

MONTCLAIR STATE UNIVERSITY

The Institutional Review Board (IRB) for the Protection of Human Participants in Research*

Internal Policies and Procedures

Revised February 25, 2008

Adopted January 27, 2010

Revised (Section V only) & Adopted April 28, 2010

Revised & Adopted September 21, 2011

Revised (II, XI and XII) & Adopted July 25, 2012

Revised (V) Adopted December 12, 2012

New (XV) Adopted September 18, 2013

Revised (Adopted Noncompliance Policy) August 20, 2014

Revised (multiple sections) November 2014

Revised July 15, 2015

Revised December 16, 2015

Revised (Adopted COI Section) August 24, 2016

Revised (Section II and IV) November 16, 2016

*Adapted to reflect the Code of Federal Regulations

Table of Contents

I.	Statement of Principles and Purpose.....	5
II.	IRB Membership	5
III.	IRB Chairperson and Vice Chairperson.....	6
IV.	Ethical Concerns	7
	A. Conflict of Interest.....	7
	B. Confidentiality of IRB Proceedings.....	7
V.	IRB Functions and Procedures.....	8
	A. Procedures for Determining Categories of Proposals for IRB Review.....	8
	B. IRB Members Required for Action on Protocols.....	10
	C. Review Procedures	10
	D. Notification of IRB Findings.....	12
	E. Minutes of Meetings	14
VI.	Research Determination and Activities that Constitute Research	15
	A. Research Definition	15
	B. Determining Research	15
	C. Specific Activities Not Considered Research	15
	a. Institutional Research.....	15
	b. Course Assignments	15
VII.	Required Training.....	16
VIII.	Criteria for IRB Approval for Research.....	16
	A. PI and Primary Contact Status – Submissions using Cayuse Electronic IRB	16
	B. Submission requirements.....	16
	C. Criteria for review.....	17
IX.	Continuing Review/Renewal of Approved Research.....	19
	A. Overview.....	19
	B. Requirements for Continuing Review/Renewal.....	20
	C. Materials Needed for Continuing Review/Renewal	20
	D. Deadlines for Continuing Review/Renewal.....	21
X.	Changes/Amendments/Modifications in Protocol and/or Consent Forms and/or Personnel	21

- A. Changes/Amendments/Modifications to Protocol or Consent Form 21
- B. Addition or Removal of Personnel; Addition or Removal of research sites 21
- XI. IRB Review and HIPAA 22
 - A. HIPAA Authorization if a study involves Protected Health Information (PHI) 22
 - B. Waivers or Alteration of HIPAA Authorization 22
 - C. Alteration of Authorization 23
- XII. Data Retention and Study Closure 23
 - A. Data Retention 23
 - B. Study Closure 23
- XIII. Report of Injury, Adverse Events, and/or Unanticipated Problems 24
 - A. Injury or unanticipated problem involving risks to subjects or others 24
 - B. IRB Response to reports of Injury or unanticipated problem involving risks to subjects or others 24
 - C. Subject Complaints 25
- IX. Noncompliance 25
 - A. Overview 25
 - B. Definitions 26
 - C. Handling Allegations and Findings of Noncompliance 27
 - a. Initial Inquiry 27
 - b. Investigation and Investigative Subcommittee 28
 - D. Corrective Actions 30
 - E. Investigator Appeals 31
 - F. Reporting 31
 - G. Record Retention 31
- XIV. IRB Right to Ensure Compliance 32
- XV. Post Approval and For-Cause Monitoring of Research with Human Participants 32
 - A. Goals 32
 - B. Audit Categories 32
 - C. Audit Notice 32
 - D. Report of Findings – Serious non-compliance 33
 - E. For-Cause Investigations 33
 - F. Regulatory Authority and References 33
- XVI. Suspension or Termination of IRB Approval of Research 34

XVII. Appeal Procedures 35
XVIII. Enactment 35
XIX. Related Regulations/Guidance 35

I. Statement of Principles and Purpose

Persons conducting research involving human subjects have an ethical as well as professional obligation to ensure the safety, protection, and rights of participants. It is the intent of Montclair State University through the Institutional Review Board (IRB) to assist those engaged in research involving human participants to conduct their research according to ethical principles that reflect professional as well as community standards, regardless of the source of funding. It is also the intent of the university and the IRB to facilitate competent, ethical and sound research involving human subjects. To that end, the university requires all research involving human subjects to meet regulations established by the United States Code of Federal Regulations (45 CFR 46).

The procedures and regulations followed by the IRB are intended to help researchers ensure that their research does not pose risks to participants that are unwarranted and that the potential benefits of the research outweigh the risks. The procedures are intended to ensure that all participants in research are respected as autonomous persons, that special care is taken not to exploit those with diminished autonomy, and that no group or category of people is given undue opportunity or undue burden through participation in research.

II. IRB Membership

IRB members are appointed by the Office of the Provost, who is the Institutional Officer. When a new member or staff is to be appointed, the IRB Chair may seek recommendations from current IRB members and make a recommendation to the Provost. The Provost will then make the decision about whom to appoint.

Membership in the Montclair IRB shall consist of a minimum of seven members. The following members are appointed for one-, two-, or three-year renewable terms by the Provost:

- (a) at least one person who is not affiliated with Montclair and who is not an immediate family member of someone who is affiliated with the university;
- (b) at least one person whose primary concerns are in nonscientific areas (NOTE: This person and the person not affiliated with Montclair may be one and the same person);
- (c) faculty or staff members from units in which research involving human subjects is conducted

These voting members must constitute a mix of both men and women. The members of the IRB must be sufficiently qualified through experience and expertise as well as through their diversity of backgrounds and experiences and their sensitivity to community issues to promote respect for the IRB's advice and counsel, and to competently review specific research activities.

Alternate IRB members replace regular IRB members who are unable to attend convened meetings of the IRB. Alternate members have qualifications comparable to the applicable regular

member and may be alternates for more than one IRB member. A list of alternate members will be maintained with OHRP. Alternate members are subject to the same requirements and obligations as regular IRB members. Alternate members are also appointed by the Provost.

The IRB may invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available to the IRB. These invited individuals are not voting members. Invited individuals will be required to sign confidentiality agreements.

