

Institutional Review Board for the Protection of Human Subjects (IRB)



Policies and Guidelines

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Table of Contents

Institutional Review Board for the Protection of Human Subjects	5
Statement of Principles	5
1.0 Marian University Policy on Research Involving Human Subjects	5
1.1 General Policy Statement	5
1.2 Authorized Institutional Official (AIO)	6
2.0 Institutional Review Board on Human Subjects Research (IRB)	6
2.1 Role of the IRB	6
2.2 Authority of IRB	7
2.3 IRB Functions	7
2.4 IRB Membership	8
2.5 Membership Appointment	9
2.6 Ad-hoc Consultants	10
2.7 Conflict of Interest and IRB	10
2.8 Operations of the IRB	10
2.8.1 Meetings	10
2.8.2 IRB record requirements	11
2.8.3 Retention of records	11
2.9 Confidentiality	12
2.10 IRB Training for Board Members	12
2.11 Role of the Office of Research and Sponsored Programs (ORSP)	12
2.11.1 ORSP Administrative support	12
2.11.2 Compliance Responsibilities	12
2.11.3 Grant proposals and IRB –	13
3.0 Definitions	13
3.1 Definition of Human Subject	13
3.2 Definition of Research Covered by this Policy	14
3.3 Special Classes of Human Subjects Safeguards and Consent	14
3.3.1 Research with Pregnant Women	14
3.3.2 Research with Prisoners as Subjects	15
3.3.3 Research with Children	16
3.3.4 Research with Children in School Settings	18
3.3.5 Students as Subjects	18

3.3.6 Other Special Classes of Subjects.....	19
4.0 General IRB Review Process	19
4.1 IRB Protocol	19
4.2 Due Dates for IRB Protocol Submissions	19
4.3 IRB Review and Action Notification	20
4.3.1 Review of Protocols	20
4.3.2 Authorized IRB Actions	21
4.4 Appeal of IRB Decision	21
4.5 Report of Adverse Events	21
4.6 IRB Review of Formerly Approved Research Projects	22
4.6.1 Changes or Modifications to Original IRB Submissions	22
4.6.2 Continuing Review	22
4.6.3 Suspension or Termination of IRB Approved Research	23
5.0 Exempt Status, Expedited, and Full Board Review	23
5.1 Exemption from IRB Review	23
5.1.1 Exempt Categories.....	23
5.1.2 Determination of Exempt Status	25
5.2 Expedited IRB Review (minimal risk):.....	25
5.2.1 Expedited Review Applicability	25
5.2.2 Nine Expedited Review Categories	26
5.2.3 Criteria for Expedited Review.....	27
5.2.4 Expedited Review Process	28
5.3 Full IRB Review.....	28
5.3.1 Full IRB Review Applicability	28
5.3.2 Criteria for Full Board Review	29
5.3.3 Full-IRB Review Process	29
6.0 Course Assignment.....	29
6.1 Course Assignments that must be reviewed by IRB.....	30
6.2 Responsibilities of Faculty.....	30
7.0 Informed Consent.....	31
7.1 Purpose of Informed Consent	31
7.2 Elements of an Acceptable Informed Consent Document.....	31
7.2.1 Required information	32
7.2.2 Oral Consent	33
7.2.3 Audio or video recording	33

7.3 Waiver of Requirements to Document Informed Consent	34
8.0 Education and Certification of Researchers	34
8.1 Purpose of Education and Certification of Researchers	34
8.2 Initial Education and Certification of Researchers	35
8.3 Continuing Education	35
8.4 Alternative Training for Special Circumstances	35
8.5 Collaborating with Researchers at Other Institutions.....	35
9.0 Archival Data, Cooperative Research, and Data Sharing.....	35
9.1 Archival Data.....	35
9.2 Cooperative Research with Other Institutions.....	36
9.3 Data Sharing	37
9.4 Record Retention	37
10.0 Engaging in Human Subject Research without IRB Approval	37
10.1 Marian University Policy.....	37
10.2 Possible Ramifications for Faculty and Staff	38
10.3 Possible Ramifications for Students	38
11.0 Interpretation of IRB Policy	38

Institutional Review Board for the Protection of Human Subjects

Statement of Principles

Marian University encourages and supports free and responsible investigation by faculty, staff and students. The policies and procedures of Marian University for protection of human subjects have been established to protect the rights and welfare of human subjects utilized in research projects. When research is conducted using University facilities or resources under its sponsorship, the individuals conducting the inquiry act as University representatives. Safeguarding human subjects protects not only the individual subject, but the researcher and the institution sponsoring the research project as well.

All research involving human subjects will be conducted in accordance with appropriate local, state and federal law, using the guidelines established in Title 45, Part 46 of the Code of Federal Regulations, the Federal Policy on the Protection of Human Subjects or "Common Rule," and are in accordance with Department of Health and Human Services Regulations (45 C.F.R. Part 46, 21 C.F.R. Part 50, and 21 C.F.R. Part 56. (The University is guided by the ethical principles regarding research involving human participants in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the Belmont Report), the Nuremberg Code, and the Declaration of Helsinki.

In circumstances where the Marian policy is more restrictive than federal regulations, the Marian policy will be considered binding. In circumstances not explicitly addressed by this policy, relevant federal regulations will be binding. In all cases, researchers will be responsible for following Marian policies or other applicable regulations.

1.0 Marian University Policy on Research Involving Human Subjects

1.1 General Policy Statement

Any research project, sponsored or unsponsored, originated at or supported by the University that involves human subjects must be reviewed and approved by the Institutional Review Board for the Protection of Human Subjects (IRB). Approval by the IRB is required before initiating any collection of data from human subjects for research purposes. This includes research involving human subjects conducted by Marian personnel and student research supervised by faculty or staff, even if it has obtained prior approval from an external IRB.

This policy applies regardless of whether or not the subjects are members of the Marian community. Although some research may be ruled exempt, all research involving human subjects must be submitted to the IRB for review to determine its status. This policy applies to research conducted at other institutions by Marian faculty, staff, and students, even if that institution has its own review process.

This policy includes research using any property or facility of this institution or research involving the use of Marian University's nonpublic information to identify or contact human research participants or prospective participants.

Marian University will comply with all local, state, and federal laws as they may relate to research covered by this activity.

This policy assures that:

- a) The rights and welfare of the human subjects are adequately protected;
- b) The procedures used to obtain informed consent are adequate and appropriate;
- c) The risks to the human subject are reasonable in relation to the anticipated benefits to the subject.
- d) Any exceptions are consistent with federal and university guidelines.

Because the regulations of individual federal agencies may deviate from the Common Rule, Marian policy will be amended accordingly whenever a federal agency (or, if more than one, all federal agencies) from which the university is seeking funds requires the changes. Therefore, it may be necessary for Marian's policies and procedures to be amended in accordance to the government's response to an application the college may make for an assurance, through which the government would be bound to accept the results of the IRB's review of a particular proposal for research.

1.2 Authorized Institutional Official (AIO)

The Vice President for Academics, whose authority has been delegated by the President of Marian University, serves as the Authorized Institutional Official (AIO) for Marian University. The AIO provides oversight of research and IRB functions and represents the University in any legal matters concerning IRB decisions.

The AIO oversees the enforcement of IRB decisions in instances where members of the Marian community fail to follow proper protocols designed to protect human subjects or act in ways that could potentially harm human subjects.

2.0 Institutional Review Board on Human Subjects Research (IRB)

In accordance with 45 CFR 46, Marian University has established and will maintain the Institutional Review Board on Human Subjects Research, referred, hereafter, in this document as the IRB.

2.1 Role of the IRB

The role of the Institutional Review Board is to protect human subjects by ensuring the adequacy of research conducted with human subjects, and to minimize risks and maximize the potential for benefit from human subjects' participation in research.

To minimize risks, the IRB ensures that the ongoing conduct of the research protects subjects at Marian, and at other sites as negotiated through Assurances. The IRB is registered with Department of Health and Human Services, Office for Human Research Protections (OHRP) under the Marian's Federal Wide Assurance (FWA #00014929).

These protections ensure that human subjects participate in research only after providing legally effective, fully informed consent when consent is required by law for the ethical and legal conduct of the research. The IRB's decisions are based on the ethical principles in the Belmont Report and the "Declaration of Helsinki". IRB operates under the rules of conduct established from the Code of Federal Regulations, most frequently 45 C.F.R. Part 46, 21 C.F.R. Part 50, and 21 C.F.R. Part 56 and from Marian University policies.

If research requires the use or disclosure of protected health information, the IRB is also responsible for ensuring that the standards of the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) (45 C.F.R. Parts 160 and 164) are met. The IRB reviews authorization agreements, applications for the use or disclosure of limited or de-identified data sets, and applications for waiver of the Privacy Rule's authorization requirements. The Vice President for Academics provides information for compliance with HIPAA.

In order to enable the IRB to exercise autonomy in decision making, the administrative home of the IRB is the Office of the Vice President for Academics. This supports the IRB's independence from external influences. The Office of Research and Sponsored Programs (ORSP) acts as the primary contact between the IRB and Marian community members and any others who require assistance or desire interaction with the IRB.

