research in ways that respect the human subjects involved in the project (see Section 1.2.3).

**3.2 PRINCIPAL INVESTIGATOR REPORTING REQUIREMENTS**

**3.2.1 Circumstances**

There are several circumstances under which the PI is obligated to report to the IRB:

* Any occasion when a human subject in a research study experiences an adverse event (e.g., an injury related to the study);
* Unanticipated problems or new information that may affect the risk/benefit ratio (e.g., a new drug becomes available);
* Any changes to the application must be submitted as an amendment and approved before implementation (e.g., change of research team, purpose, location);
* Annual reports for projects approved under Full review; and
* Requests for continuing review beyond the IRB approval expiration date.

**3.2.2 Keep Accurate Records That Are Accessible for Audits**

Unless a longer period of time is specified by the sponsor agency, federal regulations (45 CFR 46.115(b)) require that records relating to research that is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner. Research will be deemed completed when all research activities have ceased or in the case of sponsored research, when the final research report has been submitted. If the PI leaves Marymount University before the retention period of records is completed, the PI, in consultation with the IRB Chair and other authorized institutional officials, will identify a successor responsible for maintaining the research records.

**3.3 RESPONSIBILITIES OF STUDENT RESEARCHERS**

Student researchers work under the supervision of a faculty or staff PI. Although students may have primary research responsibility and take a lead role in the research, the ultimate administrative and fiscal responsibility for the project remains with the PI. Doctoral students may serve as a point of contact with the IRB; however, for all student research (including doctoral, masters, and undergraduate) the faculty advisor must be the identified PI and must submit the application and subsequent revisions to indicate he or she has reviewed and approved the investigation as proposed. Student researchers are responsible for protecting human subjects in accordance with the guidelines specified in the IRB Manual, and for complying with all IRB findings, determinations, and requirements. All students must complete a CITI basic course prior to the submission of the IRB application.

**3.4 ADMINISTRATORS**

The University community is responsible for supporting the ethical conduct of research. Those who hold administrative positions or hold positions with administrative duties (e.g., deans, administrators of non-academic units, department chairs) may learn that a faculty or staff member is conducting or planning to conduct research or supervise student research during the course of carrying out their regular administrative duties, such as evaluating grant applications, reviewing syllabi, or conducting annual evaluations. In these situations, confirmation of IRB status should be requested, and if IRB approval has not been received, the research must be discontinued.

**4.0 TRAINING AND RESOURCES**

**4.1 COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)**

In order to ensure that the rights and safety of human subjects are properly protected during the conduct of research, all Marymount faculty, staff, and students who are involved in research with human subjects must have up-to-date training on how to protect human subjects during the conduct of research. Marymount faculty, staff, and students who are involved in research with human subjects must complete an online training course from CITI, which is valid for three years. Instructions for accessing the CITI training courses are available on the IRB website <https://my.marymount.edu/Offices-Resources/Institutional-Review-Board/CITI> .

There are four different CITI training courses specific to Human Subjects Protection relevant to Marymount faculty, staff, or students:

1) Science & Health Sciences Research,

2) Social & Behavioral Research,

3) Student research,

4) IRB Members.

There are three CITI training courses relevant to personnel participating in externally funded research, or seeking external research grant funding:

1) Responsible Conduct of Research (RCR-Group 2) for PIs, co-PIs, or grant project directors;

2). Responsible Conduct of Research (RCR-Group 1) for research personnel on a grant-funded project who are NOT in a grant leadership position (NOT PI or co-PI).

3) Conflict of Interest (COI) modules which must be completed by all investigators receiving funding through the National Institute of Health or any Department of Health and Human Services Federal Agency prior to starting the project.

 Faculty and staff should complete the course that best matches the types of research they conduct and supervise, either Science & Health Sciences or Social & Behavioral.

All researchers conducting health-related research should take the Science & Health Sciences Research course, which includes a module on the Health Insurance Portability and Accountability Act (HIPAA).

Because students conduct research under the direction of a PI, they may complete the short course designed for students. However, PIs supervising student researchers may require them to complete additional modules or an additional basic course beyond the IRB CITI requirements.

Honors students whose Theses require submitting Expedited/Full Applications need to complete the discipline-specific CITI course. This would be either the Social and Behavioral Sciences Course or the Science and Health Science Course. Most Honors students submitting an Exempt application should only need the Student Course, but the IRB reserves the right to elevate the requirement based upon the research proposal submitted.

The optional modules provide additional education on specific types of research. The IRB requires the completion of optional modules in some cases (e.g., international research, research with minors). These requirements are explained in the Special Topics section of the IRB Manual (see Section 7.0).

The minimum cumulative passing score for all CITI modules is 80 percent. In the event this score is not achieved, the researcher will be asked to repeat module(s). Upon completion of the required CITI modules, the researcher should save a copy of the certificate. The IRB will automatically receive an electronic copy of the certificate as well and this will be uploaded to Mentor.

**4.2 IRB MEMBERS**

Because they are tasked with reviewing applications in many different fields, IRB members must complete the CITI courses for Biomedical and Social & Behavioral Investigators in addition to the basic course for IRB members. IRB Members act as resources to fellow faculty and staff members.

**4.3 OHRP WEBSITE**

The Office for Human Research Protections (OHRP) website is an excellent source of information about conducting research with human subjects: <http://www.hhs.gov/ohrp/> .

**4.4 MARYMOUNT UNIVERSITY IRB POLICY & PROCEDURE MANUAL**

As stated in the Faculty Handbook, all Marymount University faculty are required to follow the Marymount University IRB Policies and Procedures when conducting research with human subjects. Marymount staff members also are required to follow these policies and procedures.

**5.0 PREPARING IRB APPLICATIONS**

**5.1 ACCESSING THE APPLICATION**

IRB forms are available on the IRB website: <https://my.marymount.edu/Offices-Resources/Institutional-Review-Board/Application-Forms> . Researchers should complete one of the following forms, depending on the nature of the project:

* Exempt research: “Application for Exempt Review”; there is an accompanying document with Instructions / Worksheets to determine if EXEMPT level of review is appropriate & including an Informed Consent Checklist.
* Expedited or Full review research: “IRB Application Form”

**5.2 PREPARING THE APPLICATION**

The PI should complete all sections of the application form. Leaving a section blank or providing incomplete responses may delay the review process. If researchers have questions about the process of completing the application, they should contact a member of the IRB to obtain clarification in advance of submitting the application. Current membership of the IRB is available on the IRB Website.