Reasons for seeking additional or special competence from outside experts may include (but are not limited to) the need for additional scientific, clinical, or scholarly expertise; the need for particular knowledge and understanding about potentially vulnerable populations of subjects; the desire to ensure appropriate consideration of race, gender, language, cultural background, and sensitivity to such issues as community attitudes.

In the unlikely event that a member of the IRB should conduct him/herself in a manner contrary to the policies and ethical and professional responsibilities of the IRB, such member can be removed from the board at any time by the IRB Chair, with the approval of the Provost.

All IRB members must complete the approved Montclair human subjects training within the first month of beginning their tenure on the IRB. New members to the committee will also be paired with an experienced IRB member and mentored at minimum for the first 10 protocols or until the mentor and IRB chair agree on readiness to conduct independent reviews. New members will receive relevant IRB resources within 30 days of appointment to the committee.

III. IRB Chairperson and Vice Chairperson

The IRB Chairperson shall be appointed to a three-year renewable term by the Provost. The chairperson can only be removed from that position by the Provost. The IRB Chair should be a highly respected individual from within the institution, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. Specific duties of the Chair are described throughout the remainder of this document. An IRB Vice Chairperson may be appointed by the Provost (or his/her designee). The basic duties of the IRB Vice Chair will consist of chairing the IRB meeting or signing approval documents in the IRB Chair's absence.

IV. Ethical Concerns

A. Conflict of Interest

No IRB member may participate in the IRB's initial review, continuing review/renewal, or amendment/modifications of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

B. Confidentiality of IRB Proceedings

Through its policies and procedures, the IRB seeks to maintain the fundamental principle of openness in research and, at the same time, to protect personal privacy and proprietary information. The value of openness with respect to the business of the IRB must be limited by considerations of the privacy of human participants in research, the confidentiality of proprietary data, the need to encourage free discussion at IRB meetings, and the desire to promote cooperation in carrying out the responsibilities of the IRB.

The following policy guidelines have been established to promote a balance between openness and privacy concerns:

1. Responsibility of IRB Members to Maintain Confidentiality of Proceedings

Members of the IRB and administrative staff who attend meetings are responsible for maintaining the confidentiality of all IRB deliberations and discussions. They shall not discuss the protocols or the discussions of the protocols with others outside the IRB other than the research team of the proposal unless identifiers have been removed. They shall take care to properly store and dispose of materials that are discussed at meetings. A confidentiality statement must be signed by the IRB members or invited guests prior to the first meeting they attend.

2. Attendance at Regular IRB Meetings

Normally, IRB meetings are closed to the public, although exceptions may be made by the IRB, IRB chair, or Provost. The IRB may hold special public sessions on issues of interest to the broader University community or in response to concerns raised about matters related to IRB business.

3. Minutes of IRB Meetings

In order to encourage open and frank discussion at IRB meetings and to have detailed records of IRB business (including confidential issues and matters under investigation), minutes of IRB meetings normally are not made available to others outside the Provost's office unless otherwise required by law or external regulations. Individual IRB members are not identified in the minutes in relation to discussions of research protocols, unless that IRB member requests to be identified.

4. Protocols, Study Documents and Informed Consent Forms

The IRB shall consider a research protocol and all associated application materials to be confidential documents.

Requests to release a protocol or a consent form should be directed to the relevant Principal Investigator. Such requests must state the reason for the release of the protocol or consent form.

The IRB maintains the right to allow the following individuals access to protocols and related study documents:

- IRB members
- IRB Staff
- Institutional Official (IO) and/or his/her designee
- Other Designated Officials within the University whose responsibility is to oversee University-wide policy (e.g. Research Compliance Officer, Health Directors, IBC members etc.)
- OHRP or other federal authorities responsible for Human Subject Protections
- Invited individuals with specialized knowledge concerning research procedures or populations to assist in the review of complex issues that require expertise beyond or in addition to that available to the IRB. Invited individuals will only be provided with the minimum necessary details or documentation to allow for their guidance. The PI will be notified that an outside expert will be used in the review.

V. IRB Functions and Procedures

The primary function of the IRB is to categorize (as defined by 45 CFR 46), evaluate and review proposals that fall into exempt, expedited and full review categories. The duties of the IRB Chairperson include delegating review tasks to committee members and IRB staff and coordinating the reviewing of all research protocols submitted for consideration.

A. Procedures for Determining Categories of Proposals for IRB Review

1. All research protocols by Montclair faculty, students, and other affiliated personnel that involve human subjects must be submitted to the IRB. The Chair of the IRB will review all submissions and assign them for initial review to an IRB member or IRB staff member. The IRB Chair may designate the IRB Coordinator to assign reviews to all appropriately trained IRB Member reviewers or IRB staff. The IRB staff will assign all continuing reviews/renewals and amendments/modifications for review by the board member who initially did the review (if possible) or another committee member after consultation with the Chair.
2. The Chair of the IRB and/or another person designated by the Chair of the IRB will review all research proposals. The person must be well-acquainted with the Federal Regulations regarding human participants in research and the specific categories defined by the federal regulations.

If the reviewer determines that the research does not meet the criteria for human

subjects research, the investigator is notified within twenty (20) work days of protocol submission.

If the reviewer/analyst determines that the research qualifies for either Exempt or Expedited review, the investigator is notified within 20 work days of protocol submission with a judgment of approval or with feedback specifying specific required changes needed to qualify for approval. If the reviewer cannot determine the appropriate category in which to classify the protocol, he/she must either request needed clarification from the investigator within 20 work days or designate the protocol for full board review.

If the reviewer determines that the research qualifies for Full review, the reviewer notifies the IRB staff of that fact. The IRB staff notifies the investigator within 20 work days of protocol submission that their submission will be considered at the next Full board meeting for which it qualifies (see 4. Below).

3. In conducting an exempt or expedited review, the IRB reviewers may exercise all the authorities of the IRB except that they may not disapprove the research. A research activity may be disapproved only after review by the convened IRB.

Exempt and Expedited reviews shall be as thorough as a full IRB review. These reviews must fulfill all the requirements of review found in the regulations, including those for informed consent and documentation of consent.

Review documentation will include:

- (a) the category under which review is justified,
- (b) findings regarding any special actions related to informed consent or other protection of subjects,
- (c) action taken: approval, specific directed changes required, or substantive changes required (see C below).