The major responsibility of the IRB is to decide whether research projects place subjects at risk, and if so:

- a. Will the rights and welfare of subjects be adequately protected?
- b. Will the risks be outweighed by the benefits to the subject and the knowledge to be gained from the study?
- c. Will legally effective, informed consent be secured from subjects?
- d. Will ethically appropriate, informed consent be secured from subjects?
- e. Will the protocol meet all standards established by the federal government and University guidelines, including those pertaining to special populations such as minors, pregnant women, and prisoners?

2.2 Authority of IRB

The IRB has the following authority:

- to approve research, require modifications to research protocols in order to approve research, or disapprove research;
- to require progress reports or other information from investigators in order to effectively oversee the conduct of the research and the informed consent process; and
- to review suspected and alleged protocol violations, subject complaints, or violations of Marian IRB policies and/or applicable state and federal regulations;
- to place restrictions on the approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects. (Failure by the researcher to respond to IRB decisions on these matters in an appropriate manner will be referred to the AIO.)
- to suspend or terminate approval of research that is not conducted in accordance with its requirements or that pose serious threat to human subjects, and to report suspensions and terminations to the AIO.

2.3 IRB Functions

The IRB has the following functions:

- a) To conduct the initial review of research protocols and approve, disapprove, or require modifications of any research activity covered by this policy;

- b) To notify the principal investigator, in writing, of its determinations and decisions. If the IRB does not approve a research activity, the notification shall include a statement of the reasons for the decision and specific suggestions for enhancing the likelihood of approval;
- c) To provide the principal investigator(s) with an opportunity to respond in writing or in person to the IRB for reconsideration if the research project is not approved;
- d) To require the researcher
 - i. to provide research subjects with adequate information concerning the risks and benefits associated with participating in a study and inform subjects of their rights as subjects;
 - ii. to provide research subjects contact information in the informed consent document for someone other than the Researcher of Record;
 - iii. to obtain the informed consent of all research subjects;
- e) To require that proposed changes in research or any unanticipated problems involving risks to subjects or others are promptly reported to the IRB, and when appropriate, by the ORSP, Vice President for Academics and AIO to pertinent federal agencies;
- f) To observe or have a third party observe the consent process and the research when deemed appropriate by the IRB;
- g) To conduct reviews of continuing research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year;
- h) To require that any serious or continuing noncompliance with Marian IRB Policies and/or federal regulations, or the requirements or determinations of the IRB, be promptly reported to the AIO, and when appropriate, via the ORSP, Vice President for Academics and AIO, to pertinent federal agencies;
- i) To require that any suspension or termination of IRB approval be promptly reported to the AIO, and when involving federal grants, via the ORSP, to the Vice President for Academics and AIO to pertinent federal agencies.

The IRB, as part of the execution of its responsibilities, shall provide an annual report of the activities of the IRB to the Vice President for Academics.

2.4 IRB Membership

The IRB shall be composed of members with varying backgrounds who bring sufficient experience, expertise, diversity, including race, gender, and cultural backgrounds, and sensitivity to issues, such as community attitudes, to promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of human subjects (Federal Policy {_.107}) These members will be mostly representatives of the university and include members who are scientists, members who are non-scientists, and one member from the community.

Although the IRB may have as many members as necessary to perform its duties effectively, the IRB must have at least 5 members, including one member who is a scientist, one member who is a non-scientist, and one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with Marian. The IRB must include both men and women and must consist of members from more than one profession. The members of Marian's IRB shall possess the professional competence to review the types of research activities regularly conducted by Marian University. This includes expertise in a range of health and behavioral sciences, familiarity with relevant standards of professional conduct and practice, and knowledge of vulnerable or special populations.

In reviewing proposals involving a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB membership shall be expanded, if

necessary, to include an appropriate representative who is knowledgeable about and experienced in working with these special subjects. [34 CFR 350.3(d)2); 34 CFR 356.3(c)(2); 45 CFR 46.304].

The IRB may also invite ad-hoc consultants, as needed, to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

2.5 Membership Appointment

The Vice President for Academics will solicit nominations from Marian University and the community of Fond du Lac and its vicinity. These nominations will be solicited as needed and typically when board members resign, take a leave, or their terms end.

A slate of nominees for membership and officer positions on the IRB shall be developed by the current members of the IRB. The chair of the IRB will forward the recommendations to the Vice President for Academics. The Vice President for Academics will issue the appointment letter for IRB membership.

Faculty members will serve on the IRB for a term of three years, with at least one faculty member rotating off the IRB each year. Faculty may serve consecutive terms. Membership selection shall be made in order to promote complete and adequate review of research activities involving human subjects. As a representative of Marian University, an IRB member must exhibit high standards of moral integrity and ethical conduct.

IRB members are expected to attend the required IRB committee initial and continuing education training programs, conduct reviews of research protocols in a timely manner, attend IRB full board meetings and contribute to the IRB review and discussion of protocols. The Vice President for Academics may remove an IRB member at any time, after consulting with ORSP, the IRB Chair, and the Vice President for Academics.

A staff member in the Office of Research and Sponsored Programs will serve as an ex-officio member on the IRB without vote and act as the recording secretary.

The Vice President for Academics will appoint a member to serve as chair. The IRB members will forward a recommendation to the Vice President for Academics for consideration. The IRB Chair will be selected from the IRB membership for a one- to three-year term and may serve two consecutive terms at the discretion of the Vice President for Academics, who may remove the IRB Chair at any time, after consulting with the IRB members.

The IRB Chair fosters an environment that encourages the free and full participation of all IRB members in its deliberations. The chair holds voting rights equal to those of other members. The chair has the added duties of reviewing adverse events, reviewing and signing correspondence coming from the IRB, and handling the initial triage of protocol violations. Regulations (45 CFR 46.110) empower the chairs (or experienced members designated by the chair) to conduct expedited review on certain categories of minimal risk research. The time commitment required of an IRB chair is significantly greater than that of the other IRB members.

The IRB shall have one Vice-Chair, appointed by the Vice President for Academics after consultation with the IRB Chair. The Vice-Chair shall be considered a Chair-in-Training and may serve two consecutive terms of one to three years at the discretion of the Vice President for Academics. Complaints about IRB matters should be directed to the Vice-Chair.

When a new member is appointed to the IRB, the IRB Chair will hold a new member orientation. This orientation will introduce these new members to the federal regulations, IRB meeting procedures, levels of review, consent requirements, and vulnerable populations. They will also be instructed on how to fill out the IRB review sheets and Informed Consent Checklist. IRB members should complete the CITI program within four months of their appointment.

2.6 Ad-hoc Consultants

The IRB Chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available within the membership. Ad-hoc consultants may not be present during deliberations and voting.

2.7 Conflict of Interest and IRB

IRB members may not vote or serve as a reviewer of studies in which they, their spouses or dependent children serve as Principal Investigator, co-investigator or key personnel. At the request of the IRB Chair, such individuals may be present at an IRB meeting to answer questions but may not be present during deliberations or voting.

No IRB member may participate in the IRB initial or continuing review of any project in which the member has an active role or conflict of interest, except to provide information requested by the IRB.

The IRB member must make any potential conflict of interest known to the IRB Chair when protocols are first submitted to the ORSP for IRB review. The IRB Chair may designate another IRB member from the same department to review the protocol. The fact that an application is submitted by another investigator from an IRB member's department or area does not, in and of itself, constitute a conflict of interest. If a member has been assigned to review an expedited application, they should inform the IRB Chair so the application can be reassigned to another reviewer. When an investigator involved in research enrolling human subjects has disclosed a potential financial conflict of interest to the ORSP, the ORSP may refer the case to the Marian University Conflict of Interest Committee as appropriate before IRB review.

At the beginning of the IRB meeting, IRB members must disclose any known potential conflict of interest to the IRB Chair. Members are not required to identify the exact nature of the conflict of interest. They may simply inform the Chair that one exists. When the research is being reviewed for the IRB member with a potential conflict of interest, the member may be asked to participate in the discussion to answer questions regarding the application under review to the same extent as any investigator when attending an IRB meeting. Once the member has answered any committee questions, the member will be asked to leave the room for the duration of the discussion and review of the protocol.

2.8 Operations of the IRB

2.8.1 Meetings

The IRB generally meets once a month during the academic year on the Marian University campus but does not convene during summer or winterim sessions. The meeting schedule is available on the IRB website. Although investigators are invited to participate in protocol discussions, the IRB meets in closed session.

The agenda for the meeting includes all research protocols needing action by the IRB and any other items necessary to perform its duties. The agenda also informs IRB members of all research that has been approved through exempt or expedited review procedures by the Chair. One week in advance of a full board meeting, the ORSP provides IRB members with an agenda and meeting packet, which include a list of approved protocols for ratification and a copy of each protocol needing full-board review with

supporting documents (informed consent documents, etc.) and other relevant material. This allows IRB members sufficient time to review the research protocols and contact investigators, if necessary, for additional clarification.

A quorum is defined as greater than 50% of the voting membership. The approval of research requires the vote of a simple majority (greater than 50%) of the voting members present at the meeting. IRB members must be in attendance to vote.