Both IRB forms request information on the following components:

* CITI Training completed and current for all research team members
* Research objectives are clear with valid end goals based on disciplinary standards
* Selection of subjects is equitable and fair
* Risks to subjects are minimized
* Informed consent is obtained and properly documented

Depending upon the research design and the category of review, the following items may also need to be addressed / included:

* Explain how anticipated benefits of the project outweigh the potential risks
* Data collection procedure is monitored to ensure safety of subjects
* Permission to conduct research at off-campus location
* Recruitment materials
* Research instruments (e.g., survey or interview questions)
* Public display of video or images of subjects (Supplement A)
* Deception or incomplete disclosure (Supplement B)
* Conflict of interest (Supplement C)
* Research Abroad or in Non-English-Speaking Communities (Supplement D)
* Use of Protected Health Information (Supplement E)

**5.2.1 The Consent Process**

The Informed Consent process should clearly and concisely describe the research to prospective participants in language that is easily understandable. Researchers should consider the following:

* A common guideline is that the language should not exceed a 4th grade reading level.
* A prospective participant should have a clear idea of ***exactly*** what is expected of them should they choose to participate in the research.
* Researchers must be confident that participants truly understand the research and the consent process. The researcher should have confidence that a signed form represents this.
* In situations where non-English-speaking participants are involved, researchers should meet the requirements for translation of Informed Consent documents (see Section 7.6 in the IRB Manual).
* The MU IRB provides a template for Informed Consent which includes headers and sample language for each required section; the use of the template is strongly recommended.

Federal guidelines require that the following components be covered in the consent process and that each subject or the subject’s legally authorized representative be provided the following information, unless a waiver is approved:

* State that the study involves research and explain the purpose(s) of the research.
* Describe the procedures to be followed and identify any of which are experimental.
* Include the expected location, duration and frequency of subject’s participation.
* Describe any foreseeable risks or discomforts to the subjects.
* Explain how these risks will be minimized by the research procedures.
* Describe any benefits to the subject or to others that may reasonably be expected from the research.
* Disclose appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
* Provide each subject or the subject’s legally authorized representative with the name and telephone number of the PI and the person to contact for answers to questions regarding the research and to report a research-related injury to the subjects. Include a statement of the subject’s rights. Also include this contact information for the IRB: irb@marymount.edu
* State that participation is voluntary, explaining that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. Indicate that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
* Describe the extent, if any, to which the confidentiality of records identifying the subjects will be maintained.
* For research involving more than minimal risk, explain whether any compensation is available and whether any medical treatments are available if injury occurs. If so, indicate what is available and where further information can be obtained.
* Conclude with a statement to the effect that "I understand the above statements and I hereby consent to participate in the research as it has been explained to me."
* Include lines for the signature of the subject, parent(s) or guardian, as appropriate, and the date at the bottom of the form.

Research involving the collection of identifiable private information or identifiable biospecimens requires additional information be provided to each subject. ***Identifiable private information*** is information by which the identity of the subject is or may readily be ascertained by the investigator or others associated with the information. ***Identifiable biospecimen*** is a biospecimen by which the identity of the subject is or may readily be ascertained by the investigator or others associated with the biospecimen. Research involving either of these requires the researcher to include one of the following statements in the informed consent:

* Identifiers might be removed from the identifiable private information or identifiable biospecimens and after 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; or
* 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.

In some cases, more information is required to provide subjects with important material that may influence their decision about participation. Any of the following elements of information, if appropriate, should be provided to each subject or the legally authorized representative in the informed consent:

* A statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable;
* Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s or the legally authorized representative’s consent;
* Any additional costs to the subject that may result from participation in the research;
* The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
* A statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject;
* The approximate number of subjects involved in the study;
* A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
* A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing

**Broad consent** allows subjects to agree to a wide range of future secondary research studies using their identifiable information or biospecimens. Seeking prospective consent to unspecified future research is permitted as an “alternative” to the standard informed consent requirements. A researcher can seek broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. If subject or the legally authorized representative is asked to provide broad consent, the following shall be provided:

* A description of any reasonably foreseeable risks or discomforts to the subject;
* A description of any benefits to the subject or to others that may reasonably be expected from the research;
* A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
* 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;
* If appropriate, a statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
* If appropriate, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing;
* A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens;
* A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
* A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
* Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject’s identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
* Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject;
* An explanation of who to contact for answers to questions about the subject’s rights and about storage and use of the subject’s identifiable private information or identifiable biospecimens, and who to contact in the event of a research-related harm.

**5.3 CONSIDERING THE SPECIAL CHARACTERISTICS OF THE PROJECT**

At Marymount University, researchers undertake a wide range of research projects and research occurs in all Schools (Arts & Sciences, Business Administration, Education & Human Services, Health Professions, and Library & Learning Services), as well as in administrative offices and departments. The IRB will carefully review all applications, keeping in mind that different disciplinary or professional standards can guide responsible conduct of research. In this context, the primary concern of the IRB is the protection of human subjects.

**5.3.1 Research Using Existing Classroom Data**

The IRB does not approve research retroactively. However, if data is collected without the intent of analysis for research or dissemination purposes (e.g., data is collected for assessment of student performance or student perception related to a classroom activity), but later an instructor develops interest in analyzing the data for research or dissemination purposes, IRB review is required at that time. As soon as there is intent to analyze the data for research / dissemination purposes, this marks the need for IRB review.

For example:

* An instructor collects anonymous survey data to determine student perceptions about a class related service-learning project to determine the usefulness of the project. Data from several years of the activity demonstrates themes that the instructor determines may be useful for dissemination in her field and applies for IRB review to allow for analysis and dissemination of findings.
* An instructor modifies a method of classroom instruction in a particular course after studying alternative instruction techniques. After observing trends of improvement in student assessment data in the course, the instructor decides to perform more in-depth data analysis and hopes to disseminate these findings in an education journal. The instructor applies for IRB review to allow for analysis and dissemination of findings.

The relevant component that marks the need for submission of an IRB application for each of these projects is that the INTENT of the project has changed. IRB approval is required PRIOR to the analysis and dissemination of data/findings. Many of these types of projects will qualify for exempt review (e.g., if they are no or minimal risk, if data is anonymous or de-identified). Researchers will need to explain why, how, and by whom the data was initially collected in the IRB application. Researchers will have to clarify their new intent for the data. Many of these types of projects will qualify for an informed consent waiver.

Please be advised, this is NOT an alternative to procuring IRB Approval for planned projects. If you have any intention of using future classroom data for research purposes, or you are anticipating dissemination of data analysis findings, you must procure IRB approval PRIOR to the collection of data.

**5.4 DETERMINING THE TYPE OF REVIEW**

There are three levels of IRB review: Exempt review; Expedited review; and Full review. Each review level varies in terms of the amount of information requested on the forms as well as the number of reviewers required to examine the application.

To determine the level of review required, researchers are encouraged to read Section 5.5 and to consult with an IRB member to confirm whether the project is subject to the federal regulations for human subjects’ research and, if so, to determine the level of review required. Current IRB members are listed on the IRB Website.