4. Research proposals that are determined to be categorized as "Full" by initial reviewers are put on the agenda for an upcoming IRB meeting. (Deadlines for submission of proposals to be considered for IRB meetings are listed on the IRB website.) Such proposals are reviewed following the procedures described in C below.

B. IRB Members Required for Action on Protocols

Following Federal Regulations (45 CFR 46.108), the IRB will review proposed research that requires a full committee review at convened meetings at which a quorum is present as defined as one more than half of committee members including at least one member whose primary concerns are in nonscientific areas.

C. Review Procedures

The IRB shall meet monthly according to a regular schedule, with additional meetings as needed. The schedule of IRB meetings and deadlines for submission of proposals will be posted on the website of the IRB.

All documents submitted for review will be available to IRB members before each scheduled meeting.

IRB staff shall prepare the agenda with input from the IRB Chair. The Chairperson will facilitate the meeting according to the following format:

1. Call the meeting to order
2. Education Item (optional)
2. Announcements
3. Review of Protocols
3. Reading and approval of minutes from previous meeting
4. General business
5. Adjournment

Both the agenda and minutes from the previous meeting shall be posted for the committee no later than one week prior to the scheduled meeting except in extenuating circumstances.

The IRB member (or members) who conducted the initial review of a given protocol will present the protocol to the committee, if present at the meeting. The protocol will be discussed until every member of the IRB has had his/her concerns and questions addressed. The IRB members will refer to the Criteria for IRB Approval of Research as articulated in the Federal Regulations (45 CFR 46.111) in making their determination as to what action to take regarding each proposed study (see section VIII below). After an adequate period of discussion of the research protocol, the Chairperson may call for a "motion to consider," at which point any IRB member may move for one of the following:

APPROVAL:	Protocol and all associated documents are satisfactory as presented, and Investigator may begin research immediately upon receiving notification of approval.
-----------	---

SPECIFIC DIRECTED CHANGES REQUIRED:	Study is not satisfactory as submitted. Investigator must make modifications and/or alterations to protocol and/or associated documents as directed by the IRB or modify the protocol another way to meet the IRB concerns. However, in this case, the application would not have to come back for full committee review. Revisions and modifications will be reviewed by the IRB Chairperson (acting on behalf of the IRB), who will then determine whether the changes are sufficient for APPROVAL.
SUBSTANTIVE CHANGES REQUIRED (motion is not requiring return to full IRB):	Study is not satisfactory as submitted. The IRB members see the need for major changes in the protocol. The investigator will be asked to revise the protocol based on IRB feedback and resubmit for IRB review. Revisions and modifications will be reviewed by the IRB reviewer and the IRB chairperson who will then determine whether the changes are sufficient for APPROVAL.
SUBSTANTIVE CHANGES REQUIRED (returning to full IRB/tabled):	Study is not satisfactory as submitted. The IRB members see the need for major changes in the protocol. The investigator will be asked to revise the protocol based on IRB feedback and resubmit for full IRB review at a later meeting. Substantive changes may be required if the protocol is not written clearly enough to describe the research procedures.
DISAPPROVAL:	The protocol places subjects at unacceptable risk relative to benefits. Research project as designed and described is not suitable for involvement of human subjects.

Following the “motion to consider” and a second to that motion there will be opportunity for further discussion and clarification. If the motion is for approval or approval with specific directed changes, the motion will also include the length of time for which the protocol will be approved before a continuing review/renewal is required (See IX below for a description of procedures for continuing review/renewal.). The motion can then be and voted upon.

In order for the reviewed research to be approved, it must receive the approval of a majority of those members present. When there are tie votes, the Chair will facilitate further discussion in an effort to have the committee reach a consensus or majority on the status of the proposal. If a consensus or majority is not possible, consultation with others, who are not members of the IRB, may be solicited to aid in resolving the issues.

D. Notification of IRB Findings

After a full IRB review, the IRB Chairperson or IRB staff shall notify investigator(s) of the findings and actions regarding their protocol within five (5) work days of the IRB meeting.

Approved	The investigator(s) may begin the proposed research project after receiving the notification of approval.
Specific directed changes are required	<p>The investigator shall be notified within five (5) working days of the IRB meeting of the specific changes to the protocol and/or associated documents necessary to proceed with IRB approval of the research protocol. The Chairperson of the IRB shall communicate, in writing, the findings of the IRB to the IRB administrator who will communicate those findings to the PI with a request for the necessary modifications. Until the investigator convincingly demonstrates, in writing, that all required changes have been made to the IRB's satisfaction, the project CANNOT begin. After the IRB Chair determines that the PI has responded to the requested changes, approval notification will be sent to the PI and the project can begin.</p> <p>Every responsible effort will be made to assist the investigator in bringing a non-approved project into compliance with IRB regulations r to be approved. However, meeting deadlines and time demands is entirely the responsibility of the investigator.</p>

	<p>If the investigator does not respond to the IRB's notification of required changes within thirty (30) calendar days of receiving notification of the changes needed, the proposed project must be resubmitted for full IRB review at the next regularly scheduled IRB meeting.</p> <p>If the investigator submits the specific directed changes within thirty (30) calendar days, the IRB chair will review the changes and respond to the investigator within 20 work days of receipt of the changes. If the required changes have been made, the research will be approved. If the required changes have not been made, the IRB chair will require that the needed changes be made before the research is approved.</p> <p>Notification to the investigator will convey these stipulations and the time limit.</p>
Substantive Changes	<p>The investigator will be notified that the project requires such described changes. The notification will explain changes needed and the reasons for the changes. The investigator will be asked to resubmit the proposal for review by the IRB reviewer or for a later regularly scheduled IRB meeting.</p>
Disapproved	<p>The investigator will be notified and the findings of the IRB resulting in such a decision will be conveyed, , to the investigator within five (5) days of the IRB review.</p>

For Exempt and Expedited reviews, any changes requested by the reviewer will be communicated to the PI within 20 working days. The reviewer and IRB Chair or chair's designee requesting the changes, will review the changes and if the changes have been adequately addressed the research will be approved. If the changes are not significantly addressed the reviewer will require that the needed changes be made before the research is approved.

At the discretion of IRB staff, if the PI does not respond to the IRB's requested revisions or does not certify the submission After (90) calendar days, the PI may be required to re-initiate an IRB submission for IRB review.

All final notifications of IRB findings for funded studies will be copied to oversight office for that sponsored award (i.e. the Office of Research and Sponsored Programs, Foundation Office).