Ad-hoc members, consultants, and guests may not participate in the IRB deliberations and may not vote or serve as a reviewer of studies. At the request of the IRB Chair, such individuals may be present at an IRB meeting to answer questions but may not be present during deliberations or voting.

2.8.2 IRB record requirements

2.8.2.1: IRB membership roster

The IRB Chair will submit to OHRP a copy of the membership roster along with the registration renewals or updates as necessary. The membership of the IRB is also maintained by the ORSP on the IRB website.

2.8.2.2: Written procedures and guidelines

Written procedures and guidelines are contained in the Marian University IRB for the Protection of Human Research Subjects Policies and Guidelines manual.

2.8.2.3: Minutes of meetings

Minutes will be taken at each meeting by the IRB secretary whose sole responsibility is accurate recording of the minutes.

The minutes of regular meetings must contain:

- i. Names and roles of each person present (members, invited guests, PIs, etc.)
- ii. Each application reviewed (initial, continuing, and amendments)
 1. A summary of findings regarding each of the following:
 - a. Scientific design
 - b. Subject selection and recruitment
 - c. Additional safeguards for vulnerable subjects
 - d. Privacy and confidentiality
 - e. Minimization of risks to subjects
 - f. Risk/benefit assessment
 - g. Determination that all required elements of the consent document are present
 - h. Controverted (Disputed) issues
 2. Stipulations and recommendations
 3. Record of all motions and voting; recusal of members due to conflict of interest
- iii. Report of adverse event(s)
- iv. A list of:
 1. Exemption applications approved since the last meeting
 2. Expedited applications approved since the last meeting
 3. Expedited amendments/renewals for full board applications approved since the last meeting

2.8.3 Retention of records

All applications reviewed, consent documents and related materials will remain on file at the ORSP for a minimum of three years after the completion of the expiration of the application.

Meeting agenda, minutes, and IRB rosters will remain on file at the ORSP as a permanent record of the committee's activities. Policy guidance and forms will be disseminated from and stored at the ORSP until replaced by new and/or revised documents.

2.9 Confidentiality

Proceedings of the IRB are considered confidential when members deliberate and vote on protocols. IRB members, alternate members, and ex-officio members should not disclose information about studies, including, but not limited to, contents of files, details of discussions, and the attribution of comments to specific committee members. All IRB members (voting and non-voting) are required to sign a statement of confidentiality prior to performing any IRB duties. This statement provides a written assurance that activities related to research protocol review or other IRB-related activities performed during the time of an IRB member's appointment will be conducted in strict confidence and not discussed outside of the context of these duties.

2.10 IRB Training for Board Members

IRB members are required to attend the initial on-line education program through the Collaborative Institutional Training Initiative (CITI) and attend any required continuing education for IRB members. IRB members are expected to conduct reviews of research protocols in a timely manner, attend, and contribute to the IRB review and discussion of protocols during full board meetings.

2.11 Role of the Office of Research and Sponsored Programs (ORSP)

2.11.1 ORSP Administrative support

ORSP will provide administrative support for the IRB by establishing and maintaining the website for the IRB, setting up the IRB meeting schedule, attending IRB meetings to provide assistance and recording the IRB's discussion and decisions. The ORSP will receive all protocols, supporting documents and IRB materials, as well as requests from researchers for reconsideration of IRB decisions, and ensure that all questions have been completed and documents submitted. The ORSP shall manage the IRB records for Marian University and communicate the IRB's decisions, in writing, to investigators. The ORSP shall return all disapproved protocols to the research investigators. ORSP will retain copies of all research protocols, copies of all correspondence between the IRB and principal investigator(s), records of continuing review, and statements of significant findings.

For protocols submitted under the exempt category, the ORSP contact the IRB Chair who will review and verify exempt status. The ORSP will communicate this to researchers. All non-exempt research protocols will be forwarded to the IRB Chair for preliminary review. As appropriate, the IRB or the ORSP may negotiate protocol modifications with the research investigator.

The ORSP will be responsible for maintaining documentation of human subjects research training required by the University and for forwarding documentation to granting agencies as required. The ORSP will ensure that necessary administrative and educational activities are completed that allow the University to provide federal assurances regarding human subjects protection.

2.11.2 Compliance Responsibilities

The ORSP will remain abreast of policy changes made by OHRP, federal, state and local agencies and make recommendations, as needed, to the IRB to ensure compliance with regulatory requirements.

The ORSP shall be responsible for promptly reporting information, as outlined below, to the IRB, the appropriate institutional authorities, the federal Office for Human Research Protections (OHRP), or other federal agencies as necessary.

- a) Report promptly to the IRB, appropriate institutional authorities or to the OHRP any instances of injuries to participants and unanticipated problems involving risks to participants or others;
- b) Report to the IRB information received concerning noncompliance by research investigators, injuries to participants, unanticipated problems involving risks, changes proposed in research activities and the progress of the research;
- c) Report promptly any changes in IRB membership to the OHRP, when required.

When the proposal involves a test article (i.e., drug biologic or device) requiring certification to the HHS, the ORSP shall identify the test article in the certification to HHS and state whether the 30-day interval required for test articles has elapsed or was waived by the FDA.

- a) If the 30-day interval has expired, the ORSP shall state in the certification to HHS whether the FDA has requested that the sponsor continue to withhold or restrict the use of the test article for application in human participants.
- b) If the 30-day interval has not expired and a waiver has not been issued, the ORSP shall send a statement to HHS upon expiration of the interval.

2.11.3 Grant proposals and IRB –

The ORSP identifies grant proposals that entail possible research with human subjects and provides the IRB with current federal policies and guidelines applicable to the proposal under review. ORSP shall communicate with the project officer of the potential funding agency about the status of board review. If the university is required to enter into an assurance in order for the IRB to review a proposal being considered by the government, ORSP will contact the appropriate officials and obtain the assurance, if possible.

In accordance to 45 CFR 690.118, ORSP shall ensure that IRB approval or exemption from review has been obtained for each project that utilizes human subjects prior to releasing any funds granted to Marian University. In addition, ORSP shall require written notification of continued approval according to the IRB timetable before additional funds are expended beyond the required date communicated in the timetable.

For cooperative projects, if the project has already been approved by an Institutional Review Board of another institution, the ORSP may approve the research upon receipt of evidence of approval signed by the appropriate officials at the cooperating institution. The ORSP may require the completion of Marian University's IRB application forms before considering the research protocol.

3.0 Definitions

3.1 Definition of Human Subject

A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. The specimen(s)/data/information must be collected

from live subjects. Cadavers, autopsy specimens or specimens/information from subjects now deceased is not human subjects. 45 CFR 46.102

3.2 Definition of Research Covered by this Policy

Research covered by this policy includes systematic investigation involving human subjects, (including research development, testing, evaluation, and/or data analysis), designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purpose of the IRB, whether or not they are conducted by Marian personnel (faculty, staff or students) or by researchers using Marian University resources, and whether funded externally, internally or from the researcher's own resources, or whether or not they are supported under a program that is considered research for other purposes.

For example, some demonstration and service programs may include research activities. Research includes all master theses, action research projects, dissertations, publications, and/or presentations.

Research generally does not include operational activities, such as practice activities in medicine, psychology, social work, and public health (e.g. routine outbreak investigations and disease monitoring) and studies for internal management purposes, such as program evaluation, quality assurance, and quality services. It generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where the intent is to contribute to generalizable knowledge.

Activity conducted for instructional purposes in conjunction with classroom coursework, the results of which is not meant for publication or presentation outside of the classroom in any public forum or display, are not considered research for purposes of this policy and are not typically subject to review by the IRB. However, activities in conjunction with classroom coursework that might pose more than minimal risk to the human subjects involved must be reviewed by the IRB. Minimal risk definition from HHS 45 CFR 46.102 (i) means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For any question concerning risks to human subjects, the instructor should contact the ORSP (See Student Research Activity, Section 6.0).

Any activity conducted for instructional purposes, the results of which are intended or later become considered for public display or presentation, must be reviewed by the IRB.

3.3 Special Classes of Human Subjects Safeguards and Consent

Marian University recognizes some research subjects as being more vulnerable to coercion or influence or to have special health needs requiring special protections when involved in research. These subjects include, but are not limited to, pregnant women, prisoners, and children. This section outlines some of the safeguards researchers must address when working with special classes of subjects. More detailed information about special populations can be found in the federal guidelines. Marian University adheres to local, state, and federal (45 CFR 46.201 to 46.409, Subparts B, C, & D) guidelines when research involves especially vulnerable subjects. The IRB may require appropriate professional oversight to ensure the welfare of special classes of human subjects.

3.3.1 Research with Pregnant Women

Pregnancy encompasses the period of time from implantation until delivery.