**5.5 CRITERIA FOR DETERMINING CATEGORY OF REVIEW**

**5.5.1 Exempt Status**

Research activities involving minimal risk, which are in one or more of the following categories, may qualify as exempt from federal guidelines. (45 CFR 46.101(b)) The term “exempt” here does not mean that the PI does not have to apply to the IRB. Rather, the PI submits an Application for Exempt Review and the IRB will assess the protection of human subjects, and verify the exempt status of the research. The categories eligible for exempt review are:

1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
	1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
	2. Any disclosure of the human subject’s responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
	3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by applicable federal regulations.
	4. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
		1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
		2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
		3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by applicable federal regulations.
	5. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
	6. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
3. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
	1. The identifiable private information or identifiable biospecimens are publicly available;
	2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
	3. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under applicable federal regulations for the purposes of “health care operations” or “research” or for “public health activities and purposes” as those terms are defined and described under applicable federal regulations; or
	4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with applicable sections of the E-Government Act of 2002, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995.
4. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as applicable sections of the Social Security Act, as amended.
	1. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
5. Taste and food quality evaluation and consumer acceptance studies:
	1. If wholesome foods without additives are consumed, or
	2. 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.
6. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by applicable federal regulations.
7. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
	1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with applicable federal regulations;
	2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with applicable federal regulations;
	3. An IRB conducts a limited IRB review and makes the determination required by applicable federal regulations and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (8)(i) of this section; and
	4. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

*Exceptions:*

Research in the above categories is not exemptif any one of the following applies:

* Research could reasonably place subjects at risk of criminal or civil liability or damage subjects’ financial standing, employability, or reputation.
* Research collects sensitive information from subjects. **Sensitive information** *may* include, but is not limited to: information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, insurability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual’s psychological well-being or mental health; and genetic information or tissue samples.
* Subjects are considered to be members of certain vulnerable populations as defined by DHHS (see Section 7.4). Exemptions may be applied to research involving pregnant women, human fetuses and neonates as subjects if the conditions of the exemption are met. Exemptions do *not* apply to research involving prisoners as subjects except for research aimed at involving a broader subject population that only incidentally includes prisoners. Exemptions (1), (4), (5), (6), (7), and (8) may be applied to research involving children as subjects if the conditions of the exemption are met. Exemptions (2)(i) and (ii) only may be applied to research involving children as subjects in educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Exemption (2)(iii) does *not* apply to research involving children as subjects. Additional guidelines apply to research involving children (see Section 7.4.2). When Marymount faculty or staff conduct research using Marymount students over whom they have a supervisory role as subjects, the students are potentially vulnerable and care must be taken to avoid any perception of coercion to participate in the research (see Section 7.4.3.1).

## 5.5.2 Expedited Review

According to OHRP, “The expedited review procedure may not be used, for example, when 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, educational advancement, 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.” The research activities listed below are eligible for the Expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. More specific information may be obtained from <http://www.hhs.gov/ohrp/policy/expedited98.html> .

* The research proposal does not meet criteria for Exempt status.
* Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy adults or children (consult the federal guidelines for amounts of blood that may be obtained).
* Collection of biological specimens by noninvasive means (such as hair and nail clippings, saliva, sputum, mucosal, and skin cells collected by buccal scraping or swab, skin swab, or mouth washings).
* Collection of data through noninvasive procedures (e.g., anthropometric data, electrocardiography, magnetic resonance imaging, and body composition assessment).
* Moderate exercise.
* Voice, video, digital, or image recordings made for research purposes.
* Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. (45 CFR 46.101(b)(2) and (b)(3))
* Research involving the collection or study of existing data, documents, or records when the information recorded by the researcher is private, can identify subjects through linked records and disclosure of that data could pose greater than minimal risk. To qualify for Expedited review, research must include reasonable and appropriate protections so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
* Continuing research previously approved by the IRB as long as: (1) no new subjects are being enrolled; (2) research is active only for long-term follow-up; and (3) the original proposal was reviewed in the Expedited category.

**5.5.3 Full Review**

Research activities involving more than minimal risk and that do not meet criteria for Exempt status or Expedited review are subject to Full review. Full reviews take place at convened meetings during the academic year as announced by the IRB Chair and posted on the IRB website at the beginning of each academic semester. The Principal Investigator(s) on the project should plan to be available to the IRB during the scheduled meeting in which their full review is being discussed to clarify any questioned points. The aim of this request is to better understand the project and more effectively communicate needed revisions, thus leading to fewer resubmissions. Only in extraordinary circumstances, will the IRB convene during the summer to complete a Full review.

**5.6 SUBMITTING AN APPLICATION TO IRB**

Applications are submitted electronically using the Mentor online system. Instructions for using the Mentor system are posted on the IRB website: <https://my.marymount.edu/Offices-Resources/Institutional-Review-Board/Mentor> .

**6.0 IRB REVIEW AND NOTIFICATION PROCEDURES**

 **6.1 REVIEWING PROCEDURES**

IRB Applications are reviewed as outlined below:

* Applications for Exempt Review are reviewed by one IRB Board member, usually the Chair.
* Expedited review applications are reviewed by at least two IRB Board members, one of which can be the IRB Chair.
* Full review applications are reviewed, discussed, and voted upon by a majority of IRB Board members, including at least one member whose primary concerns are in nonscientific areas, at a scheduled IRB meeting. It is requested that the Principal Investigator(s) on the project be available to the IRB during the scheduled meeting in which their full review is being discussed. This allows for clarification of questioned points and will aim to reduce the number of times an application must be revised. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. These applications must be received at least 10 business days prior to a scheduled IRB meeting to allow IRB members the opportunity to review the application prior to the meeting. Submission deadlines are posted on the IRB website.

**6.2 REVIEW PROCESS**

After confirming that an application is complete, the IRB Chair forwards the application for review to appropriate members of the IRB, ensuring that each application is considered by at least one reviewer in the same general area of investigation (i.e., bio-medical, social-behavioral science). Incomplete applications or applications that fail to address the key review components will be returned to the PI with detailed comments for further development.

Reviewers have 10 business days to submit a written evaluation of the application to the IRB Chair. Reviewers evaluate each application using the following criteria specified by the federal guidelines:

* Identification information complete; review category accurately identified
* Research objectives are clear with valid end goals based on disciplinary standards
* Data collection and analysis is monitored to ensure safety of subjects
* Selection of subjects is equitable and fair
* Risks to subjects are adequately identified and minimized
* Risks to subjects are reasonable in relationship to the anticipated benefits of the project
* Informed consent process is explained and properly documented; form included with all required elements (45 CFR 46.111)

After consideration of these criteria, reviewers make one of the following recommendations:

* Approve as submitted (no revisions necessary)
* Approve with minor revisions (detailed revisions required are listed and required revisions will be reviewed by the IRB before approval is given)
* Defer consideration until additional information is provided (detailed information provided about additional information required)
* Recommend disapproval of IRB Application

When a reviewer recommends disapproval, the IRB Chair will contact the reviewer to get further clarification and consult, when appropriate, with other reviewers to assess whether the key issues of concern can be addressed within the scope of the current project. In the event such revision is not possible, the application will be referred to an IRB Board meeting for review by the IRB Board.

After the review, the IRB Chair will send the PI a notification letter indicating one of the following IRB review outcomes depending on the type of application submitted:

**6.2.1 Exempt Review**

* Exempt status verified; or
* Approve with minor revisions; or
* Change in category of review required. This application is referred for Expedited or Full review (this decision requires that the PI submit a different IRB Application); or
* Not Approved. The research as proposed is unacceptable based on noncompliance with federal guidelines and/or the MU IRB guidelines and should not be conducted. In this case, the request will be referred to the full IRB for review.

**6.2.2 Expedited Review**

* Approved as submitted; or
* Approve with minor revisions; or
* Deferred pending additional information; or
* Not Approved. The research as proposed is unacceptable based on noncompliance with federal guidelines and/or MU IRB guidelines and should not be conducted. The application will be referred to the full IRB for review.