E. Minutes of Meetings

The minutes of IRB meetings shall be in sufficient detail to show:

- (1) Attendance at meetings
- (2) A written summary of business conducted and announcements made that were unrelated to the particular protocols being considered
- (3) A written summary of the discussion of issues related to each research protocol being considered
- (4) Actions taken by the IRB on each research protocol considered
- (5) The vote on these actions, including the number of members voting for, against, and abstaining
- (6) The basis for requiring changes in research, as relevant
- (7) The date at which continuing review of the research project is required and, if less than one year, the reasons for such
- (8) The basis for disapproving research, as relevant
- (9) A written summary of the discussion of issues related to each research protocol being considered for continuing review
- (10) Actions taken by the IRB on each research protocol considered for continuing review
- (11) The vote on these actions, including the number of members voting for, against, and abstaining

These minutes shall serve as IRB records of full review proceedings. All remarks, commentaries, opinions, and votes of board members are eligible to become part of the official record of the meeting, which will be confidential.

VI. Research Determination and Activities that Constitute Research

A. Research Definition

Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” (45 CFR 46.102(d))

B. Determining Research

The IRB keeps track of activities involving human participants that may not fall into the research definition. The purpose of the Research Determination is to allow the IRB to determine if an activity involving human participants is research.

If a P.I. believes that their project does not meet the criteria of research as defined by 45 CFR 46, they can submit for a Research Determination via the submission process to the IRB office. The IRB Chair or an experienced IRB reviewer reviews the RD and determines whether or not the project falls into the category of research. The determination is made within 10 working days. The P.I. is notified of the determination. If it is determined that the project requires IRB review, the P.I. is encouraged to submit a complete submission of human subjects research as soon as possible.

If the project does not require IRB review the determination notification is kept by the IRB office. For any project receiving funding the ORSP office is copied on the determination notification.

C. Specific Activities Not Considered Research

Following from this definition, two specific types of activities are not considered research and therefore do not require IRB review:

a. Institutional Research

The purpose of institutional research is to gather data about one particular institution (e.g., Montclair State University) to be used in-house by the institution. There is no intention to use the data to contribute to generalizable knowledge. Such “research” does not require IRB review.

b. Course Assignments

If course projects are conducted solely for the purpose of learning about and getting practice with research techniques (not to produce generalizable knowledge) and if the data from those projects are not used outside the class for which they were collected, they are not considered research and do not require IRB review.

VII. Required Training

It is the policy of Montclair State University that all Principal Investigators and Faculty Sponsors of student research provide evidence that they have completed an appropriate course of training related to the protection of human subjects in research. Faculty, staff, and students affiliated with Montclair must complete the human subjects training available through the IRB website. For research team members unaffiliated with Montclair the IRB Chair or staff will consider documentation of such training from another established human subjects protection program previously completed by PIs and Faculty Sponsors. However, if they have not completed previous training, they must complete the approved Montclair tutorial that is available through the IRB website.

VIII. Criteria for IRB Approval for Research

A. PI and Primary Contact Status – Submissions using Cayuse Electronic IRB

The PI must either be a:

- (1) permanent Montclair faculty or staff member or;
- (2) Montclair adjunct faculty member, currently teaching at Montclair or under contract to teach this year.

The Primary Contact may be:

- (1) The Principle Investigator
- (2) A currently enrolled student (with their Faculty sponsor listed as PI, if this is a student led research project)or;
 - a. A Faculty Sponsor is defined as a permanent Montclair faculty member willing to ensure that the study is conducted in accordance with all Montclair State University's IRB policies, guidelines, and approvals and federal, state, and local laws that relate to research involving human participants
- (3) Another permanent Montclair employee supporting the PI in research activities such as IRB approval

B. Submission requirements

In order to review the research, the Principal Investigator, with human subjects protections training, must submit the following to the IRB.

- (1) Complete IRB Submission
- (2) Required documents that might be used in the course of the proposed study, depending on the study:
 - a. Funding application and proposal
 - b. Consent Form
 - c. Parent/Guardian Consent Form
 - d. Assent Form
 - e. Implied Consent Letter
 - f. Debriefing Form
 - g. Site Approval Letter(s)-on letterhead of site

- h. IRB Approval letters from other institutions
- i. Participant testing materials (e.g., questionnaires, surveys, tests)
- j. Scoring instructions for tests (e.g., questionnaires)
- k. Scripts (i.e., for interviewers)
- l. Screening materials
- m. Recruitment materials (e.g., flyers, posters, internet or newspaper ads)
- n. Pictures/Images/Diagrams of devices that will be used
- o. Information (i.e., User Manual) for devices that will be used

C. Criteria for review

The IRB shall determine that ALL of the following requirements are satisfied:
(45 CFR 46.111)

(1) Risks to subjects are minimized:

(i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to the 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 or activities they would engage in 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.

(3) Selection of subjects is equitable, and the special issues related to research with vulnerable populations have been adequately addressed.

In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, students, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) 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 §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, students, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

(9) If applicable, waiver or alteration of documentation on informed consent process shall only be considered, in accordance with, and to the extent required by §46.116 or §46.117(c).

(10) If applicable, faculty use of their own students shall only be considered, if issues of authority and coercion are appropriately managed, and to the extent required by §46.111.

(11) If applicable, faculty and graduate student use of SONA shall be considered, where current SONA policies as detailed on the Montclair website are appropriately implemented.

(12) If applicable, the IRB application protocol should be in congruence with the protocol detailed in the grant proposal or funded award.

(13) If applicable, the IRB must take into consideration whether the potential conflicts of interests might adversely affect subject welfare.

D. Conflict of Interest

Research personnel who are responsible for the design, conduct or reporting of a human research project must disclose individual protocol-specific financial conflicts of interest. The Principal Investigator must inform the IRB of those research personnel who have protocol-specific conflicts, by naming the affected individual on the IRB submission.

Significant Financial Interest is defined in the Montclair State University Financial Conflict of Interest Policy accessible here: <http://www.montclair.edu/orsp/compliance/conflict-of-interest>

The IRB must take into consideration whether the potential conflicts of interests might adversely affect subject welfare. The IRB must ensure that steps to manage, reduce, or eliminate potential or real conflicts of interest have been taken. These steps are taken during the review process. During the initial review process, the IRB will review any potential conflicts of interest that may be present. If the IRB determines that the investigator's financial or other interest could adversely affect subject welfare, the IRB will take appropriate action to approve, disapprove, or require modifications to reduce the conflict and inform study participants.

