



Institutional Review Board Policy

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MCLA Institutional Review Board Policy

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Massachusetts College of Liberal Arts (*MCLA*) Institutional Review Board (*IRB*) is established to protect the rights of human subjects (*human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.*) who volunteer to participate in research. The IRB exists as a safeguard to promote the ethical and responsible treatment of participants in research.

MCLA requires that all research involving human participants must be reviewed and approved by the IRB before any research may be started. Guiding the review process is the application of federal and state laws and regulations outlined in the Code of Federal Regulations Title 45 Part 46 (*45 CFR 46*), and the ethical principles of the Belmont Report as the criteria for the review of all research studies.

1.0 COMMITTEE MAKEUP

- 1.1 Committee will include seven members – six campus members and one external member.
- 1.2 Members will be appointed by the President or designee for a three year term.
- 1.3 Chair will be appointed by the President or designee.
- 1.4 The committee will include a minimum of one member from the social sciences and one from the natural sciences. External member will have no affiliation with the institution and will not be part of the immediate family of a person who is affiliated with the institution.
- 1.5 All members will be required to complete online certification training course by NIH Office of Extramural Research. <http://phrp.nihtraining.com/users/login.php?l=3>
- 1.6 All members will be required to be recertified every three years.

2.0 APPLICATIONS PROCESS

- 2.1 All investigators seeking expedited or full review will be required to complete online NIH Office of Extramural Research training course. <http://phrp.nihtraining.com/users/login.php?l=3>
- 2.2 Researchers are required to submit a protocol and application. No proposal will be reviewed until both the protocol and application have been received.
- 2.3 Research protocol must include the following information:
 - a) Abstract: This section should explain the specific nature of the study with clear justification for the participation of human subjects at this stage of the investigation. Researchers should keep in mind that most members of the IRB are

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not experts in the research being reviewed. Adequate explanations should be provided to allow the members of the IRB to understand the objectives, the methods, and the research implications, especially noting any procedure that may cause harm or injury (*risk*) in any way.

- b) Participants: This section should note who the participants will be and how they are to be recruited. Justification must be provided for the use of subject groups that are members of a population whose capability of providing informed consent is or may be absent or limited. These include children, persons with mental disabilities, and those who are confined to institutions (*whether voluntary or involuntary*). A detailed and specific discussion of potential problems involving the subject groups must be given.
- c) Ability to Consent: A detailed description on how informed consent (*Informed consent means the knowing consent of an individual or his/her legally authorized representative so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.*) will be obtained and copies of all documentation must be included. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

If your proposed research includes minors (*under 18 years*), a detailed description on how assent will be obtained and copies of all documentation must be included. The information that is given should be in language appropriate and understandable for the subjects.

- d) Risks: A discussion of the risks, even if they are anticipated to be minimal, is required. Such deleterious effects may be physical, psychological or social. Some research involves neither risks nor discomfort, but rather violations of normal expectations. Such violations, if any, should be specified.

Further, discussion of the management of risk is required. Procedures for protecting against or minimizing potential risks should be described. An assessment of their likely effectiveness should be discussed. Management of risk procedures ranges from those applicable to a group to those applicable to an individual subject.

- e) Benefits: This section must present a justification for the proposed study. The discussion should focus on the significance of the new knowledge that is being sought and an evaluation of the direct benefits to participant(s) (i.e. credit, awareness, gift) with respect to the risks involved in the study.
- f) Confidentiality: Describe how confidentiality will be maintained within the proposed research, with consideration for:
- the separation of informed consent documents and results of such items as a completed surveys or data gathered

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- the protection of participants' anonymity or a description of why select participants will not remain anonymous
 - the protection of confidentiality in presentations or publications
- g) Debriefing: The debriefing procedure should include:
- the purpose of the experiment
 - the relation of the purpose to the conditions that they participated in
 - the overall results and conclusions drawn from the experiment (*or where and when information about results will be available in the future*)
- This should be written in plain English (*i.e. not laden with jargon*). Participants should receive this information immediately after their participation. Also, rather than simply providing debriefing information on paper participants should be verbally debriefed by the researcher(s).
- h) Materials: Attach copies of all materials (*e.g., questionnaires, etc.*) to be used in the study.
- i) Other: Include any other information that may aid the IRB in the review process.