**6.2.3 Full Review**

* Approve as submitted (requires a majority vote); or
* Eligible for approval upon IRB acceptance of requested modifications (requires a majority vote); or
* Deferred pending additional information; or
* Disapproved (requires a majority vote). The research as proposed is unacceptable based on noncompliance with federal guidelines and/or MU IRB guidelines and should not be conducted as proposed.

**6.3 MODIFICATIONS**

When the PI is asked to make modifications to the application or provide additional information, the IRB will provide a written summary of specific concerns indicating the aspects of the project that failed to meet federal and/or Marymount IRB guidelines. In some cases, the IRB will suggest revisions to address these problems. The PI must make requested modifications and/or provide additional information and submit a modified proposal to the IRB, which will be reviewed again by the same IRB members who reviewed it the first time. If the changes are acceptable, the PI will be notified that the proposal has IRB approval and the research may begin.

**6.4 DISAPPROVALS**

A disapproval decision indicates that the proposed research should not be conducted as submitted in the IRB Application and the nature of any modifications required would significantly alter the proposed research. The IRB will provide the PI with a written summary of specific concerns indicating the aspects of the project that failed to meet federal and/or Marymount IRB guidelines. In some cases, an application that has been approved by the IRB can be disapproved by the Provost as the Authorized Organizational Representative. In this event a written letter outlining the basis for disapproval will be sent from the Provost to both the IRB Chair and the PI.

**6.5 APPEALS**

PIs may appeal an IRB disapproval decision. To appeal a decision, the PI should first request a meeting with the IRB Chair to discuss the specific concerns outlined in the IRB notification letter. After this meeting, if the PI feels new information could address the identified concerns, the PI can make a written request for reconsideration of the disapproved application. With this request, a revised application should be submitted that includes the new information addressing the specific issues outlined in the IRB notification letter. The appeal will be considered by the IRB at a meeting with the majority of members present. This second review is the final review. If the revised application is also disapproved, the decision may not be appealed.

**6.6 AMENDMENTS TO PREVIOUSLY APPROVED PROJECTS**

Once the IRB has approved a project, it must be carried out as documented in the IRB Application submitted and approved. However, in some cases it may be necessary to make a change to an approved project. Projects that are verified as Exempt status may be amended without notifying the IRB **if** the changes are minor. Examples of minor changes to Exempt status research include: extending the length of the project, changing the location, and changing research team members. Major changes to Exempt status research, which substantially alter the nature of the project, require IRB approval.

Any changes—minor or major—to research approved through Expedited or Full review must be approved as an amendment to the application prior to enacting the changes. For example, changes in the research team, subject population, consent process, data collection methods, and location must be approved by the IRB. The level of review required for the proposed amendment will depend on the nature of the changes proposed. Minor changes are handled quickly by the IRB Chair. Many changes receive Expedited review. Changes that affect the risk/benefit ratio may require Full review.

Amendments are submitted through the Mentor system following the instructions posted on the IRB website. Depending on the nature of the changes proposed, new recruitment and consent materials may need to be submitted for review. The proposed changes may not be implemented until the PI receives written notification of IRB approval of the amendment.

**6.7 ANNUAL REPORT, CONTINUING REVIEW AND TERMINATION**

Research projects that have been verified by the IRB as Exempt status or approved through the Expedited review procedure do not require continuing review and do not need to be formally closed. All Full review research require the submission of an annual report and either a request for continuing review or termination (45 CFR46.108(e)). This section (6.7) applies only to Full review research.

While initial IRB review is based on the PIs’ best assessment of the anticipated benefits, risk, and procedures, ongoing monitoring is based on the conduct of the study; actual risk can be evaluated and preliminary results can be used to assess the risk/benefit ratio. In addition, the risk/benefit ratio may change not only because of unexpected results and effects of the research intervention itself, but because new knowledge resulting from related research may affect the balance. The annual report, with a request to continue the project for another year, provides an important opportunity for the IRB to review the research conducted. If continuing review is requested, the IRB can ensure that changes in federal or state policy and Marymount IRB policies and procedures are reflected in the continuing research.

The IRB approval expiration date is printed in the notification letter. Typically, the expiration date is calculated as 364 days from the approval date, thus requiring that the PI either requests continuing review or closes the project annually. To request continuing review or to close the project, the PI must complete an annual report on Mentor. However, in cases of increased risk, the IRB may require more frequent continuing reviews be conducted. Reminders to submit an annual report are emailed to the PI seven weeks prior to the IRB approval expiration date. If the PI is closing the project, the annual report must be submitted no later than the IRB approval expiration date. If the PI wishes to continue the research, the annual report requesting continuing review must be submitted at least four weeks prior to the expiration date. These procedures are discussed in more detail below.

Federal regulations make no provision for any grace period extending the conduct of research beyond the expiration of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires or the project must cease.

Applying for Continuing Review

To continue research beyond the IRB approval expiration date, the PI must seek continuing review. This is done by submitting an annual report on Mentor at least four weeks prior to the expiration date. The IRB must have time to complete a thorough review and request additional documentation from the PI as needed. If the PI has applied for continuing review but has not been notified of re-approval by the expiration date, the PI is required to suspend contact with subjects and all data collection must cease until the project is approved to continue. For ongoing studies where subject safety is a concern, federal regulations allow some flexibility towards the continued treatment for those who are currently enrolled (e.g., medical treatment with follow-up).

The approval criteria for continuing review are the same as the criteria for initial review published in the current IRB Manual. The IRB has access to the approved IRB application and amendments through Mentor. For continuing review, the PI must submit an annual report via Mentor with the following information:

* The number of subjects enrolled since the last review and the total number of subjects enrolled to date;
* A summary of the results of the research to date, including:
	+ Any amendments to the research approved by the IRB since the IRB’s initial review or the last continuing review;
	+ Any unanticipated risks or adverse outcomes;
* Any difficulties recruiting or retaining subjects, an explanation of the difficulties, and the number of subjects who withdrew from the study and their reasons for withdrawing; and
* If still open to new subjects, a copy of the recruiting materials and *consent form currently* in use (the consent form must be uploaded under the report).

Note that while amendments to the research project may be considered in tandem with a request for continuing review, amendments must be submitted separately (see Section 6.6).

Unless the IRB determines otherwise, research projects that initially required continuing review will no longer require continuing review if the research has progressed to the point that it involves only one or both of the following:

* Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
* Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

In reviewing the request to continue the project, the IRB has the authority to approve, require modifications, suspend, or terminate approval of research that is not being conducted in accordance with the IRBs requirements or that has been associated with unexpected serious harm to subjects. If approved, the PI will be notified of the new expiration date of IRB approval, which cannot be longer than one year.

If the PI fails to submit an annual report by the approval expiration date, the project will be classified as “closed” by the IRB and all data collection and analysis of identifiable data must cease. In order to obtain IRB approval for the closed project, the PI must complete the past due annual report and re-apply following the current IRB policies and procedures. Until the past due annual report is submitted, the PI will be unable to submit any IRB applications or amendments for review.