If the research is federally funded, the IRB may consult with the Research Compliance Officer and COI committee as established under the Montclair State University Financial Conflict of Interest Policy. The IRB will request that the COI committee provide a copy of any protocol-specific recommendation(s) made in the COI report to the Institutional Official.

IX. Continuing Review/Renewal of Approved Research

A. Overview

Federal regulations require that expedited and full category research projects be reviewed at intervals appropriate to the degree of risk, but not less frequently than once a year.

The Montclair IRB will stipulate when each approved continuing research project must be reviewed. Most projects will undergo an annual review, but some projects will be reviewed more often than annually. They include, but are not limited to:

- a. Any research involving human subjects for which there have been reports of injury or unanticipated problems as a consequence of participating in the research;

In continuing review, the IRB seeks to ensure that:

- a. The currently approved informed consent process is still accurate and complete;
- b. Any significant new findings that may relate to a subject's willingness to continue participation are provided to the subject.
- c. Any new findings or other aspects not evaluated earlier that may impact risk to the participants are found to be in accordance with the approval criteria (Section VIII)

B. Requirements for Continuing Review/Renewal

- a. For research initially reviewed and determined Full by the IRB

Continuing review for protocols originally reviewed as full, must be conducted by the convened IRB, with a recorded vote on each study. The following are exceptions to this requirement; for these situations an expedited review process may be conducted for continuing review of research initially given a Full Review.

- (1) The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; OR
- (2) No subjects have been enrolled and no additional risks have been identified; OR
- (3) The remaining research activities are limited to data analysis.

- b. For research initially reviewed through the Expedited review process

Research initially reviewed through the expedited process must be submitted for continuing review 30 to 60 days prior to the protocol expiration date. The continuing review is also conducted through the expedited process, unless changes in the research place the participants at more than minimal risk.

- c. For research initially given Exempt status

Research that is deemed exempt from IRB review does not require continuing review.

C. Materials Needed for Continuing Review/Renewal

For continuing review, the Principal Investigator must submit a Continuing Review/Renewal submission. These materials will be reviewed by (1) an IRB reviewer selected by the IRB chair or by (2) the entire IRB board if the protocol was initially

designated for full board review. These materials should include:

- The number of subjects who have participated
- The number of subjects planned for enrollment in the coming year
- A summary of adverse events and unanticipated problems involving risks to subjects
- Any withdrawal of subjects from the research
- Any complaints about the research since the previous IRB review
- A summary of any relevant interim findings and modifications to the research since the previous review
- Any other relevant information, especially about risks associated with the research
- Any new funding documentation (funding application/proposal)

D. Deadlines for Continuing Review/Renewal

Continuing review applications or Cayuse Renewal submissions, from investigators are due before the expiration date stipulated by the IRB at the time of approval and are to be submitted to the IRB Office, who will pass them on to the IRB Chair. Any studies that have not submitted renewal prior to their expiration date, will automatically be closed.

X. Changes/Amendments/Modifications in Protocol and/or Consent Forms and/or Personnel

A. Changes/Amendments/Modifications to Protocol or Consent Form

Investigators shall file with the IRB any substantive changes in protocol or consent forms using an amendment/modification submission. Any proposed change(s) cannot go into effect until IRB approval has been obtained.

EXCEPTION: A protocol may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects. However, the IRB Chairperson must be notified via an Incident Report/Adverse Event form of such a change within 72 hours and review is still eventually required.

B. Addition or Removal of Personnel; Addition or Removal of research sites

Investigators shall file with the IRB any addition or removal of personnel from the approved protocol using the appropriate Amendment/Modification Submission.

The new personnel cannot participate in the research until IRB approval has been obtained.

Investigators shall file with the IRB any addition or removal of research sites from the approved protocol using the appropriate Amendment/Modification Submission.

Research activities at the new site cannot begin until IRB approval has been obtained.

XI. IRB Review and HIPAA

A. HIPAA Authorization if a study involves Protected Health Information (PHI)

In the course of conducting research, investigators may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule. If a study will involve access to or use of PHI, then the application must also include a HIPAA Authorization Section.

Although similar to informed consent, the HIPAA Authorization focuses on privacy risks and the use or disclosure of PHI. The HIPAA Authorization is attached to the end of the informed consent form. In the HIPAA Authorization, researchers must state how, why, and to whom the PHI will be used and/or disclosed for research purposes. An Authorization may not require an expiration date; consult state and/or local law. However, a research participant has the right to revoke (in writing) his/her Authorization at any time. The participant or the participant's authorized representative must be given a signed copy of the Authorization and researchers must keep a signed copy of participants' Authorization for six years.

If the study does not involve health information, you do not need to include the HIPAA Authorization Section.

B. Waivers or Alteration of HIPAA Authorization

The following criteria must be satisfied for the IRB to approve a waiver or alteration of authorization under the Privacy Rule:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - an adequate plan to protect the identifiers from improper use and disclosure;
 - an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - adequate written assurances that the protected health information will not be

reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

2. Waiver will not adversely affect the privacy rights and the welfare of the individuals;
3. The research could not practicably be conducted without the waiver or alteration; and
4. The research could not practicably be conducted without access to and use of the PHI.

C. Alteration of Authorization

The requirement to obtain Authorization for use of PHI may also be “altered” for a specific study. An alteration allows a change in certain Authorization requirements, while still requiring authorization for the use of PHI. Examples include making an exception to the required language in an authorization or to the requirement to obtain a signed Authorization. To be granted, an alteration must meet the same criteria above as a waiver or partial waiver.

XII. Data Retention and Study Closure

A. Data Retention

All research data must be maintained for at least three years after the project is closed out or the results published, whichever occurs last. The investigator may be required to keep the data for a longer time if mandated by the funding agency, publishers, or changes in Montclair IRB policy.

Examples of research data are (but not limited to) completed surveys, electronic data files, notebooks, printouts, , photographs, slides, negatives, films, scans, images, videotapes, audiotapes, flash memory and electrophysiologic recordings.

Other documents that you are required to keep are IRB consent documents and documentation of assent.