3.0 CONSENT

- 3.1 Informed consent (*Informed consent means the knowing consent of an individual or his/her legally authorized representative so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.*) shall be obtained by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative except as provided in item 3.4 of this section. A copy shall be given to the person signing the form. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

Except as provided in item 3.4 of this section, the consent form may be either of the following: (*A sample of both forms can be found on the IRB website*).

- 3.2 Extended Consent Form – A written consent document that embodies the elements of research study and informed consent. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed. The witness shall sign and, in addition shall receive a copy of the extended consent form.
- 3.3 Short Consent Form - A short form document stating the elements of informed consent. This form may be read to the subject or the subject's legally authorized

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representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

- 3.4 The IRB may waive the requirement for the investigator to obtain a signed consent form if 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 research must still outline how consent will be obtained and provide justification for the waiver of signed consent.
- 3.5 If your proposed research includes minors (*under 18 years*), a detailed description on how assent will be obtained and copies of all documentation must be included. The information that is given should be in language appropriate and understandable for the subjects.
- 3.6 If subjects are to be compensated, the nature of the compensation and its influence on subject participation must be discussed. Experimental subjects may be reasonably reimbursed for their participation in an experiment. Compensation to subjects should never constitute an undue inducement or coercion.

4.0 REVIEW PROCESS

- 4.1.1 Committee chair or designee will ask members to check Institutional Review Board First Class conference a few times per week and will email members when a proposal has been added to the conference. The Chair or designee will make an initial decision about the review category and, depending on the research, exempt, expedited or full review will be taken.
- 4.1.2 Any member that serves as principal investigator or faculty advisor will be required to recuse themselves from the review of that proposal.
- 4.1.3 The IRB may consult with individual(s) with expertise beyond or in addition to that available on the IRB. Individual(s) consulted will not vote on matters before the IRB.
- 4.1.4 Members will submit their evaluation of each proposal in writing on the proposal review checklist.

4.2 Exempt

- 4.2.1 Exempt proposals may not be subject to review, but must be registered with the IRB. These proposals include, but are not limited to:
 - Class /lab demos where data are not shared outside class
 - When students serve as participants for each other

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- 4.2.2 Members will have 1 week (*7 days*) to raise concerns about moving a proposal from registered to expedited review. Any exempt proposal with concerns will be moved to expedited review.
- 4.2.3 If no concerns are raised the proposal will be approved for a period of 3 years from the date of approval. Written approval will be sent to the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB.

4.3 Expedited Review

- 4.3.1 Proposals that involve no more than minimal risk (*Minimal risk 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.*) may be reviewed under the expedited review process. This includes but is not limited to:
- Collecting data outside of class with adults
 - Collecting data outside of class with children, but only if data will not be shared outside of class (*not for presentation or publication*)
 - No deception
 - Anonymous participation
- 4.3.2 Committee may be divided into 2 groups of three for reviewing expedited proposals.
- 4.3.3 Review of the feedback will be done and the following decisions can be made by the board:
- Approved, no changes
 - Approved, pending changes
 - Re-submit with major changes
- 4.3.4 If Approved, no changes proposal will be approved for a period of 12 months from the date of approval. Written approval will be sent to the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB.
- 4.3.5 If Approved, pending changes the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB will be sent a list of pending changes required for IRB approval. If revisions do not meet the pending changes, the proposal may be moved to full review.
- 4.3.6 If Re-submit with major changes the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB will be sent a list of

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major changes required for IRB approval and the proposal may be moved to full review.

4.4 Full Review

4.4.1 Any proposal involving more than minimal risk will require a full review. This includes, but is not limited to, research that will involve:

- Participants under age of 18
- Use of deception and/or risk
- Special populations where informed consent is an issue
- Identifying information collected with the data
- Invasive procedures
- Any external grant-funded projects

4.4.2 A full review proposal requires full board review at a face to face meeting of the board; five voting members must be present at a full review meeting for a vote to be taken.

4.4.3 Proposals requiring full review must be submitted by set due dates. Due dates will be twice in the fall and spring semesters; research proposals may be submitted in the summer. Proposals submitted in the summer will be evaluated in the same way but under the extended timeline.

4.4.4 Majority vote “wins”, and the following decisions can be made by the board:

- Approved, no changes
- Approved, pending changes
- Re-submit with major changes
- Disapproved

4.4.5 If Approved, no changes proposal will be approved for a period of 12 months from the date of approval. Written approval will be sent to the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB.

