

Macomb Community College Institutional Review Board

Exempt Project Application Form

ACTIVITIES EXEMPT FROM IRB REVIEW

Research activities involving human subjects in the following categories may be exempt from review by Macomb Community College's IRB. The principal investigator may make the first determination of eligibility for exemption, but **must obtain concurrence from the IRB Chairman** based on information provided in the Exempt Project Application on page 4.

The IRB Chairman makes the final determination of the exempt status of a research project. A principal investigator cannot begin recruiting or contacting subjects in any way without first receiving the IRB Chairman's concurrence on the exempt status of the project.

*The exemptions do **NOT** apply under any of the following research conditions:*

- (a) **Deception** of subjects is an element of the research;*
- (b) Subjects are **under the age of eighteen**;*
- (c) The activity **exposes the subject to discomfort or harassment** beyond levels encountered in daily life;*
- (d) Fetuses, pregnant women, or human in vitro fertilization are study participants, or*
- (e) Individuals involuntarily confined or detained in penal institutions are study participants.*

Except for the above exclusions, there are eight federally-approved categories of exemption, which are briefly described below.

Exempted Categories of Research

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: (a) research on regular and special education instructional strategies; (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods. To qualify as exempt, the research must not be likely to adversely impact the student's opportunity to learn the educational material or impede their assessment of the instructor.

Examples of research qualified under Exemption 1:

- Evaluating the use of a standardized test
 - Testing or comparing alternative curricula
 - Comparing the effectiveness of different instructional texts
2. Research that **only** includes the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless:** (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** (b) any disclosure of the human subjects' responses outside the research reasonably places the subjects at risk of criminal or civil liability or damage to the subjects' financial standing, employability, reputation or educational advancement; **and** (c) the research protocol does not provide adequate privacy and confidentiality protections to the subjects.

Examples of research qualified under Exemption 2:

- Surveying teachers or administrators about an educational method
 - Interviewing faculty and students about a their experience with a diagnostic tool
 - Conducting a focus group to obtain opinions of an innovative service process
3. Benign behavioral intervention research (see description below) involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is **not** exempt under Category 2 if: (a) Information recorded cannot be readily linked back to the subjects in such a manner that subjects' identity can be readily ascertained, directly or through identifiers linked to the

subjects; **or** (b) Any disclosure of this information would not place the subjects at risk of certain harms; or (c) Information is recorded in an identifiable manner, even if sensitive, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study. Exemption 3 is NOT applicable to biomedical research or research involving children.

Benign behavioral intervention must be brief in duration, harmless, painless and not physically invasive. It cannot have an adverse lasting impact on a subject. The study must not include material or activity that is offensive or embarrassing to subjects. Seek guidance from the IRB Chair if unclear whether a research proposal would be considered benign.

Example of Exemption 3 Research:

- A survey of identifiable individuals over the age of 18 that asks their opinions about an educational program or intervention in which they participated; and the IRB has determined that adequate privacy and confidentiality protections have been designed into the research proposal.
4. Secondary research involving the study of identifiable information (e.g., data, case files, etc.) or identifiable biospecimens under one or more of the following conditions:
- a. The identifiable materials are publicly available, **or**
 - b. Information is recorded by the investigator in a non-identifiable manner, **or**
 - c. The research involves the secondary use of private health information regulated under HIPAA, **or**
 - d. The research is conducted by or on behalf of a federal agency, using data collected by the government for non-research purposes, **AND** the information is subject to federal privacy standards and other requirements specified under 45 CFR 46.104(d)(4).

Example of Exempt 4 Research:

- Analyzing the Michigan “State of the State Survey” data set which is publicly released without identifiers.
 - An examination of student mental health diagnoses across providers to determine prevalence levels.
5. Research and demonstration projects which are conducted by or supported (e.g., grant funded) by a federal agency, and which are designed to study, evaluate, or otherwise examine:
- a. Public benefit or service programs; **or**
 - b. Procedures for obtaining benefits or services under those programs; **or**
 - c. Possible changes in, or alternatives to, those programs or procedures; **or**
 - d. Possible changes in methods or levels of payment for benefits or services under those programs.

Examples of Exemption 5 Research:

- The program delivers a public service (e.g. nutrition education)
 - The research project is conducted pursuant to a specific federal statutory authority (e.g. Trade Adjustment Assistance Act)
6. Taste and food quality evaluation and consumer acceptance studies:
Not applicable to Macomb Community College
7. Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research. This exemption can apply when the materials were originally obtained for non-research purposes, or for research other than the current research proposal. This exemption can apply **ONLY IF Broad Consent was obtained** from the subjects for the secondary research of their identifiable materials.

8. Secondary research on identifiable private information or identifiable biospecimens that were originally obtained for non-research purposes or for research other than the current research proposal.

There are four requirements that must be satisfied for Exemption 8 to apply:

- a. Broad consent must be obtained from the subjects for the secondary research on their identifiable materials, **and**
- b. Documentation or waiver of documentation of informed consent must be obtained, **and**
- c. An IR must conduct a limited review* to make certain determinations relating to privacy and confidentiality protections and broad consent, **and**
- d. Investigators cannot include the return of individual research results to subjects in the study.

**The IRB limited review will be conducted to determine whether there are adequate privacy and confidentiality protections in place, and the research will be conducted within the scope of the broad consent.*

Exempting an activity from review does not absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

Exempt Project Form

____/____/____
 Date Submitted

Macomb Community College
 Institutional Review Board

 IRB Project Number

Title of Research Project

Principal Investigator/Project Director

Department

Phone

Email address

Co-investigator/Student Investigator

Department

Phone

Email address

Anticipated Funding Source, if any: _____

Projected Duration of Research: _____

(months)

Projected Starting Date: _____

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

Seeking exemption category (See categories, pgs. 1-3 – check one) 1 2 3 4 5 6 7 8

SUMMARY ABSTRACT and Other Required Documents: Please supply the following information as attachments: Brief description of the participants, the location(s) of the project, the procedures to be used for data collection, whether data will be confidential or anonymous, disposition of the data, and names of all individuals who will have access to the data. Attach a copy of all instruments to be used (e.g., questionnaires, surveys), all recruitment materials, and the grant application, if applicable.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- Any additions or changes in procedures in the research that lead to increased risk to participants (greater than would occur in normal, daily life) or a reduction in confidentiality or privacy will be submitted to the IRB Chair for consideration prior to these changes being implemented.
- Any problems connected with the use of human subjects once the project has begun will 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 for the destruction of any identifiable participant data after completion of the research.

_____/_____/_____
 Principal Investigator Signature

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

Signature of IRB Chair: _____				Date: ____/____/____	
IRB Chair: Check 1:	<input type="checkbox"/> Approved	<input type="checkbox"/> Approved with Conditions	<input type="checkbox"/> Refer to Expedited	<input type="checkbox"/> Refer to Full Board	