Unless described in the approved protocol, research data may only be altered or destroyed before this period with written permission from the Montclair IRB.

B. Study Closure

All IRB protocols must submit a Closure submission at the end of their study, including exempt protocols. The closure submission form should be completed and signed/certified electronically. Students certify the closure and acquire their faculty sponsor’s certification on the closure submission.

The IRB reviews the Closure submission, and if additional information is needed, it is

requested of the P.I. P.I.s should submit their Project Completion form within 90 days of the completion of their study.

The IRB will not accept new or continuing review submissions if the P.I. has any outstanding Project Completion forms or Closure Submissions.

XIII. Report of Injury, Adverse Events, and/or Unanticipated Problems

A. Injury or unanticipated problem involving risks to subjects or others

Investigators must report to the IRB, within 3 days of its occurrence, any injury or unanticipated problem involving risks to subjects or others as a consequence of the research project. Studies in Cayuse IRB must utilize the Incident report form, legacy (paper) studies may complete an Adverse Event Form.

By definition, an adverse event is any injury, problem, or unfavorable occurrence experienced by human participants or others during conduct of research activities. Adverse events may or may not be caused by the research protocol. They are recognized as occurring in the same span of time with the research. An adverse event may be anticipated and thus listed in the risks section of your protocol. If it is not included in the risk section of your protocol, it would be considered unanticipated.

Unanticipated Problems should have the following characteristics:

1. Must be unexpected in terms of nature, severity, or frequency.
2. Must be related or possibly related to the participation in research
3. May suggest that the research places subjects or other persons at a greater risk of harm than previously recognized

Investigators should use their best judgment regarding the nature and degree of a reportable injury or unanticipated problem. In general, whether anticipated or not, anything serious enough to warrant medical or psychiatric intervention is reportable, as are verbal or written complaints of subjects in which they proclaim that participation presents substantial discomfort, risk, and/or endangerment beyond that explained to them, or as otherwise stated in the consent form.

B. IRB Response to reports of Injury or unanticipated problem involving risks to subjects or others

Reports to the IRB Office of injury and/or unanticipated problems, or adverse events will result in one or more of the following:

1. Acceptance of the PI's changes to the protocol
2. Suspension of research activities

3. Require submission of amendment/modification to alter current protocol procedures
4. Termination of the research
5. Notification of current participants (required when such information might relate to participants' willingness to continue to take part in the research).
6. Filing of report by the Montclair IRB to:
Office for Human Research Protection
National Institutes of Health
Department of Health and Human Services
Bethesda, MD 20205

C. Subject Complaints

Investigators or research staff must report to the IRB, within 3 days of its occurrence, any complaint received from a research participant, parent or guardian. The IRB office and Compliance Officer will track receipt of any complaints and follow-up with the IRB chair on any necessary mitigation.

The IRB chair will contact the PI in response to a research subject concern. The PI is required to respond to that request at the first possible opportunity and address the questions posed by the IRB chair. If a amendment/modification to the protocol or consent form is required, the PI must submit this amendment/modification with the appropriate documents to the IRB within 7 working days.

A summary of all subject complaints and any repeated non-compliance will be reported to the full IRB committee at the regularly scheduled meetings. The IRB committee will consider any repeated non-compliance as a serious matter and may consider a vote to suspend the IRB approval of research in accordance with 45 CFR 46.113.

IX. Noncompliance

A. Overview

Investigators, research staff, the IRBs, Office of Human Research Protections (OHRP), and the organization share responsibility for the ethical conduct of human subjects research and for compliance with federal regulations, applicable state and local laws, and university policy.

The following policies apply to all research activities of faculty, staff, students and others who are involved in human research as defined above.

B. Definitions

Noncompliance: Failure (intentional or unintentional) to comply with applicable federal regulations, state or local laws, the requirements or determinations of the Montclair IRB, or university policy regarding research involving human subjects. Noncompliance can result from action or omission. Noncompliance may be non-serious (minor) or serious, and may also be continuing (see below).

Non-serious or minor noncompliance: Noncompliance that does not increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human research protection program. Examples of minor noncompliance may include, but are not limited to, the following: lapses in continuing IRB approval, failure to obtain exempt determination before exempt research involving human subjects is conducted, minor changes in or deviations from an approved protocol, or administrative errors.

Serious noncompliance: Noncompliance that has the potential to increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human research protection program. Examples of serious noncompliance may include, but are not limited to, the following: conducting or continuing non-exempt human subjects research without IRB approval; lack of legally effective informed consent from research participants; failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or inappropriate oversight of the research to ensure the safety of human subjects and the integrity of the research/data.

Continuing noncompliance: Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention.

Examples of continuing noncompliance may include, but are not limited to, the following: repeated failures to provide or review progress reports resulting in lapses of IRB approval, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

Allegation of noncompliance: An unconfirmed report of noncompliance.

Finding of noncompliance: An occurrence or determination of noncompliance that does not require further confirmation or investigation (e.g., failure to respond to the IRB within established deadlines, allegation of noncompliance

determined by the IRB to be true).

C. Handling Allegations and Findings of Noncompliance

Allegations of noncompliance should be forwarded to the IRB (staff or member) or Compliance Officer. IRB staff will process all allegations and findings of noncompliance, whether these reports arise internally (e.g., from faculty, staff, ORRP staff, IRB members, or investigator self-reports) or from outside the university (e.g., research participants or regulators). Allegations of noncompliance will remain confidential to the extent permitted by law, consistent with the need to conduct an adequate investigation.

Actions undertaken in response to an allegation or finding of noncompliance will be completed in a timely manner, based on the circumstances or seriousness of the potential noncompliance. Under federal regulations, the IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. The IRB Chair, IRB Investigative Subcommittee, or IRB may suspend or terminate approval of an investigator's research and/or secure critical documents at any time during or following an inquiry or investigation if necessary to assure the protection of research participants. Academic Affairs will be contacted to assist with obtaining the necessary resources to investigate and address noncompliance.

a. Initial Inquiry

1. IRB staff will consult with the Chair of the IRB and as necessary university counsel and administrators, on all allegations or findings of noncompliance. Any individual with a potential conflict of interest may not participate in the initial inquiry. The Principal Investigator (PI) and co-investigator(s), as applicable, may be informed of an allegation of noncompliance or contacted for a response during the initial inquiry, depending on available information and the nature of the potential noncompliance.