4.4.6 If Approved, pending changes the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB will be sent a list of pending changes required for IRB approval. If the revisions do not meet the pending changes the principal investigator and in some cases the faculty advisor (*if not principal investigator*) may be asked to meet with the board.

4.4.7 If Re-submit with major changes the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB will be sent a list of major changes required for IRB approval and the principal investigator and in some cases the faculty advisor (*if not principal investigator*) may be asked to meet with the board.

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- 4.4.8 If Disapproved the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB will be sent a letter outlining the reasons the proposal was not approved.

5.0 APPEAL OF DISAPPROVED RESEARCH

- 5.1 If a proposal is disapproved, an applicant may appeal the decision made by the IRB. The applicant should notify the President or designee, who shall direct a new review of the proposal by the IRB. Reconsideration can be requested by the principal investigator and/or the faculty advisor (*if not principal investigator*). The researcher may provide expanded information and explanation to the IRB. The reconsideration shall take place and a decision shall be reached within 10 working days. The researcher and the President or designee shall be notified of the results of the reconsideration.

6.0 MODIFICATION OF APPROVED RESEARCH

- 6.1 If during the course of any research, modifications are made that significantly differ from the approved plans, the researcher is required to submit these modifications to the IRB and have them approved before any modifications may be implemented into the research. In general, any change which alters the risk or modifies the informed consent in some way requires approval.

7.0 RENEWAL OF APPROVED RESEARCH

- 7.1 Renewal is required for all research. A research renewal form is required to be submitted to the IRB.

If research has been modified (*see section 6.0*) from the previously approved research then the project will require board review before renewal may be approved.

8.0 DATA COLLECTION EXTENSION

- 8.1 If data collection will continue past the approved period a data collection extension form will be required to be submitted. The principal investigator and in some cases the faculty advisor (*if not principal investigator*) may also be required to submit additional information explaining why an extension will be needed.
- 8.2 Extensions that are approved will be for a period of 12 months from the date of approval. Written approval of the extension will be sent to the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB.

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9.0 RECORDS

- 9.1 All records will be retained in the Office of Institutional Research, Assessment and Planning.
- 9.2 The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:
 - a) Copies of all research proposals reviewed and any other documents.
 - b) Minutes of IRB meetings.
 - c) Copies of all correspondence between the IRB and the investigators.
 - d) A list of IRB members.
 - e) Written procedures for the IRB.
- 9.3 The records required by this policy shall be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research. The records of the IRB pertaining to individual research activities will not be accessible outside the IRB and the individual researcher, except for purposes of audit or inspection to assure compliance.
- 9.4 The principal investigator shall retain for three years beyond the date of completion of the research or project all protocols, copies of correspondence with the IRB, informed consent forms, and other correspondence related to the project.

10.0 SUSPENSION/TERMINATION OF APPROVED RESEARCH

- 10.1 The IRB has 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 be sent in writing to the principal investigator and the faculty advisor (*if not principal investigator*) with the reason(s) for the IRB's action.

The suspension or termination may also be reported to the President or designee.

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11.0 UNANTICIPATED PROBLEMS

- 11.1 Any unanticipated problems involving risk to participants must be reported immediately to the IRB chair. Reports should include:
- a) Identification of individual(s) involved.
 - b) Identification of principal investigator and the faculty advisor (*if not principal investigator*), title of project and IRB case number.
 - c) A description of adverse reactions.
 - d) Any relevant information on the subject.

12.0 COMPLAINTS (PARTICIPANTS OR VETTED PARTIES)

- 12.1 Parties that believe that their rights as participants in any research have been violated should submit in writing to the IRB chair and to the President or designee the following:
- a) Name and contact information of the participant.
 - b) Name of principal investigator and the faculty advisor (*if not principal investigator*), title of project and IRB case number.
 - c) A description of adverse reactions.
 - d) Any relevant information on the subject.

13.0 VIOLATIONS

- 13.1 Any noncompliance with this policy is subject to disciplinary action.
- 13.2 Violations should be reported to the IRB immediately.
- 13.3 The IRB will review the violations and will report these violations to the President or designee for disciplinary action.

14.0 POLICY REVIEW

- 14.1 The policy will be reviewed annually by IRB and the President or designee.

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Appendix

A IRB DEFINITIONS

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

Informed consent means the knowing consent of an individual or his/her legally authorized representative so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

Institution means any public or private entity or agency (including federal, state, and other agencies).

IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the requirements set forth by the IRB and by other institutional and federal requirements.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk 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.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.