Women, because of conditions related to their pregnancy, are particularly vulnerable when asked to participate in research studies. Because of their vulnerability, Marian University requires the following safeguards for all research involving pregnant women:

Scientifically appropriate information from prior studies is considered in assessing potential risks for pregnant women and fetuses in the proposed research;

Any risk to the woman or fetus is the least possible;

In the case where any risk is possible, the research is likely to result in important knowledge which cannot be obtained by other means;

Risks and benefits to both the woman and the fetus are clearly discussed in the informed consent agreement;

The informed consent of both parents, if at all possible, is required when research may impact only the fetus;

For pregnant minors, both assent of the minor and consent of their parent(s) or legal guardian(s) are obtained;

No inducements, monetary or otherwise, will be offered to terminate a pregnancy, nor will individuals engaged in the research have any role in decisions related to the termination of a pregnancy.

Federal statutes provide more detailed research concerns related to pregnant women, fetuses, and neonates. Marian University will follow federal guidelines (45 CFR 46.201 to 46.207).

3.3.2 Research with Prisoners as Subjects

A prisoner is any individual involuntarily confined or detained by a government agency in a penal institution, including those temporarily detained in a penal facility, those already sentenced, and those awaiting arraignment, trial or sentencing.

Prisoners, because of conditions related to their incarceration, are particularly vulnerable to coercion when asked to participate in research studies. Because of their vulnerability, Marian University requires the following safeguards for all research involving prisoners:

Any possible advantages to the prisoner resulting from participation in the research should not be so excessive that they would greatly alter the normally limited prison environment and thus unduly influence the prisoner to participate in the research;

At least one Institutional Review Board, either that of Marian University or that of the penal institution, must have at least one prisoner or person qualified by experience or background to serve as a prisoner representative;

Risks involved in the research are commensurate with risks that would be accepted by non-prisoner subjects;

Prisoners must be selected in a fair and non-arbitrary manner from the prison population, and should be randomly selected from the group unless specifically stated research procedures preclude random selection;

The informed consent agreement will specify that participation in the study will not influence parole decisions;

Research shall not involve prisoners except where the research involves study of issues specific to the prison population, (including studies of the possible causes, effects, and processes of incarceration), or criminal behavior where no more than minimal risk is likely, studies of prisons as institutions, or research specific to conditions commonly found in prisons (for example, research related to hepatitis, which is much more prevalent in prisons than elsewhere). With these exceptions, biomedical or behavioral research shall not involve prisoners.

Federal statutes provide more detailed research concerns related to prisoners. Marian University will follow federal guidelines (45 CFR 46.301 to 46.306)

3.3.3 Research with Children

Children are persons who have not attained the age of 18 years. When doing research with children, special protections include securing the child's assent or affirmative agreement to participate, seeking informed consent from parent(s) or guardian(s), and explaining risks and benefits in terms understandable to the child.

Because of conditions related to childhood, children are particularly vulnerable when asked to participate in research studies. Because of their vulnerability, Marian University requires the following safeguards for all research involving children. In other research on children not covered by these guidelines, the IRB may approve research that follows federal guidelines detailing conditions under which such research can be conducted. In these cases, Marian University requires researchers to adhere to all regulatory procedures (45 CFR 46.407).

1. If the research poses no more than minimal risk (minimal risk definition from HHS 45 CFR 46.102 (i) means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) to the children in the research, then:
 - a. Adequate provisions must be made for soliciting the assent of children;
 - b. The permission of parent(s) and/or guardian(s) must be obtained according to the guidelines for securing permission when children are subjects (see parts 4 and 5 below in this section);
 - c. The normal protections afforded to other subjects must be provided.
2. If the research poses minimal risk, then:
 - a. The risk must be justified by the anticipated benefit to the subjects;
 - b. The anticipated benefit must be at least as favorable to subjects as that presented by available alternative approaches;
 - c. Adequate provisions must be made for soliciting the assent of children and permission of their parent(s) or guardian(s);
 - d. Explanation of anticipated risks and benefits of the research must be explained to child subjects in terms as understandable as possible (see Assent and Permissions section below).

3. If the research involves greater than the minimal risk, and has no prospect of direct benefit to child subjects, but is likely to yield generalizable knowledge, then:
 - a. The risk represents only a minor increase over minimal risk;
 - b. The intervention or procedure must present experiences to subjects that are reasonably commensurate with those they might normally encounter in their actual medical, dental, psychological, social, or educational situations;
 - c. The intervention or procedure must yield generalizable knowledge about the disease or condition of the subject which is important to the eventual amelioration of the condition;
 - d. Adequate provisions must be made for soliciting assent of the children and permission of their parent(s) or guardian(s) as set forth below (see Assent and Permissions sections below).
4. Assent of children: When the participants in non-exempt research are between the ages of 6-17, the IRB requires a participant assent process after parental permission has been granted.

Unless specifically required by the IRB during its protocol review and approval process, no formal assent process is required for children under 6 years of age. As appropriate, the researcher may ask the child if he/she wishes to play a game or complete some other activity, but, generally speaking, these young children exhibit their assent or refusal to participate through their behavior.

Assent of child subjects must be obtained when the children are capable of providing assent. In determining whether children are capable of assenting, consideration should be given to children's ages, maturity, and psychological state. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as appropriate. The assent of the children is not a necessary condition for proceeding with the research if:

- a. The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
- b. The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the children's health.

Even when the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with the normal policies for waiver of informed consent.

Specific guidelines for securing the assent of children are:

- Assent should be presented in oral and/or written format, depending on the age and maturity of the child.
- Assent should be sought in a manner understandable to the child, given their age and maturity. Templates for this assent form, depending on the age of the child, can be found on the IRB Website.
- Assent should be sought in the child's primary language, with the help of an interpreter if necessary;
- Mere failure of children to object should not be construed as assent.

5. Securing Permission from Parent(s) or Guardian(s) of Minors.

For all research requiring informed consent as specified in this document, the following requirements apply when securing permission for children subjects:

- a. Adequate provisions are made for soliciting the permission of each child's parent(s) or guardian(s);
- b. Where parental or guardian's permission is required, permission of one parent may be sufficient;

- c. When more than minimal risk is involved in the research, both parents or the child's guardian must give their permission, unless one parent is deceased, unknown, legally incompetent, or not reasonably available, or when only one parent has the legal responsibility for the care and custody of the child;
 - d. For situations in which permission is not a reasonable requirement (such as child abuse), permission from a parent or guardian may be waived, as long as another appropriate mechanism for protecting the children is included;
 - e. Templates for this consent form can be found on the IRB Website.
6. Children who are wards of the state or another entity, may be subjects in research studies if:
- a. The research relates to their status as wards; or
 - b. The research is conducted in institutions or agencies in which most other subjects are not wards; and
 - c. The child is represented by an advocate appointed to represent them in addition to any other individual acting on behalf of the child as guardian or in loco parentis; (45 CFR 46.409).
 - d. Templates for this consent form can be found on the IRB Website.
- Federal statutes provide more detailed research concerns related to children. Marian University will follow federal guidelines (see 45 CFR 46.401 to 46.409).

3.3.4 Research with Children in School Settings

With respect to research involving children in a school setting, Marian University requires the following safeguards:

1. Evidence of both the risk and potential benefits to the subjects must be examined. These include physical, social, emotional, psychological, and/or academic risks.
2. Because the informed consent process in school settings is often complex, it may be necessary to include:
 - a. Permission from the school district;
 - b. Permission for the school site, for example from the building principal;
 - c. Permission from the classroom teacher, where applicable
3. As with other research involving children, child assent and parental permission must be obtained, as described above.

3.3.5 Students as Subjects

Students in a course may participate in research as part of a course requirement only when alternative means of obtaining the same credit is made available to students who do not wish to volunteer as research subjects. The IRB Committee will carefully review these alternatives to make sure that students are not being coerced into becoming subjects. For example, the alternatives to participating in the research cannot require considerably more time, effort, involvement, or stress than would the participation in the research.

The informed consent statement should make clear the consequences of withdrawing from a project prior to completion (e.g., will credit be given despite withdrawal?). As a general matter, the IRB Committee suggests giving credit even if the subject withdraws, unless the student withdraws immediately or there is evidence of bad faith on the part of the student. The IRB Committee further suggests that grades be calculated prior to the inclusion of the extra credit to avoid any possible coercion of the students. Once

grades are calculated without the extra credit, the professor could then add the extra credit into the numerical grade.

3.3.6 Other Special Classes of Subjects

Though not mentioned above, other special classes of subjects may also require additional protections. These include but are not limited to individuals with cognitive or other mental difficulties, non-native language speakers, or people vulnerable because of health, education, or financial factors. When research involves other special classes of subjects not otherwise mentioned in this section, the IRB will review each protocol to determine if the individual is adequately protected. In particular, the IRB will determine if:

1. The potential benefits of the research to the individual directly or indirectly outweigh the risks to the individual;
2. Any risks involved are minimal and the researcher has taken precautions to minimize them;
3. Informed assent or consent is secured in a manner understandable to the subject, with an interpreter as needed;
4. Permission is secured from the appropriate representative(s) of the individual when the individual cannot realistically provide informed assent or consent.

4.0 General IRB Review Process

4.1 IRB Protocol

A researcher seeking approval of a project involving human subjects by the IRB must complete an IRB Protocol Submission Form available on the IRB Website. The completed forms must be printed, signed and submitted to the Office of Research and Sponsored Programs. In addition, an electronic copy, including all attachments, must also be submitted to the Office of Research and Sponsored Programs.