2. Possible outcomes of the initial inquiry include:

- Dismissal of the allegation (e.g., unsubstantiated)
- Referral to other appropriate university process (e.g., misconduct review)
- No further action required (e.g., for minor violations)
- Corrective action(s) recommended (e.g., for minor violations)
- Review by convened IRB required (e.g., noncompliance may be serious and/or continuing but further investigation is not needed)
- Further investigation required.

Further investigation will be undertaken when the results of the initial inquiry indicate that additional fact-finding is required to assess the alleged or reported noncompliance.

3. When further investigation or convened IRB review is not warranted (e.g., dismissal of the allegation or minor violations), the investigator(s) and the IRB will be notified in writing within 14 days of the allegation/finding of noncompliance and the outcome of the initial inquiry. The Institutional Official (IO), investigator(s)' Dean, Department Chair (or equivalent), and/or research collaborators may also be informed, at the discretion of the IRB Chair. Notification will be sent to the person(s) originating the report of noncompliance within 30 days, as applicable. In some cases, the convened IRB may be asked to recommend corrective actions. Suspended IRB approval may be reinstated, as appropriate, based on the outcome of the initial inquiry and the response of the investigator(s). Reinstatement of IRB approval(s) will be reported to the Research Compliance Officer within 30 days and to those previously informed of the suspension (i.e., Institutional Official, OHRP, any other sponsoring federal department or agency, etc.) and others (e.g., ORSP), as necessary.

4. If the investigator(s) is contacted for a response during the initial inquiry, a written response will be requested within 14 days. If the potential noncompliance is reviewed by the IRB, the PI and co-investigator(s) may be invited to respond in person at the meeting during which the review will take place, to be scheduled within 30 days following the receipt of the investigator(s)' response; or if no response, within 60 days. A personal advisor or legal counsel may accompany the investigator(s), but the advisor or legal counsel may not participate in the discussion.

5. Initial inquiries will be completed within 30 days of receipt of the allegation or the finding of noncompliance, depending on the nature of the potential noncompliance.

b. Investigation and Investigative Subcommittee

1. An Investigative Subcommittee (appointed by the IRB chair or vice chair) of the IRB will investigate allegations or reports of noncompliance when the results of the initial inquiry indicate that additional fact-finding is required. Members of the IRB may serve as the Investigative Subcommittee with support from the Research Compliance Officer (non-voting official). Any individual with a potential conflict of interest may not participate in the investigation. At least one IRB member should possess expertise appropriate for review of the potential noncompliance; additional IRB members or

external consultants may also be included as determined necessary by the subcommittee chair. The subcommittee will be facilitated by the Research Compliance Officer. The Investigative Subcommittee will meet as necessary to ensure timely review of pending allegations.

2. The investigator(s) will be informed in writing of the allegation and investigation. A written response may be requested by the subcommittee and a response is required within 14 days, depending on the nature of the potential noncompliance, to facilitate review and conclusion of the investigation. The PI, research staff, or others may be interviewed and/or an audit of the investigator(s)' research may be conducted during the investigation, as necessary.

3. The Investigative Subcommittee will consider materials and recommendations from the initial inquiry, the investigator(s)' response, and other information relevant to the investigation (e.g., interviews, audit reports, literature searches, etc.). A summary report that includes the allegation, information considered by the Investigative Subcommittee, and its conclusions and recommendations will be prepared.

4. Possible outcomes of the investigation include:

- Dismissal of the allegation (i.e., unsubstantiated)
- Referral to other appropriate university process (e.g., misconduct review)
- No further action required (i.e., for minor violations)
- Corrective action(s) required (i.e., minor violations)
- Corrective action(s) with review by convened IRB required (i.e., noncompliance is considered to be serious and/or continuing).

5. When the Investigative Subcommittee believes that serious and/or continuing noncompliance has occurred, the subcommittee's summary report will be forwarded to the entire IRB. The summary report will be reviewed at a convened IRB meeting.

Based on the summary report, the IRB chair (or chair's designee) will draft letters to the IO and PI. The PI and co-investigator(s), as applicable, will be given an opportunity to respond to the findings in writing within 14 days of receipt of the report. The investigator(s) may be invited to respond in person to the IRB at the convened meeting during which the noncompliance review will take place. A personal advisor or legal counsel may accompany the investigator(s), but the advisor or legal counsel may not participate in the discussion.

6. When review by the convened IRB is not warranted (e.g., dismissal of the allegation or minor violations), the investigator(s) will be

notified in writing and the IRB will be notified at the next monthly meeting. The Institutional Official, investigator(s)' Dean, Department Chair (or equivalent), and/or research collaborators may also be informed, at the discretion of the IRB Chair. If deemed appropriate by the IRB chair, notification will be sent to the person(s) originating the report of noncompliance within 30 days. In some cases, the convened IRB may be asked to recommend corrective actions. Suspended IRB approval may be reinstated, as appropriate, based on the determinations of the Investigative Subcommittee and the response of the investigator(s). Reinstatement of IRB approval(s) will be reported by IRB staff within 30 days of the action to those previously informed of the suspension (i.e., Institutional Official, OHRP, any other sponsoring federal department or agency, etc.) and others (e.g., Office of Sponsored Programs), as necessary.

7. Investigations will be completed within 60 days of completion of the initial inquiry, depending on the nature of the potential noncompliance and the complexity of the investigation.

D. Corrective Actions

A. Corrective action(s) will be based on the nature of the noncompliance, degree to which research participants were placed at risk, occurrence of previous noncompliance, etc. The range of possible corrective actions that the Chair, IRB Investigative Subcommittee, IO, or IRB may consider includes, but is not limited to, the following:

- Modification(s) of the research protocol or procedures
- Modification(s) of the consent process or consent form
- Providing additional information to current research participants (required when such information may relate to their willingness to continue in the research)
- Providing additional information to past research participants
- Reconfirming consent of current research participants
- Requiring additional follow-up/monitoring for current and/or past research participants
- Monitoring of the research (including audits) or consent process
- Education or mentoring for the principal investigator and/or research staff
- Additional reporting, including modifications of the continuing review schedule
- Requiring additional resources to support the investigator's research activities
- Placing limitations (e.g., restriction to co-investigator status) on the investigator's research activities or use of research data
- Suspension of IRB approval for one or more of the investigator(s)' studies

- Termination of IRB approval for one or more of the investigator(s)' studies.