Terminating Research Projects

The PI is responsible for maintaining current IRB approval until all of the following occur:

* Subject recruitment has concluded (i.e., no subject recruitment is in progress or anticipated);
* All subject specimens, records, data have been collected (i.e., no further collection of data/information from or about living individuals is needed);
* All interactions or interventions with subjects are completed (i.e., no further contact with subjects is necessary or anticipated); and
* Analysis of identifiable data, records, and specimens are finished (i.e., use or access to subject identifiable data is no longer necessary).

When all of these have occurred, the PI should terminate the project. The project may be terminated by the PI at any time but no later than the IRB approval expiration date. The procedure for terminating the project is to complete the annual report on Mentor noting the date the project was closed. Until the project is terminated, the PI is required to submit annual reports requesting continuing review. If the PI fails to either terminate the project or request continuing review, the PI will be blocked from submitting new applications or amendments until the past due annual report is submitted.

**7.0 SPECIAL TOPICS**

**7.1 UNANTICIPATED PROBLEMS AND ADVERSE EVENTS DURING RESEARCH PROJECT**

During the course of a research project, unexpected problems may occur. Unanticipated problems and adverse events must be reported immediately through Mentor under the Adverse Events tab for the approved protocol. In such cases, the IRB may need to reassess the balance of risks to benefits and may require that the research be modified or halted altogether.

Even isolated incidents of unanticipated adverse reactions must be reported to the IRB. It is the responsibility of the researcher to keep the IRB informed of significant findings that affect the risk/benefit ratio. The IRB must decide whether the research should be modified or halted. Federal policies require that researchers inform human subjects of any important new information that might affect their willingness to continue to participate in the research project. The OHRP provides specific guidance to help researchers assess the severity of these unanticipated problems as well as the federal requirement for reporting them.

**7.2 NONCOMPLIANCE OF RESEARCHERS**

According to the federal government’s *IRB Guidebook* (1993), researchers are the most frequent source of noncompliance with human subjects’ regulations. The most common compliance failures are: failure to submit applications to the IRB before research commences; avoiding or ignoring the IRB; unreported significant changes in projects; and misuse or nonuse of the informed consent document. Regardless of intent, these are all serious issues that place human subjects at an unacceptable risk and expose the University to sanction or liability.

When unapproved research is discovered, University officials will act promptly to halt the research. Data collected may not be used and should be destroyed. The IRB does not grant retroactive approval of research. In the case of noncompliance on federally funded research, the IRB may be required to report the incident to DHHS.

All members of the Marymount community are expected to report noncompliance with IRB policies and procedures if discovered. If a faculty or staff member discovers human subjects’ research taking place that has not been through IRB review, it is the responsibility of that faculty or staff member to report the research to an IRB member. Any “serious or continuing noncompliance” with IRB policies, requirements, or determinations should be reported to the IRB Chair or the Provost’s designee to the IRB committee. The IRB Chair will notify the PI immediately of the suspected noncompliance and provide the Provost’s designee to the IRB committee with IRB records relevant to the case. The Provost’s designee will conduct an investigation during which time the researchers involved may not submit new applications for review. Depending on the nature of the suspected noncompliance, the researchers may be directed to stop any or all research projects until they are notified of the outcome of the investigation. If noncompliance did occur, the Provost will determine the appropriate response from the University and notify the PI and the IRB Chair, as well as the Dean(s) and Department Chair(s) of the researchers.

The University regards IRB policy & procedures noncompliance as a breach of the expected standard of conduct of University employees and students and considers this behavior detrimental to the University. Sanctions for faculty or staff may include a poor performance evaluation or involuntary termination of employment; Sanctions for students may include a failing grade in a course or dismissal from the University.

**7.3 RESEARCHERS FROM OTHER INSTITUTIONS**

**7.3.1 Review for Unaffiliated Researchers**

Occasionally Marymount University may be asked to provide IRB review for researchers who are affiliated neither with Marymount University nor with another institution that has an IRB. If the unaffiliated researcher is collaborating on a research project based at Marymount, the MU faculty member with whom he/she is collaborating would serve as the PI and submit the application to MU IRB. Marymount University does not extend IRB oversight to research by unaffiliated researchers with whom the University is not otherwise engaged.

**7.3.2 External Researchers Studying the Marymount Community**

Occasionally a PI from another institution will request to conduct a study on campus involving Marymount faculty, staff, or students that has already been approved by an external IRB. In these situations, the external PI must collaborate with a Marymount faculty or staff member who serves as a co-investigator for study at Marymount and the point of contact (i.e., PI of record) with the MU IRB.

Before initiating any research involving Marymount faculty, staff, or students, the Marymount collaborator must submit a copy of the approved IRB application with an explanation of the situation via Mentor. In addition, the PI should complete those portions of the MU IRB Application that apply specifically to the Marymount population intended to be studied. Because students and employees could be vulnerable to coercion, the PI should explicitly address those sections of the application that consider fairness of subject selection and risk versus benefit for the Marymount population.

**7.3.3 Cooperative Research Projects (Sharing IRB Oversight Among Institutions)**

Research projects may involve researchers at multiple institutions with multiple IRB oversight. In these cases, each institution is responsible for safeguarding the rights and welfare of human subjects. To avoid duplication of effort, however, it may be appropriate for one institution to rely on the IRB of another for review and continuing oversight of the research. In this case, the two institutions will share an authorization agreement in which Marymount University may be either the institution deferring to another institution or the institution to which the IRB review is delegated. This decision is made by the IRB Chair, and researchers are encouraged to consult with the Chair early in the planning process.

**7.4 VULNERABLE POPULATIONS**

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| The three basic ethical principles for conducting research involving human subjects in the *Belmont Report* are critical safeguards for all human subjects and must be assiduously considered especially when the research involves vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, or anyone who may be unduly coerced. These principles, respect for persons, beneficence, and justice, apply universally to all human subject populations but one, respect for persons, is especially crucial in the case of vulnerable populations (see Section 1.1).  |
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| Respect for persons requires researchers to treat individuals as autonomous human beings who are capable of making their own decisions and free to do so. Under this principle, the PI has the responsibility to ensure that members of a vulnerable population are afforded extra protection from undue influence, coercion, or reprisals resulting from their decision to volunteer for or withdraw from a research study. The principle of respect also requires PIs to develop and implement a meaningful consent process that provides full disclosure of all information necessary for potential subjects to make informed decisions about their participation and/or withdrawal from the research project. Beneficence and justice, the other two Belmont Principles, also have unique meanings for research involving vulnerable populations. Beneficence requires that PIs minimize the risks of harm and maximize the potential benefits of their research. Justice requires the fair and equitable selection of human subjects. Subjects must be selected based solely on scientific justification and not because they are available, unable to refuse participation, or simply because they are a convenient and pliable population. Under the principle of justice, those who benefit from the research should share, as equitably as possible, in its burden.  |

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Research involving members of a vulnerable population may result in potential harm to individual human subjects who are members of the vulnerable population as well as to the group as a whole. For example, information gained as a result of the research may indicate that a certain group of individuals has a higher prevalence of alcohol abuse or sexually transmitted diseases. This information could cause social stigmatization and economic repercussions. Minimizing group harms is an important consideration for researchers and should be carefully considered prior to the start of any research project.

