

EXPEDITED REVIEW APPLICATION FORM
Macomb Community College Institutional Review Board

Human subject research activities involving no more than minimal risk to the subjects, or research involving minor changes to previously IRB approved studies may be eligible for expedited review by Macomb Community College's IRB Chair or designee. The principal investigator/project director is authorized to make the first determination of eligibility for expedited review; however, the IRB Chair bears the responsibility for concurring in that determination based on information provided by the principal investigator in the Expedited Review Application.

To be eligible for expedited review, the proposed research must fit appropriately into one of nine categories shown below. Expedited review can apply if data collection is not anonymous, but appropriate privacy and confidentiality protections are in place, and the study involves no more than minimal risk to subjects.

Categories of Research Eligible for Expedited Review

Health and Medical Clinical Research (Items 1-5)

1. Clinical studies of drugs and medical devices only when certain condition are met.
2. Collection of blood samples from healthy volunteers under certain circumstances.
3. Prospective collection of biological specimens for research purposes by noninvasive means. For example, studies involving the collection of hair, saliva, sputum or dental plaque samples.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Research involving materials (data, documents, records, or biospecimens) that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis).

Social, Behavioral and Education Research (Items 6-7)

6. Collection and analysis of data from voice, video, digital, or image recordings made for research purposes. (Depending on the project specifics, this type may also qualify as Exempt Research.)
7. Low risk behavioral research, including research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Depending on project specifics, this type may qualify as Exempt Research.)

IRB Previously Approved Research (Items 8-9)

8. Review of minor changes in previously approved research.
9. Continuing review of previously approved research, if the IRB has determined the continuing review is required to adequately protect the human subjects.

Questions about whether a research activity may be appropriate for Expedited Review can be directed to the IRB Chair, Deirdre Syms, at symsd@macomb.edu.

Expedited Review Application

____/____/____
Date Submitted

Macomb Community College
Institutional Review Board

IRB Project Number

Title of Research Project

Principal Investigator/Project Director Department Phone Extension Email address

Co-investigator/Student Investigator Department Phone Extension Email address

Anticipated Funding Source: _____

Projected Duration of Research: _____ (months) Projected Starting Date: _____

Other education institutions, organizations
or agencies, if any, involved in the study: _____

Expedited Review Category (See categories on page 1 to select appropriate expedited category number below)

My project fits into category: 1 2 3 4 5 6 7 8 9

SUMMARY ABSTRACT

Please supply the following information: Brief description of the research and participants, the location(s) of the project, the procedures to be used for data collection, whether data will be confidential or anonymous, data security procedures, disposition of the data, and a list of persons who will have access to the data.

ADDITIONAL ATTACHMENTS

- All brochures, advertisements or recruitment material given to subjects,
- A copy of the completed Consent Form Checklist,
- A copy of the Consent form that will be provided to the participants,
- If the research is associated with a grant, include the complete grant application.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented.
- Any unanticipated problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair.
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project and responsible for identifiable data destruction at project completion.
- If the IRB requires modifications in project *prior to* approval, IRB will notify the PI. The PI can make changes and resubmit the application for final IRB approval.

_____/_____/_____
Investigator/Project Director Signature

_____/_____/_____
Co-Investigator/Student Signature (if appropriate)

Signature of IRB Chair:			Date: ____/____/____
IRB Chair: Check one:	<input type="checkbox"/> Approved	<input type="checkbox"/> Approved with Conditions	<input type="checkbox"/> Refer to Full Board Review