Upon receipt of the IRB protocol, the IRB Chair will review the application to determine one of the following:

- a. The protocol is exempt from IRB review; or
- b. The protocol requires expedited IRB review; or
- c. The protocol requires full review.

The exempt and expedited proposals will be reviewed upon submission; disposition usually requires no more than two weeks. Full reviews usually require three to four weeks for disposition, as they involve a meeting of the full IRB Committee and attendance by the primary investigator.

4.2 Due Dates for IRB Protocol Submissions

The IRB will meet monthly during the fall and spring academic semesters but normally not during the summer. This schedule will be published on the IRB Website in August for the fall semester and December for the spring semester.

Protocols must be submitted by the deadlines specified on the IRB website in order to be reviewed at the meeting that month. Protocols submitted after the deadline will be considered at the next meeting.

4.3 IRB Review and Action Notification

4.3.1 Review of Protocols

The IRB will consider the following when reviewing protocols:

a. Study design

Federal regulations, the Nuremberg Code, and the Declaration of Helsinki require that the IRB consider the scientific design of a study to determine that risks to subjects are minimized by using procedures that are consistent with sound research design and that the benefits of the research justify the potential risks [45 CFR 46.11(a)].

The IRB must assess whether the study design will produce reliable and valid information of sufficient value and importance to justify the risks. The scientific quality will have more potential weight in the risk/benefit evaluation in studies posing more than minimal risk to participants. In university settings, many social science student studies may have less than optimal design, but involve little or no risk to participants. In the absence of significant risk, the benefits of the study to participants, society, and the student's education may be weighed more heavily.

b. Risks and benefits

The IRB will assess whether the risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subjects and to society as well as the importance of the knowledge reasonably expected to result from the research. The IRB will consider only those risks and benefits that may result from the research. The federal regulations do not allow the IRB to evaluate the possible long range effect of applying the knowledge gained through the research. [45 CFR 46.111]

The IRB is required to review any possible benefits a subject may derive from participation in research, and/or the benefits of new knowledge that may justify asking a person to undertake the risks of the study. Payment for participation in research is not considered a benefit.

c. Equitable selection of subjects

The selection of subjects should be equitable and free of coercion or undue influence. The IRB will consider the purpose of the research and the setting of the research.

The IRB will closely examine research that is conducted on Native American tribal lands or that targets vulnerable subject populations, such as children, prisoners, subjects with cognitive disorders, or economically or educationally disadvantaged subjects.

d. Identification of subjects and confidentiality

The IRB is required to review the method for prospective identification of subjects. They will examine the means of identifying and contacting potential subjects and the methods for ensuring the subjects' privacy and confidentiality. Investigators are required to submit plans for ensuring the privacy and confidentiality of subjects.

e. The informed consent process

Informed consent is a process, not a document. The consent form is the written documentation of the consent process. The IRB will carefully review the informed consent process: when, where and how consent is obtained and any provisions for the ongoing consent of subjects.

f. Additional review

The IRB will determine whether the research requires more than annual review and may require an appropriate monitoring procedure that could include monitoring of the consent process, observation of the research procedures, and review of research-related records.

4.3.2 Authorized IRB Actions

When reviewing protocols, the IRB is authorized to take one of the following actions:

- a. Approved as Submitted - Research may begin immediately;
- b. Modifications Required - Approval in principle at the convened meeting but request for additional information or modification to the protocol; final approval pending the researcher's response to modifications required by the IRB and submitting documentation of these responses to the IRB Chair.

The IRB Chair may, upon receipt of this documentation, authorize the researcher to begin the research. The Chair may also determine that the full IRB should review the revised submission and if so, will present the revision at the next scheduled meeting of the IRB. Research may not begin on the project until written IRB approval has been received.

The Chair will report to the IRB at the next scheduled meeting the status of any protocols that had been approved with IRB required modifications.

- c. Not Approved – The research activity may not be conducted. Justification for reaching the decision will be included.
- d. Table or defer a study – The committee has run out of time or a quorum has been lost; the study will be reconsidered at the next full board meeting.

The researcher will be advised in writing by the Chair of the action taken by the IRB. This notice will be sent via email to the Researcher of Record, and to the Faculty Advisor, if applicable.

Research that has been approved by the IRB may be subject to further appropriate review by University officials. However, University officials cannot approve research that has not been approved first by the IRB.

4.4 Appeal of IRB Decision

Research involving human subjects conducted under the auspices of Marian University may not take place without the prior and continuing approval of the IRB. A researcher who disagrees with a decision of the IRB may request a hearing before the duly-convened IRB to appeal its decision. Relevant arguments and/or witnesses may be presented on behalf of the researcher. The researcher may also request that the Authorized University Representative be informed of the appeal. However, the final decision rests with the IRB.

4.5 Report of Adverse Events

Adverse events include any unanticipated negative consequences that occur as a result of participating in research. Any adverse event that occurs as a result of participation in research must be reported to the IRB Chair within 48 hours of the event using the Adverse Event Report Form found at the IRB Website. The IRB Chair will inform the Authorized University Representative of the event and what action the IRB is taking.

4.6 IRB Review of Formerly Approved Research Projects

4.6.1 Changes or Modifications to Original IRB Submissions

Any and all proposed changes or modifications to originally submitted and approved IRB submissions must be resubmitted to the IRB for approval prior to amended changes or modifications being implemented by the researcher. These changes may include a change in a survey instrument, the addition or deletion of a research site, a change in personnel, a change in methodology, or a change in the Researcher of Record.

If the study protocol approved by the IRB is intended to encompass development of one or more research instruments, or if it is based on certain qualitative research protocols, it may also be necessary to give relatively wide professional latitude to researchers in the application of approved methods so that a researcher does not need to come back to the IRB repeatedly for approval of changes that would be considered normal and routine under the circumstances. However, the IRB should make clear to the researcher, that significant changes, including all changes that could increase risk for the human subjects (for example, the addition of a new topic in a survey), must be approved in advance by the IRB.

In the case of any such significant change, a Request for Modification of Previously Approved or Exempt Protocol must be completed by the Researcher of Record and submitted to the IRB committee (see IRB Website).

4.6.2 Continuing Review

Federal regulations [see 45 CFR 46.109(e)] require the IRB to conduct continuing review of all approved research within one year of original approval. All expedited and full committee human subject research proposals approved by the IRB are subject to continuing review. However, investigators must consult with the IRB in the event of a change in the population being studied, scope of research being performed or methodology used to recruit, interview or study participants that increases the risk involved in participation in the study or includes in the study previously excluded special groups of subjects as defined in Section 2.5 of these guidelines.

Continuing review must occur not less than once per year after the initial IRB approval. For example, if a proposal is approved on July 25, 2009, it must be reviewed by July 24, 2010.

Six weeks prior to the continuing review date, the IRB will submit a request to the Researcher about the status of the research, and notification of any changes made to the protocol.

Researchers are responsible for responding to or notifying the IRB if:

1. The research is completed. Researcher sends email or other written notice to ORSP that the research project is complete. Marian considers a study complete when all subject accrual is completed and/or data pertaining to subjects collected.

2. The research is ongoing by using the “Status of IRB Approved Research Projects” form (see the IRB Website);
3. There are any modifications to the previously approved or exempt protocol by completing the “Request for Modification of Previously Approved or Exempt Protocol” form (see the IRB Website).

In conducting continuing review of research not eligible for expedited review, all IRB members should at least receive and review a protocol summary and a status report on the progress of the research, including:

1. The number of subjects accrued;
2. A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
3. A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
4. Any relevant multi-center trial reports;
5. Any other relevant information, especially information about risks associated with the research; and
6. A copy of the current informed consent document and any newly proposed consent document.

The Chair of the IRB committee will review a copy of the original protocol and have access to the minutes of the meeting during which the original protocol was approved.

Research originally subjected to review and approval by the full committee must have continuing review by the full committee. The continuing review proposals will be covered at convened meetings in which a majority of the members of the IRB committee are present. Research originally subject to review and approval by an expedited review can receive an expedited continuing review.

While continuing review occurs on a yearly basis, the IRB committee may request more frequent review on approved research protocols that involve extreme risk.

4.6.3 Suspension or Termination of IRB Approved Research

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB action and shall be reported promptly to the researcher, the Authorized Institutional Officer (AIO) and other appropriate university officials, and any appropriate governmental Department or Agency head (45 CFR 46.113).

5.0 Exempt Status, Expedited, and Full Board Review

5.1 Exemption from IRB Review

5.1.1 Exempt Categories

1. Research activities that pose no more than minimal risk and in which the only involvement of human subjects will be in one of the following categories may be exempt from IRB review:

- i. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or
 - ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods [see 45 CFR 46.101(b)(1)];
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - i. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - ii. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation. [see 45 CFR 46.101(b)(2)]

Research involving children (subjects who have not attained the age of 18 years) as subjects is not exempt under Section 4.2(b) unless the research involves only the observation of public behavior and the researchers do not participate or impact the activities being observed [See 45 CFR 46.401(b)];

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 4.2(b) if:
 - i. the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter [see 45 CFR 46.101(b)(3)];
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects [see 45 CFR 46.101(b)(4)];
5. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - i. Public benefit or service programs;
 - ii. Procedures for obtaining benefits or services under those programs;
 - iii. Possible changes in or alternatives to those programs or procedures; or
 - iv. Possible changes in methods or levels of payment for benefits or services under those programs [see 45 CFR 46.101(b)(5)];
6. Taste and food quality evaluation and consumer acceptance studies,
 - i. If wholesome foods without additives are consumed or
 - ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an 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 [see 45 CFR 46.101(b)(6)].