Researchers should take steps to minimize group risks. These steps include:

1. Determining what harms could befall a group as a result of the research.
2. Determining if there are any possible unintended consequences that are likely to arise from the research.
3. Answering the question: How would I feel if I were part of this group?
4. Determining if the potential harms of the research outweigh the potential benefits.
5. Considering carefully how others such as employers, insurers, etc., could be influenced by the research findings.
6. Consulting with the community to which the group belongs to determine if there are potential risks the researcher had not considered.
7. Planning to hold on-going consultations with the group to minimize risks to the group members.

**7.4.1 Prisoners**

There are special federal regulations for conducting research with prisoners as subjects noted in Subpart C of 45 CFR 46. PIs are urged to contact the IRB early in the planning stages of such research for guidance on complying with these regulations, which are only briefly summarized here. Additional restrictions apply to research funded by the DHHS. For additional details see 45 CFR 46.301. All researchers involved in research with prisoners must complete the CITI module “Vulnerable Populations-Research Involving Prisoners” before submitting an IRB Application.

Prisoner is defined by DHHS regulations as any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute; individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; and individuals detained pending arraignment, trial, or sentencing (45 CFR 46.303(c)).

Though respect for persons, beneficence, and justice must guide all human research, they are especially crucial in the case of prisoners. Subpart C states, “Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.” (45 CFR 46.302)

When the IRB reviews research that will involve the use of prisoners as subjects, a prisoner or prisoner representative must participate in all types of these reviews (e.g., initial review, continuing review, amendments, and reports of adverse events). In order for the IRB to approve a study, there are seven conditions that must be met and the research must fit into one of four categories.

The provisions of Subpart C also apply when a research subject becomes a prisoner after the research has commenced. If a subject becomes a prisoner during a study, it is crucial that the PI contact the IRB immediately because additional review is necessary to comply with 45 CFR 46 Subpart C.

When the IRB is reviewing an application in which prisoners will be subjects, the following seven conditions must be met in addition to other requirements under 45 CFR 46, Subpart A:

1. The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2);
2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. The information is presented in language which is understandable to the subject population;
6. Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
7. Where the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner’s sentences, and for informing subjects of this fact.

 **7.4.2 Children**

There are special federal regulations for conducting research with children as subjects. Children are defined by DHHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted.” (45 CFR 46.102, Subpart A)

When reviewing research with children as subjects, in addition to ensuring adherence to the general regulatory requirements of 45 CFR part 46, Subpart A, the IRB also must consider the potential benefits, risks, and discomforts of the research to children and assess the justification for their inclusion in the research. In assessing the risks and potential benefits, the IRB considers the circumstances of the children to be enrolled in the study, e.g., their health status, age, and ability to understand what is involved in the research, as well as potential benefits to subjects, other children with the same disease or condition, or society as a whole.

Additional protections of children include requiring IRB review of some research activities involving children that would be exempt if the research subjects were adults; use of parental permission and child assent instead of the procedures for obtaining informed consent used for research involving adults; conditions for IRB approval of proposed research activities in three categories depending on the level of risk and other specified features of the proposed research activity; review by the Secretary of Health and Human Services for research that an IRB finds not approvable under any of the three categories; and, additional conditions for certain research activities involving children who are wards of the State or any other agency, institution, or entity.

All researchers involved in projects with children as subjects must complete the additional CITI module “Research with Children – SBE” prior to submitting an application for IRB review. In addition, if the project involves research in public schools, all researchers must complete the CITI module “Research in Public Elementary and Secondary Schools – SBE” prior to submitting the application. For complete regulatory guidelines see 45 CFR 46.404 and Subpart D, Additional Protections for Children Involved as Subjects in Research.

Subpart D permits IRBs to approve three categories of research involving children as research subjects:

1. Research involving no greater than minimal risk to the children. (45 CFR 46.404) To approve this category of research, the IRB must make the following determinations:
* The research presents no greater than minimal risk to the children;
* Permission of one parent/guardian; **and**
* The assent of the child, as set forth in DHHS regulations at 45 CFR 46.408.
1. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research. (45 CFR 46.405) To approve research in this category, the IRB must make the following determinations:
* The risk is justified by the anticipated benefits to the subjects;
* The relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available standard approaches;
* Permission of one parent/guardian; **and**
* Adequate provisions are made for soliciting the assent of the child as set forth in DHHS regulations at 45 CFR 46.408.
1. Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition. (45 CFR 46.406) In order to approve research in this category, the IRB must make the following determinations:
* The risk of the research represents a minor increase over minimal risk;
* The intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;
* The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition;
* Permission of both parents/guardians; and
* The assent of the child as set forth in DHHS regulations at 45 CFR 46.408.

A fourth category of research that requires a special level of DHHS review beyond that provided by the IRB is research that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406 but does present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children (45 CFR 46.407 B). If the IRB believes that the research does not meet the requirements of 45 CFR 46.404, 46.405, or 46.406, but finds that it presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, it may refer the project to DHHS for review. The research may proceed only if the Secretary of DHHS, or his or her designee, after consulting with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) deems that:

* The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
* The research will be conducted in accordance with sound ethical principles; **and**
* Adequate provisions are made for soliciting the permission of both parents/guardians and the assent of child, as set forth in HHS regulations at 45 CFR 46.408.

If the research involves a product that is FDA-regulated, FDAs regulatory requirements at 21 CFR 50.54 must also be met. (45 CFR 46.407)

**Wards**

Children who are wards of the state or any other agency, institution, or entity can be included in research approved under 45 CFR 46.406 or 45 CFR 46.407 only if such research is:

1. Related to their status as wards; or
2. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

When research with children is conducted in the schools, the following apply:

* 45 CFR Subpart D
* Family Educational Rights and Privacy Act (FERPA)
* Protection of Pupil Rights Amendment (PPRA) (unless the research occurs in a private school that does not receive any federal funding)

**7.4.3 Marymount University Community**

**7.4.3.1 Marymount Students**

In an academic institutional setting, students play an integral role as subjects in certain research situations (e.g., research dealing with teaching methods,curricula, and other areas related to the scholarship of teaching and learning). An underlying principle of the regulations governing the involvement of human subjects in research is that the subject’s participation is voluntary and based upon full and accurate information.

Marymount students may, on occasion, be the subjects in a research project and PIs may include them as long as certain risks are considered and addressed in the IRB application and research design. Researchers should take particular care to avoid the unintentional or subliminal coercion that may occur when potential subjects are also current or future students who will receive a grade from the researcher. *For this reason, researchers who serve as instructors, in particular, should avoid involving their current or future students as research subjects.* PIs who wish to involve their own students as subjects should be able to provide a research rationale, rather than convenience, for selecting those students as research subjects. Furthermore, the research project should be relevant to the topic of the class, and participation should be part of the learning experience for the students who choose to participate.

When PIs can provide a research rationale for involving their own students in the project, the IRB generally requires that someone other than the PI (instructor) obtain informed consent and collect the data. If this is not possible, the IRB will consider other methods for obtaining consent and collecting data that would not reveal to the researcher whether or not a specific student participated in the research project until after final grades have been submitted. The students should be informed of all procedures to protect them from undue coercion in the informed consent form. In addition, it is recommended that the researcher circulate a recruitment flyer or letter to a student pool, general student population, or both so that the student may be the one who initiates contact with the researcher.