B. The Chair of the IRB, Investigative Subcommittee, or convened IRB may review the investigator(s)' response to corrective actions. If the PI and co-investigator(s), as applicable, do not comply with the required corrective action(s) within the time specified in the corrective action plan, additional action may be required, including suspension or termination of IRB approval(s) for ongoing human subjects research activities. The investigator(s) and the convened IRB will be notified of resolution of corrective actions or the need for additional action(s). If not previously reported, any suspension or termination of IRB approval will be reported to the IO due to serious or continuing non-compliance .

E. Investigator Appeals

As required by regulations, any decision of the IRB with respect to research involving human subjects is final. However, the convened IRB may review an investigator's request for reconsideration or appeal to a determination regarding noncompliance and/or corrective actions as warranted by the presentation of new information or unusual circumstances. All investigator petitions must be made within 30 days of his/her notification of the IRB's findings. The IRB will review an investigator's request or appeal within 30 days, and the investigator will be notified in writing of the IRB's decision within 14 days of the review.

F. Reporting

Noncompliance determined to be serious and/or continuing will be reported by the IRB chair and the Research Compliance Officer within 14 days of the finding to the investigator(s), IRB, Institutional Official (IO), investigator(s)' Dean and Department Chair (or equivalent), and research collaborators and within 30 days by the IO to OHRP, FDA (as applicable for FDA-regulated research), any other sponsoring federal department or agency, and others (e.g., ORSP) as necessary, in accordance with The Federalwide Assurance.

G. Record Retention

Records relating to review and investigation of noncompliance will be retained by the IRB and Research Compliance Officer for a minimum of three years after completion of the research or any corrective actions (whichever is longer), in keeping with federal regulation, applicable state and local laws, and university policies.

XIV. IRB Right to Ensure Compliance

In order to determine that all substantive and relevant changes in protocol and/or consent documents are being reported, and in order to verify compliance with IRB regulations, the IRB shall have the authority to physically inspect any research premises or review non-confidential research documents relating to the protocol and procedures being used in human subject research. Generally, the investigator will be asked to provide copies of relevant and necessary documents for IRB review. Such document requests are in addition to those generated in a continuing review process. In most cases, this will only occur when there is an indication that a substantive change is in effect which has not been reported. Failure to comply with such an IRB request for information may result in suspension or termination of IRB approval of research.

XV. Post Approval and For-Cause Monitoring of Research with Human Participants

A. Goals

The goals of this monitoring program are:

- Monitor research and IRB practices,
- Provide current information to investigators, students, and the IRB,
- Correct noncompliance through education, thereby improving research compliance and preventing situations that might increase risks to research participants or lead to regulatory citations.

B. Audit Categories

- **Self–Audit:** Studies will primarily be selected by the IRB Coordinator or Research Compliance Officer; focus will be on Faculty submissions, reviewed at either expedited or full level, from researchers who have either long-running studies or multiple active studies. All colleges/schools conducting HSR will be monitored.
- **Informed consent:** Usually requested by the IRB, this audit is intended to support researchers in conducting the informed consent process. It may include: observation (when possible) of the consent process and/or a thorough review of the process including training of people obtaining consent and review of the consent forms signed by the participants.
- **Investigator Initiated:** A PI may request an on-site review to help keep records and procedures in compliance with federal regulations and institutional policies or to prepare for an external audit by a sponsor or federal agency.

C. Audit Notice

Except in cases where the safety of subjects is a concern, written notification of an audit will be sent from the IRB Office. For Self-Audits, the IRB Coordinator will contact the PI by

email and supply access to the Self-Audit Reporting form.

- **Notification:** By email with return receipt requested.
- **Submission requirement:** PI will have 4 weeks to complete and submit self-audit.
- **Review:** Initial review by IRB Coordinator and secondary review by Research Compliance Officer.
- **Report of Findings:** If submitted self-audit meets 45 CFR 46 requirements, PI will be notified by email. If any minor problem areas are noted, the IRB Coordinator will request a meeting with PI and any Co-PIs. For serious issues, the procedures below will be followed.

D. Report of Findings – Serious non-compliance

It is anticipated that in most cases serious violations involving risk of injury to participants will have already been reported to the IRB. However, if an audit demonstrates that a serious violation involving risk of injury to participants has not been reported, it will be reported immediately to the IRB Chair and to the Institutional Official. This may lead to a for-cause investigation.

E. For-Cause Investigations

For-cause: Under 45 CFR 46.113 requirements, this review is performed when concerns regarding compliance, protocol adherence, or subject safety are brought to the attention of the IRB or the IRB Coordinator. For-cause investigations are considered non-compliance and will follow the procedures for Non-Compliance starting in section XIII of this document.

F. Regulatory Authority and References

For further information, please refer to:

- The Montclair Federal-Wide Assurance Agreement with the OHRP. The agreement's Terms of Assurance stipulates that the university must have procedures that "include formal mechanisms for monitoring compliance with human subject protection requirements."
- DHHS, 45 CFR 46.109(e). "An IRB shall conduct continuing review of research ...and shall have authority to observe or have a third party observe the consent process and the research."
- DHHS, 45 CFR 46.111(a)(6). An IRB is required to ensure "when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects."
- DHHS, 45 CFR 46.113. "An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects."

XVI. Suspension or Termination of IRB Approval of Research

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and, if relevant, the funder (45 CFR 46.113).

XVII. Appeal Procedures

There are no formal appeal procedures associated with IRB review. An IRB ruling is not subject to appeal nor can it be overturned by another group or person(s). Only the IRB can alter its previous determination. The IRB is not a judicial body, but a review board empowered to consider and uphold the rights, welfare and protection of human subjects in research. IRB approval for research that has been suspended or terminated can be reinstated with a demonstration that the protocol/project can secure IRB approval. Similarly, a disapproved project can be altered so that it can secure approval.

XVIII. Enactment

These procedures and policies are considered to be in effect immediately upon approval by vote of the IRB and remain in effect and enforceable until otherwise amended or repealed.

XIX. Related Regulations/Guidance

Montclair Research Misconduct Policy

45 CFR part 46

Belmont Report

Montclair HIPAA Privacy Policy

Montclair Financial Conflict of Interest Policy