Some subject matter is automatically deemed NOT ELIGIBLE for exemption. This includes, but is not limited to the list below:

- Human participants who are considered "Protected" or "Vulnerable" populations such as: children/minors, fetuses, pregnant women, human in vitro fertilization, or prisoners/
- Published results (If results of the study are going to be published or in some way publicized that it expands the generalized body of knowledge.)

- Medical Procedures (For students, if the research involves medical procedures of any kind, it is important to list the credentials of the faculty advisor. It is also important to emphasize that the faculty advisor will be present for these procedures.)
- Other sensitive subject matter. The NIH defines sensitive as the disclosure of identifying information that could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

Examples of sensitive research activities include but are not limited to the following:

- Collecting genetic information;
- Collecting information on psychological well-being of subjects;
- Collecting information on subjects' sexual attitudes, preferences or practices;
- Collecting data on substance abuse or other illegal risk behaviors;
- Studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants environmental or occupational exposures).

If a researcher collects identifiable information on the survey/questionnaire, the researcher's protocol cannot be considered for exemption. This excludes identifiable information collected on the consent form when it is collected prior to the survey/questionnaire and stored in a separate secure location. (EX's of identifiable information: name, SS#, etc.)

According to Subpart D, exemptions for research involving children may not be used for any of the following:

1. Research involving interviews
2. Research involving surveys
3. Observation in which the researcher participates in the activities observed

5.1.2 Determination of Exempt Status

The exemption status of research is determined by the IRB, not the investigator. The IRB Chair will review all protocols submitted to determine whether or not they meet the requirements for exemption. The IRB Chair also will review student classroom projects that meet the criteria for exemption. At the discretion of the IRB Chair, such projects may be sent to other IRB members for review. If the protocol is determined to be exempt, the researcher will receive a written notification of exemption from the IRB Chair indicating that the protocol is exempt and upon receipt of this notification, the researcher may begin the project. The IRB Chair may give an exempt study an approval date and a defined approval period for record keeping purposes or may tell the investigator that the exempt study is approved indefinitely.

If changes occur, the investigator must submit any study changes to the IRB. The IRB can then assess whether the exemption status for the project is still valid, or if the study now requires a different level of review (expedited or full committee).

Researchers are encouraged to use the Human Subject Regulations Decision Charts from the Office for Human Research Protections (available on the IRB Website) to determine whether or not they should apply for exempt status for their research protocol.

5.2 Expedited IRB Review (minimal risk):

5.2.1 Expedited Review Applicability

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following expedited review categories (and carried out through standard methods) may be reviewed by the IRB through the expedited review procedure.

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

5.2.2 *Nine Expedited Review Categories*

(<http://www.dhhs.gov/ohrp/humansubjects/guidance/expedited98.htm>)

The following is a list of categories that might be considered eligible for expedited review. The categories on this list apply regardless of the age of subjects. The activities listed should not be deemed to be of minimal risk simply because they are included in this list. Inclusion in this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. Categories 1 through 9 pertain to both initial and continuing IRB review.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
 - a) Research on drugs for which an investigational new drug application (21 CFR, Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b) Research on medical devices for which (i) an investigational device exemption application (21 CFR, Part 812) is not required, or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling;
2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:
 - a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in a 8 week period and collection may not occur more frequently than 2 times per week; or
 - b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50ml or 3ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week;
3. Prospective collection of biological specimens for research purposes by noninvasive means (www.dhhs.gov/ohrp/humansubjects/guidance/expedited98.htm).

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal

scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis); (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. See 45 CFR 46.101 (b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital or image recordings made for research purposes;
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivations, 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 HHS regulations for the protection of human subjects. See 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
 - a) where
 - i. the research is permanently closed to the enrollment of new subjects,
 - ii. all subjects have completed all research-related interventions, and
 - iii. the research remains active only for long-term follow-up of subjects; or
 - b) where no subjects have been enrolled and no additional risks have been identified; or
 - c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemptions, where categories "1" through "8" above, do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

5.2.3 Criteria for Expedited Review

Protocols reviewed either under an expedited process or by full IRB will be evaluated against the following criteria (45 CFR 46.111):

- a) Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on participants for diagnostic or treatment purposes;
- b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- c) Selection of subjects is equitable;
- d) When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, and pregnant women, see Special Classes of Human Subjects, Section 2.5 of this document), additional safeguards have been included in the study to protect the rights and welfare of these subjects;
- e) Informed Consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 7 of these guidelines;
- f) Informed Consent will be appropriately documented, in accordance with Section 7 of these guidelines;
- g) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- h) When appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data.

5.2.4 Expedited Review Process

Upon receipt of the protocol, the IRB Chair will determine if the research requires full IRB committee review or if the review can be expedited with only one member's review. The IRB Chair may review the protocol or give the protocol to another IRB member with expertise in the area of research for review and recommendation.

If the IRB Chair determines that an expedited review is allowable, then the IRB Chair will make the decision as to whether the research is approved or not, or if additional information is needed. The researcher will be notified of the decision via e-mail by the ORSP.

In reviewing the research, the IRB Chair may exercise all of the authorities of the IRB except that the IRB Chair may not disapprove the research. A research activity may be disapproved only after review by the full IRB, as set forth in 45 CFR 46.108(b).

The IRB Chair will report to the full IRB at the regularly scheduled meetings all protocols that have been approved under the expedited review process, and make these protocols available for inspection and ratification by the IRB.

If an investigator requests a waiver of parental consent for a project involving minors, the application must be reviewed by a minimum of 3 members of the IRB.

5.3 Full IRB Review

5.3.1 Full IRB Review Applicability

Any study involving greater than minimal risk requires a review by the convened (full) IRB. This includes studies with children (unless study procedures are of minimal risk) or other vulnerable populations, research that uses survey instruments with sensitive questions, research that involves deception, and studies with the possibility of physical risk. Studies with the possibility of physical risk, such as studies involving exercise, should include a medical history and review in order to determine whether or not a person should participate in the study. In some populations, such as the elderly, it is suggested that consent of a primary family doctor be obtained. In all situations where exercise is performed, researchers should be trained in handling emergency situations.

Any survey or interview that is likely to be stressful for the subject requires full committee review.

5.3.2 Criteria for Full Board Review

Protocols reviewed either under an expedited process or by full IRB will be evaluated against the following criteria (45 CFR 46.111):

- a) Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on participants for diagnostic or treatment purposes;
- b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- c) Selection of subjects is equitable;
- d) When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, and pregnant women, see Special Classes of Human Subjects, Section 2.5 of this document), additional safeguards have been included in the study to protect the rights and welfare of these subjects;
- e) Informed Consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 7 of these guidelines;
- f) Informed Consent will be appropriately documented, in accordance with Section 7 of these guidelines;
- g) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- h) When appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data.

5.3.3 Full-IRB Review Process

IRB Members will receive electronically copies of all protocols to be reviewed by the full board prior to the regularly scheduled meetings in order to prepare for discussion and action. After discussion of any concerns, the IRB then votes on whether or not to approve the study and whether or not revisions are required.

6.0 Course Assignment

Student projects conducted within an academic course may be categorized as either a course assignment or disseminated research.

Disseminated research involving human subjects must be reviewed by the IRB. Disseminated research includes data presented formally, in oral or written form, to any audience outside of the university academic course (e.g. at a seminar, conference, or to persons or organizations outside the university classroom). Marian considers all student master theses or projects, master action research projects, and doctoral dissertations to be disseminated research; if these involve human subjects research, they must receive approval of the IRB before they can be conducted.

This policy establishes the duties and obligations of Marian University faculty members as they pertain to course assignments involving human subjects. As stated in Section 3.2 of the Marian University IRB Policy Manual, activity conducted for instructional purposes in conjunction with classroom coursework, the results of which are not meant for publication or presentation outside of the classroom in any public forum or display, are not considered research for purposes of this policy and are not typically subject to review by the IRB. However, exceptions to this policy include the following:

6.1 Course Assignments that must be reviewed by IRB

1. Activities in conjunction with classroom coursework that might pose more than minimal risk to human subjects must be reviewed and approved by the IRB. Minimal risk definition from HHS 45 CFR 46.102 (i) means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
2. Any activity conducted for instructional purposes, the results of which are intended or later become considered for public display or presentation, must be reviewed by the IRB.
3. Student course projects that include research a) with protected populations or vulnerable subjects as delineated in Section 3.3, or b) collecting sensitive information will require IRB review and approval even if the intent is not to produce generalizable knowledge.
 - a. Examples of vulnerable subjects:
 - i. Children, prisoners, pregnant women; handicapped, or mentally disabled persons; or economically or educationally disadvantaged persons.
 - b. Categories of sensitive information include those:
 - i. relating to sexual attitudes, preferences or practices;
 - ii. relating to use of alcohol, drugs or other addictive products;
 - iii. pertaining to illegal conduct;
 - iv. that if released could damage an individual's financial standing, employability, or reputation within the community;
 - v. that normally would be recorded in a patient's medical record and the disclosure of which could lead to social stigmatization or discrimination;
 - vi. pertaining to an individual's psychological well-being or mental health;
 - vii. involving genetic information.