Researchers are expected to carefully consider the following issues when designing and implementing research projects that include students:

* + Student unwarranted anticipation of reward: Students may volunteer to participate in a research project in hopes of securing better grades, or other benefits such as employment or letters of recommendation. Researchers should make sure that students understand that their grade and relationship with the researcher will not be affected positively or negatively by their participation or failure to participate.
	+ Coercion/undue influence: Students may not be entering into the research project freely but rather may feel some level of coercion/undue influence even if that is not the intention of the investigator. The IRB must pay special attention to the potential for coercion or undue influence when students are the subject of the research project. In recruiting students to participate in research, PIs should recruit from the campus community as a whole (advertise for subjects generally, such as notices posted in the dining hall, school, or department) rather than by direct contact with the student.
	+ Compensation or extra credit: Requiring participation in research for course credit, giving extra credit or financial remunerations to those who volunteer is controversial and should not be excessive
	+ Underage participation: Students may be minors. Some freshmen may be under the age of 18 and therefore would need parental consent to participate. In order to restrict the subject pool to adults, the consent process must explicitly exclude anyone under 18 from participation.
	+ Confidentiality: Confidentiality can pose a problem especially if the research involves the collection of data on sensitive subjects such as mental health, sexual activity, alcohol consumption, etc. The somewhat closed society of a campus exacerbates the problem of protecting confidentiality.

**7.4.3.2 Marymount Employees**

Marymount employees share similar risks of confidentiality, coercion, and undue influence as do Marymount students who participate in research projects. The possibility exists that the decision to participate will affect performance evaluations or job advancement. It is the responsibility of the PI to consider these risks carefully when designing the research project, particularly with regard to recruiting subjects from the campus community and protecting the confidentiality of the data and the subjects.

**7.4.3.3 Other University Affiliates**

As a university, Marymount has relationships with many other people who could be recruited for participation in research studies. Potential subjects include alumni, benefactors, and other guests. PIs should be mindful that based on their relationship with the University, these populations may be more vulnerable to undue coercion. For example, alumni may think participation could result in a more positive letter of recommendation or benefactors and guests may feel undue pressure to participate in a study as “doing a favor” for the University. When a research project involves recruiting university affiliates, researchers need to ensure that any perception of reward or undue coercion is minimized.

**7.4.4 Other Vulnerable Populations**

Other vulnerable populations include pregnant women and those who are educationally, socially, and economically disadvantaged; mentally impaired persons; terminally ill patients; and elderly, as well as those who are incapable of making independent informed decisions.

The federal regulations for the protection of pregnant women, fetuses, and neonates are very detailed and available in 45 CFR 46.201. PIs anticipating working with this population should consult these regulations when developing their IRB applications and seek guidance from the IRB Chair early in the process. Additional CITI modules are required by the IRB when a research project involves pregnant women, fetuses and neonates.

Researchers should ensure that individuals from educationally, socially, and economically disadvantaged populations are represented in appropriate numbers in the research project. Over-representation of these vulnerable populations must be avoided unless the research is specifically focused on the population. When this is the case, PIs must consider carefully all factors that may impede the ability of individuals to give fully informed consent.

PIs conducting research involving subjects who are not able to make independent informed decisions must ensure that the legal guardian is fully informed and is authorized to give consent for those in their care.

**7.5 INTERNATIONAL RESEARCH**

Research conducted with human subjects outside of the United States must still conform to the same university policies, ethical guidelines, and standards as research conducted within the United States. However, government regulations recognize that the procedures normally followed in the foreign countries [in which the research will take place] may differ from those set forth in this policy (45 CFR 46.101(h)). Under such circumstances, the procedures must provide protection to human subjects, which is at least equivalent to protections provided by 45 CFR46 and Marymount IRB policies.

PIs must complete the CITI module “International Studies” before submitting their application to the IRB. Researchers must gain approval from the local IRB (or equivalent) before or in conjunction with submitting an application to Marymount University’s IRB. If there is no local IRB (or equivalent group), the PIs must attain approval from local experts or community leaders. Documentation of this approval is required by the IRB before it gives final approval of the application.

International research projects require that the submission of Supplement D: Research with Non-English-Speaking Subjects or International Research. Researchers must be knowledgeable about the local regulations in order to submit an IRB application for international research. Local customs and laws that affect the design and/or implementation of the research project must be conveyed to the IRB in the application.

PIs should consult the DHHS resources on international research, such as the 2012 *International Compilation of Human Research Standards,* which is available at <http://www.hhs.gov/ohrp/international/compilation-human-research-standards/> for further information on regulations for specific countries.

**7.6 RESEARCH INVOLVING NON-ENGLISH-SPEAKING SUBJECTS**

When research involves subjects who are non-English-speaking, the informed consent process must be presented in a language they understand. It is essential that all subjects have an opportunity to understand enough about the study and the aspects of consent to make an informed decision about participating in the research study (45 CFR 46.116 and 117 a and b).

When research involves non-English-speaking subjects, the IRB application must include all informed consent materials, recruitment materials, and surveys in English as well as the subjects’ language(s). However, the applicant may choose to postpone translation of these materials until the IRB has approved the English version. Supplement D: Research with Non-English-Speaking Subjects or International Research must be submitted with the IRB application.

**7.6.1 Translating Consent Forms/Scripts**

The consent form or oral script used with non-English-speaking subjects should be the same as that used for English-speaking subjects in content and format. The requirements regarding the translation process vary depending on the level of risk of the research. Depending of the level of risk involved, one of the following three methods must be used:

### Translations for Minimal Risk Research

For studies involving minimal risk to subjects (“no foreseeable risks involved in participating in this research beyond those experienced in everyday life”), the qualifications of the translator should be provided (e.g., native speaker, academic degrees, certified translator, etc.) to the IRB when foreign language versions of consent forms are provided. It is the responsibility of the researcher to ensure that the non-English version contains all of the key elements of the English version.

Translations for More than Minimal Risk Research

For studies involving greater than minimal risk to subjects, the IRB requires that the PI use either a certified translator (with a letter of certification from the translator or translation service) or a “back-translation” method in which one translator translates from the English version and a separate translator translates the document back to English. The back translation (back into English) serves to ensure that the non-English version contains all of the key elements of the English version. All relevant translation documents must be approved by the IRB.

Alternative Short Form Consent Method

For the occasional non-English-speaking subject, an alternative shortform methodis allowed by federal regulations but routine use of this method is strongly discouraged [45CFR 46.117 (b) (2)]. In these cases, the researcher may use a translated “short form” together with the English consent form as described in the following:

 Procedures for the Alternative Short Form Consent Method:

1. The IRB must approve use of the short form consent method before it is used by a PI. If the PI did not include this procedure in the approved IRB application, an amendment to the application must be submitted and approved prior to initiating the short form consent method.
2. A short form must be in the language of the potential subject. Typically, the short form is given to the potential subject to read; however, if the potential subject cannot read, it should be read to the subject by the interpreter.
3. Next an [interpreter](http://www.research.uci.edu/ora/glossary.htm#Interpreter), in the presence of the researcher, will orally translate the IRB-approved English consent form for the potential subject and facilitate a question and answer phase of the informed consent process between the potential subject and the researcher.
4. A [witness](http://www.research.uci.edu/ora/hrpp/informedconsentprocess.htm#witness) must be present during the oral translation of the IRB-approved English consent form. The witness must be an adult fluent in both English and the potential subject’s language. The witness cannot be a member of the research team; however, the interpreter may serve as the witness.
5. If the potential subject consents to participate, the following [signatures](http://www.research.uci.edu/ora/hrpp/informedconsentprocess.htm#required) must be obtained on the short form consent and the IRB-approved English consent form:
	* The subject will sign and date the short form consent; and
	* The witness and researcher will sign and date *both* the short form consent and the English consent form.
6. A copy of the English consent form and the short form will be given to the subject.

**7.7 PROTECTED HEALTH INFORMATION AND HIPAA**

Researchers who have access to Protected Health Information (PHI) within the context of their research are required to comply with the “Privacy Rule,” a Federal regulation (introduced in 2000) as a component of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The Privacy Rule was issued to protect the privacy of health information that identifies individuals. Researchers who will use PHI are required to complete the HIPAA module in the CITI training before submitting an IRB Application. This module is included in the basic course for health science and listed as an optional module for those who complete the basic course for students and the basic course for social behavioral researchers. Supplement E must be included with the IRB Application to demonstrate their compliance with, or to justify their request for a waiver from, HIPAA privacy guidelines. Waivers of HIPAA authorization are rarely approved.

## HIPAA Authorization is separate from consent to participate in research. HIPAA Authorization differs in that an Authorization focuses on the privacy risks and states how, why, and to whom the PHI will be used and/or disclosed for research. An informed consent, on the other hand, provides research subjects with a description of how the confidentiality of records will be protected, among other things. The two may be combined on a single form only if it they are clearly distinguished in purpose.

**7.8 INTERNET RESEARCH**

Computer- and internet-based methods of collecting, storing, utilizing, and transmitting data in research involving human subjects are developing at a rapid rate. As these research methods become more widespread in the social, psychological, and social sciences, they present new challenges to the protection of research subjects. The IRB reviews computer- and internet-based research projects using the same considerations and standards of approval (45 CFR 46.111) as all other research activities. All projects, including those using computer and internet technologies, must (a) ensure that the procedures fulfill the principles of voluntary participation and informed consent; (b) maintain the confidentiality of information obtained from or about human subjects; and (c) adequately address possible risks to subjects including psychosocial stress and related risks.

Researchers are reminded of the importance of asking questions that enable the authentication of subjects. The integrity of a research project may be threatened if proper qualification or identification of subjects is not obtained. Researchers should consider the following points when conducting internet research:

Method of Data Collection

The IRB strongly recommends that all data be collected over secure networks and transmitted via SSL encryption as discussed in the Security of Data section below. Researchers not administering their own surveys should use a reliable, professional service to administer the survey. Two commonly used services are SurveyMonkey and Psychdata. Researchers using SurveyMonkey should be aware that only the paid SurveyMonkey subscriptions offer SSL encryption. Psychdata offers SSL encryption for all studies. Marymount’s Office of Institutional Effectiveness subscribes to a professional survey site (Qualtrics) that may be used by MU faculty or staff.

Surveys should be formatted in a manner that allows subjects to withdraw at any point and to refuse to answer any questions. This is considered the best practice in conducting a survey. The IRB recommends this practice for projects seeking Exempt status and requires it for projects under Expedited or Full review.

When researchers are planning to survey large numbers of Marymount University students via email invitation, there is a policy from the Office of Planning and Institutional Effectiveness (PIE) that will impact email distribution of surveys. Researchers are encouraged to contact PIE for details that may impact survey distribution early in the process.

Informed Consent

The informed consent process must be carefully thought out when conducting online surveys. In some cases recruitment to participate is combined with the informed consent text as the introductory screen of the survey. Regardless of the format, all required elements for informed consent must be provided to potential subjects who must be given an opportunity to accept or decline the invitation to participate (see Section 5.2.1). The informed consent text should either end with a line stating that “Completion of the survey indicates agreement to participate in the research” or with radio buttons that indicate “agree” and “do not agree.”

Online surveys intended for adult subjects may be taken by minors by mistake. Researchers must take precautions to ensure that minors do not participate in research unless the project has been approved by the IRB to include minors. If minors are excluded from participation, this must be stated clearly in the informed consent text and repeated in the conclusion. For example, “Completion of the survey indicates that I am at least 18 years of age and freely consent to participate.” A consent form template is available on the IRB website (please see <https://my.marymount.edu/Offices-Resources/Institutional-Review-Board/Application-Forms>).

Typically online surveys do not require that subjects sign a consent form. When there is no signed consent form, the PI must request a waiver of the requirement to document consent on the IRB Application.

If you are emailing a survey to members of a list, or group, state if you have been authorized by the list or group owner/administrator to post messages and recruit research subjects from the group.

The informed consent text must include information regarding the safety and storage of data as noted below under Security of Data. If the PI is running his or her own server, subjects will be given a full set of instructions about the use and level of any encryption software used. Included in this should be a description of how, if at all, subjects will be identified during data collection and in dissemination of the results. Researchers using professionally available sites must indicate the use and level of encryption and if IP and email addresses are being stored. For more information on security of data see the follow web resources:
SurveyMonkey - <https://www.surveymonkey.com/mp/policy/security/>

Psychdata - <https://www.psychdata.com/content/irb.asp>

Subjects should be informed that online communications may be subject to open records requests subject to hacking, and therefore anonymity cannot be guaranteed.

Security of Data

Details regarding the security of data transmission and storage must be provided in the IRB Application and in the informed consent text. It is the responsibility of the PI to understand and identify the level of security provided by the research tools being used.

The IRB strongly recommends that all data be collected over secure networks and transmitted using at least SSL encryption methods. SSL is short for **S**ecure **S**ockets **L**ayer, and it is a protocol initially developed for transmitting private documents or information via the Internet. While SSL encryption is not required for approval of projects requesting Exempt status, it is required for all projects under Expedited or Full review.

If researchers choose to run their own server, it must be administered professionally; have limited access; and have frequent audits and undergo periodic security scans. Furthermore, data and personal identification information shall be stored on separate servers. Backups are required in case of equipment failure and any backups should be stored in a safe location.

**7.9 RECORDS-BASED RESEARCH**

Most research that utilizes secondary (existing) data sets does not meet the definitional criteria for “human subjects” research and, therefore, does not require IRB approval (see Section 1.2). Records-based research that does require IRB approval typically involves analysis of documented information in various types of paper or electronic records, including, for example, medical, motor vehicle, criminal justice, or school records.

Researchers conducting scientific research based on records should:

• Understand the specific risks to human subjects associated with such research,

• Ensure that the research protocol specifies procedures that minimize those risks, and

• Obtain all required approvals (institutional, state, federal, and international, if applicable) prior to conducting the research.

All researchers involved in projects collecting information from records for purposes of research must complete the additional CITI module “Records-Based Research” prior to submitting an application for IRB review.