6.2 Responsibilities of Faculty

In general, it is the responsibility of faculty members to ensure that student course projects are conducted according to the ethical standards of human subject research and their discipline, and to ensure that students understand and implement these ethical standards in carrying out their projects.

If faculty members believe their assignment for a course fits into one of the three categories above, it is their responsibility to submit an application to the IRB, listing themselves as the Principal Investigator and students as co-investigators (if appropriate). Further, all faculty that anticipate utilizing course projects that fit into one of the three categories are required to take the CITI on-line training on Human Subject protection.

For student course assignments that require IRB approval, it is the responsibility of faculty members to

- a. Inform students about the ethical conduct of human subject research, including basic human subject rights and the role of the IRB.
- b. Require students to complete the CITI on-line training on Human Subject Protection and provide evidence of their successful completion before beginning the project.
- c. Provide guidance to students collecting information in order to minimize any unintentional harm to other students or individuals.
- d. Review students' plans for course or group projects and, when necessary, suggest improvements in design and protections for confidentiality.
- e. Suggest that a written explanation of how the data will be used in the course, along with the name and contact number of the instructor, be included when written questionnaires are to be used.
- f. Instruct students about privacy and security vulnerabilities associated with networked computers and the internet.
- g. Report noncompliance, unanticipated problems, unexpected adverse effects or complaints involving human participants to the IRB.
- h. Follow all Marian University policies and procedures, including internet security, biosafety, and privacy. A general IRB approval for projects does not extend to other relevant policies and procedures that may apply to the project.

7.0 Informed Consent

7.1 Purpose of Informed Consent

The Informed Consent document assures that prospective human subjects understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. A signed copy of the consent form must be given to the subject, or the person authorized to act on behalf of the subject, unless doing so would jeopardize the safety of the subject.

7.2 Elements of an Acceptable Informed Consent Document

(Informed Consent templates are available on the IRB Website.)

All informed consent documents should contain the following information:

- a) The title of the study, information on the purpose(s) of the research, a description of the method(s) and procedures(s) to be followed, including the intention to publish or disseminate the results of the study, and the amount of time the subject will spend in actual project participation;
- b) A description of any reasonably foreseeable risks or discomforts to the subject, including expected total time of participation. If disguised or deceptive procedures are to be used, a plan to debrief subjects must be explained to the IRB;
- c) A description of any benefits to the subject or to others as a result of the information obtained from the research;

- d) A disclosure of appropriate alternative procedures that may be advantageous to the subject when making an informed decision regarding whether or not to participate in the research;
- e) A description of the measures to be taken to ensure the confidentiality of data and the anonymity of individual subjects as well as any circumstances under which confidentiality cannot be guaranteed;
- f) The name and phone number of a contact person(s) who will be available to answer any questions the subject or his/her legally authorized representative may have regarding the research. Student researchers must include the name, office address and phone number of his/her faculty research advisor;
- g) The name, title, office address, and office phone number of the Director of Sponsored Programs and Research as a second contact person;
- h) A clear explanation that participation is voluntary and that no penalty or loss of benefits to which the subject is otherwise entitled will occur should the subject refuse to participate or decide to discontinue participation;
- i) Disclosure of costs to the subject, if any, because of his/her participation in the research; disclosure of compensation/reward to the subjects, if any, for his/her participation in the research;
- j) For projects of more than minimal risk to the subjects, a statement must be included that describes how the costs of medical care or other therapies required as a result of injury or mishap incurred while participating in the research will be handled. The consent form should also include information about the availability and extent of on-site medical treatment.
- k) The expected duration of the subject's participation;
- l) Signature line for the subject (or authorized representative) to sign, acknowledging that they have read the consent form, understand any risks and agree to be a subject in the program. The person witnessing the consent must also sign and date the form.

7.2.1 Required information

All informed consent documents should contain the following information :) Federal Policy __.116(a).

- a) The title of the study, information on the purpose(s) of the research, a description of the method(s) and procedure(s) to be followed, including the intention to publish or disseminate the results of the study, and the amount of time the subject will spend in actual project participation;
- b) A description of any reasonably foreseeable risks or discomforts to the subject, including expected total time of participation. If disguised or deceptive procedures are to be used, a plan to debrief subjects must be explained to the IRB;
- c) A description of any benefits to the subject or to others as a result of the information obtained from the research;
- d) A disclosure of appropriate alternative procedures that may be advantageous to the subject when making an informed decision regarding whether or not to participate in the research;
- e) A description of the measures to be taken to ensure the confidentiality of data and the anonymity of individual subjects as well as any circumstances under which confidentiality cannot be guaranteed;
- f) The name and phone number of a contact person(s) who will be available to answer any questions the subject or his/her legally authorized representative may have regarding the research. Student researchers must include the name, office address and phone number of his/her faculty research advisor;
- g) The name, title, office address, and office phone number of the IRB Chair as a second contact person;

- h) A clear explanation that participation is voluntary and that no penalty or loss of benefits to which the subject is otherwise entitled will occur should the subject refuse to participate or decide to discontinue participation;
- i) Disclosure of costs to the subject, if any, because of his/her participation in the research; disclosure of compensation/reward to the subjects, if any, for his/her participation in the research;
- j) For projects of more than minimal risk to the subjects, a statement must be included that describes how the costs of medical care or other therapies required as a result of injury or mishap incurred while participating in the research will be handled. The consent form should also include information about the availability and extent of on-site medical treatment.
- k) The expected duration of the subject's participation;
- l) Signature line for the subject (or authorized representative) to sign, acknowledging that they have read the consent form, understand any risks and agree to be a subject in the program. The person witnessing the consent must also sign and date the form.

7.2.2 Oral Consent

Oral consent may be appropriate under some circumstances for research projects. Researchers using oral consent will read an age-appropriate informed consent document to participants and have participants sign an Oral Consent Short Form. Federal regulation also requires that a witness to the oral presentation be present to ensure proper informed consent. Participants in the study will only need sign the Oral Consent Short Form but should be given a copy of both the Oral Consent Short Form as well as the Informed Consent Information Sheet. However, both the witness and the person actually obtaining consent shall sign both the Oral Consent Short Form and a copy of the consent document read aloud. Templates for the Oral Consent Short Form and age-appropriate consent forms are available on the IRB website. The IRB must review and approve of both forms prior their use in any research.

7.2.3 Audio or video recording

Audio or video recordings usually increase the risk to research subjects. Therefore, if studies involve audio or video recordings, participants must be told whether:

- a) the interviews or sessions will be audio or videotaped;
- b) the cassettes will be coded so that no personally identifying information is visible on them;
- c) the recordings will be kept in a secure place (e.g., a locked file cabinet in the investigator's office);
- d) the recordings will be heard or viewed only for research purposes by the investigator and his or her associates; and
- e) the recordings will be erased after they are transcribed or coded.

If the researcher wishes to keep the recordings because of the requirements of his/her professional organization with respect to data or because the researcher may wish to review them for additional analyses at a later time, the statement about erasing them should be omitted and replaced with a statement that recordings will be retained for possible future analysis.

If the researcher wishes to present the recordings at a convention or to use them for other educational purposes, he/she should obtain special permission to do so by adding, after the signature lines on the consent form, the following statement, "We may wish to present some of the tapes from this study at scientific conventions or as demonstrations in classrooms. Please sign below if you are willing to allow us to do so with the tape of your performance." Additionally, a second signature line should be added with

the preface, "I hereby give permission for the video (audio) tape made for this research study to be also used for educational purposes." Other options may be inserted as they apply to the research project. This procedure makes it possible for a participant to agree to being taped for research purposes and to maintain the confidentiality of the information on that tape. If the researcher wants to use the data in a way other than that specified in the original informed consent, consent must be obtained for the new use of the data.

7.3 Waiver of Requirements to Document Informed Consent

The researcher must make the request for a waiver of signed informed consent on the protocol form. The IRB may waive the regulatory requirement for written documentation of consent in cases where:

- a) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- b) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

The researcher requests a waiver on the protocol form. In cases in which the documentation requirement is waived, the IRB may require the researcher to provide subjects with a written statement regarding the research.

8.0 Education and Certification of Researchers

8.1 Purpose of Education and Certification of Researchers

Marian University is committed to upholding the highest standards in research involving human subjects. This requires knowledge of ethical and regulatory obligations by all involved in the conduct of such research. In order to ensure that anyone working with human subjects becomes educated on the protection of human subjects, all researchers involved in human subject research must complete a training program. This policy is intended to assist its research community in understanding and complying with these shared obligations.

Marian University policy requires that all IRB members and those individuals considered key study personnel receive and maintain "CITI certification" in human subject protection prior to their involvement in human subject research. This applies to existing and new personnel. However, all faculty, staff, and students are highly encouraged to complete CITI training to learn of the ethical and regulatory obligations regardless of whether they intend on conducting research in the foreseeable future.

Pursuant to the above requirement, individuals are considered to be "key personnel" if they have direct contact with subjects, subject data, subject records (including records-based research), protected health information or biological samples collected and/or tested for research purposes. The definition of key personnel includes individuals who may have direct responsibilities for data analysis or who contribute in a substantive way to the scientific development of a project. Students are considered key personnel if they meet any of these criteria.

This policy applies to all faculty, staff, students, and other personnel who are engaged in the design, conduct, or analysis of human subjects research that is conducted under the aegis of Marian University, regardless of the source of funding, if any. If there are questions about whether a particular activity

constitutes human subjects research or is conducted under the aegis of the University, researchers should consult with the Institutional Review Board (IRB).

This policy also applies to all faculty and students who utilize classroom projects involving human subjects that require IRB review as delineated in the [Classroom Assignment policy Section 6](#).

8.2 Initial Education and Certification of Researchers

Initial education and certification will be completed through the Collaborative Institutional Training Initiative (CITI) web-based course (<http://www.citiprogram.org>). It is the responsibility of the Principal Investigator (or the faculty research advisor if the PI is a student) to make sure that all study personnel involved with the research have received the required training/education before beginning the research.

For classroom projects involving human subjects that don't require IRB review, faculty are encouraged to require CITI training of all students.

8.3 Continuing Education

All personnel who remain engaged in human subjects' research are required to complete continuing education every three years, with the schedule determined by the date on which initial training was done. New IRB approvals will not be granted and active protocols may be suspended if the continuing education requirement has not been completed in time. The continuing education requirement will be satisfied by the completing the current version of the CITI Refresher Training web-based course.

8.4 Alternative Training for Special Circumstances

Under limited circumstances, the IRB may approve an alternative human subjects training program to satisfy these requirements. For example, it may be impractical or inappropriate for field workers in remote areas or foreign countries to complete the Marian training program. In alternative situations, the lead researchers are responsible for training their staff.

It is the prerogative of the Marian IRB with oversight for a given project to approve an alternative program. Researchers are encouraged to consult with the IRB early in the application process if alternative circumstances may apply. These situations will be the exception and not the rule.

8.5 Collaborating with Researchers at Other Institutions

Research projects may involve collaborators external to Marian. Any collaborators who have contact with human subjects or their data are expected to complete the CITI Training Program or provide documentation to support they have completed comparable training at their home institution.

9.0 Archival Data, Cooperative Research, and Data Sharing

9.1 Archival Data

Marian researchers must obtain Marian IRB approval to use archival data. The chair of the IRB may determine the researcher's request is exempt or merits an expedited review if:

- a) The researcher who was responsible for the data's collection and management obtained the data under the auspices of their affiliation with another institution (this includes Marian researchers that hold multiple affiliations); and
- b) That researcher received IRB approval from their affiliated institution for collecting the data; and
- c) The affiliated institution's IRB review process is in accordance with the current Code of federal regulations regarding collecting data from human subjects; and
- d) No personally identifying information is included in the data set the researcher uses under the auspices of their affiliation with Marian.

9.2 Cooperative Research with Other Institutions

In all cases, research that involves Marian personnel or resources must be approved by the Marian University IRB. This policy includes research conducted by Marian faculty, staff, or students that may have been already approved by the IRB of another institution or agency.

Cooperative research projects involve research that falls under the auspices of more than one institution. When cooperative research involves more than one institution, the Marian IRB may agree to joint or cooperative review with the other institution's IRB. In these cases, Marian will follow the FDA guidelines for cooperative research. (www.fda.gov/OC/OHRT/IRBS/research/)

In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

Marian has developed the following procedures for cooperative research with other institutions:

- a) If the project has already been reviewed by a qualified IRB at another institution, then the applicant should submit the application from that institution and the IRB finding to the Marian IRB. The IRB will use this information to determine whether the review was done in a way that meets Marian responsibilities for safeguarding the rights and welfare of human subjects and for complying with the federal policy.
- b) It will not be necessary to submit the full application and IRB finding from another institution in the case of established national studies that are ongoing. In those cases, the local administrator of the project should send a letter to the chair of the IRB affirming that the project is being regularly reviewed by a qualified IRB at another institution. If in doubt, the local administrator should contact the IRB chair to discuss how much documentation will be needed.
- c) If the project has not been reviewed elsewhere, then the Marian IRB will conduct its own review in the usual way.

When the Marian IRB agrees to allow another institution to be the IRB of record and assume primary responsibility for oversight and continuing review, the Marian IRB must first determine that the rights of participants and Marian investigators are protected. The principal investigator must contact Marian's IRB to request authorization to use another IRB for Protocol Review before beginning research or submitting materials to the other IRB.

The Marian IRB will not approve a request to use another institution as the IRB of record when any of the following conditions exist:

- When any direct participant activities will take place at Marian University or outreach sites.
- When the project fulfills the requirements of a Marian student's degree program, including master's thesis, projects, action research, or doctoral dissertation.

- When the Marian PI is also the PI at the outside institution.

9.3 Data Sharing

Researchers who intend to share data collected under the auspices of their affiliation with Marian must let the Marian University IRB know they intend to share the data when they initially seek IRB approval of their research. They may also seek IRB approval to share the data using the Request for Modification to Previously Approved or Exempt Protocols form.

The IRB approval request must explain the measures the researcher(s) will take to minimize direct or indirect unauthorized disclosure of personally-identifying information. Marian requires the researcher(s) to show how they will ensure protection of human subjects' personally identifying information by either thoroughly describing the information-removal techniques they will utilize or explaining how retaining such information does not pose a risk to the research subjects. In addition to removing direct identifiers, e.g., name, address, telephone numbers, and Social Security Numbers, researchers should consider removing indirect identifiers and other information that could lead to "deductive disclosure" of participants' identities. Deductive disclosure of individual subjects becomes more likely when there are unusual characteristics of the joint occurrence of several unusual variables. Samples drawn from small geographic areas, rare populations, and linked datasets can present particular challenges to the protection of subjects' identities.

Marian researchers must receive IRB approval before allowing non-Marian personnel access to human subjects' personally identifiable information either through the original Marian IRB approval request or through the Modification to IRB-Approved Project

If the researchers intend to share data, they must mention in their consent form that personally identifying information may be shared with non-Marian research team members.

When the protocol is submitted, the researcher(s) must include a copy of the data sharing agreement they will require other researchers to sign before releasing the data. This agreement must clearly describe uses of the data and the measures the researcher or researchers are required to take to protect the data.

9.4 Record Retention

Researchers will follow federal, state, and Marian University record retention policies for research data.

Regulations at 45 CFR 46.115(b) require that IRB records be retained for at least 3 years, and records relating to research that is conducted be retained for at least 3 years after completion of the research.

10.0 Engaging in Human Subject Research without IRB Approval

10.1 Marian University Policy

Engaging in human subject research without IRB approval has serious ethical implications and violates federal and Marian University policies. Students, faculty, and staff are required to submit IRB applications before embarking on any data collection. Even pilot studies should be approved by the IRB. Anyone conducting human subjects' research without the approval of the IRB is subject to a finding of research misconduct and sanctions administered by the University. Principal investigators and other research staff are subject to any or all of the following consequences if they perform unapproved human subjects research.

10.2 Possible Ramifications for Faculty and Staff

- a) Funding may be withheld. Federal sponsors, and virtually all private sponsors, require IRB approval as a condition of funding. Sponsors may postpone review of proposals for which review is not complete or pending at the time of proposal submission. Many sponsors will not release funds to the University for the investigator's use without IRB approval.
- b) Articles may not be published. Most professional journals require evidence of IRB approval when considering articles for publication.
- c) Liability issues arising from unapproved research become the responsibility of the investigator. Persons conducting unapproved research are deemed to be acting outside the scope of authority granted them by Marian University. The University will not, therefore, provide resources to answer a liability complaint to an investigator of an unapproved project.
- d) Research may be suspended. Marian University may suspend all research activities for a specified time frame as a disciplinary measure or may require the mandatory destruction of all research data collected during a project.
- e) Disciplinary action may occur, including possible termination of employment at Marian University.

10.3 Possible Ramifications for Students

- a) Credit may be withheld. Marian may refuse to grant students course credit for research conducted without IRB approval. Thesis work may not be accepted. Degrees may not be awarded for work based on non-IRB reviewed projects.
- b) Articles may not be published. Most professional journals require evidence of IRB approval when considering articles for publication.
- c) Funding may be withheld. IRB approval is required if the student is a participant in a grant program. These programs will not release funds without IRB approval.

11.0 Interpretation of IRB Policy

The authority to interpret this policy rests with the President of Marian University, and is generally delegated to the Vice President for Academics and the IRB Chair.