



Monroe County Community College
Institutional Review Board

EXEMPT PROTOCOL SUMMARY FORM

ACTIVITIES EXEMPT FROM COMMITTEE REVIEW

Research activities involving human subjects in the following categories may be exempt from review by Monroe County Community College's Institutional Review Board. The principal investigator/project director is authorized to make the first determination of eligibility for exemption; however, the College bears the responsibility for concurring in that determination based on notice provided by the principal investigator to the Institutional Review Board.

*The following exemptions do **NOT** apply when (a) **deception** of subjects may be an element of the research; (b) subjects are **under the age of eighteen**; (c) the activity may **expose the subject to discomfort or harassment** beyond levels encountered in daily life; or (d) **fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity.*

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally-approved Categories of Exemption are:

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.
2. Research involving 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 place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research 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) the human subjects are elected or appointed public officials, or candidates for public office, **or** (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the

information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (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.
6. Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed, or (b) if a food is consumed that contains a food ingredient or at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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.

Questions about whether a research activity may be exempt from human subjects review can be directed to the Coordinator of Institutional Research, Evaluation and Assessment located in the Office of Institutional Research



_____/_____/_____
Date Submitted

Monroe County
Community College
Institutional Review Board

File Number

Exempt Protocol Summary Form

Title of Research Project

Principal Investigator/Project Director Department Phone Extension Email address

Co-investigator/Student Investigator 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 organizations and/or agencies, if any, involved in the study: _____

Exempt under code (see definitions on page one – check one) 1 2 3 4 5 6

SUMMARY ABSTRACT: Please supply the following information in a separate document attached to this application: **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 and the procedures to be used to maintain data confidentiality and anonymity, disposition of the data, who will have access to the data, and where the data will be stored.

Attach the following supporting documents to complete the application. Applications without the following documentation will be returned to the investigator(s):

1. Summary abstract attachment (see description above)
2. Informed Consent Form (see pages 5-6 for IRB approved template)
3. Data collection instrument(s)/questionnaire(s) to be used in the project
4. Conflict of Interest and Financial Disclosure Form signed by all investigators to be involved in the project (see page 7-9 for IRB approved form)

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



Monroe County Community College

IRB APPROVED INFORMED CONSENT TEMPLATE

The following suggestions are offered as guidelines. The exact language is the decision of the researcher. **Replace the red, bold, uppercase font with details of the proposed research.** Also keep in mind that the Institutional Review Board must determine if the participants will be giving *informed consent*. (Note: that in the case of children, it is *assent*).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine **(FILL IN THE PURPOSE OF THE RESEARCH; 1-2 SENTENCES)**. In this study, you (your child/ward) will be asked to **(FILL IN THE DATA COLLECTION PROCEDURES THAT PARTICIPANTS WILL BE EXPECTED TO PARTICIPATE IN)**. Your participation should take about **(FILL IN THE APPROXIMATE AMOUNT OF TIME IN MINUTES THAT PARTICIPANTS WILL BE REQUIRED TO PARTICIPATE IN THE RESEARCH)** minutes.

There are no risks to you (your child/ward).

or

The only risks to you (your child/ward) include **(FILL IN THE POTENTIAL RISK(S) TO PARTICIPANTS DUE TO THEIR PARTICIPATION IN THE RESEARCH; INCLUDE POTENTIAL PSYCHOLOGICAL, PHYSICAL, SOCIAL, OR OTHER RELEVANT RISK(S))**.

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported. **(IF INFORMATION WILL BE AUDIO RECORDED, DESCRIBE THAT HERE)**.

Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply **(FILL IN THE METHOD BY WHICH YOU PREFER PARTICIPANTS TO WITHDRAW FROM PARTICIPATION)**.

Please feel free to contact **(FILL IN THE NAME(S), TITLE(S), AND PHONE NUMBER(S) OF THE RESEARCHER(S) INVOLVED IN THE PROJECT)** if you have any questions about the study. Or, for other questions, contact the Coordinator of Institutional Research, Evaluation and Assessment at the Monroe County Community College Office of Institutional Research (734-384-4237).

IF THE PARTICIPANT IS OF AGE (18 YEARS OR OLDER), USE THE FOLLOWING SIGNATURE LINE AND DELETE ALL OTHERS:

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

Signature of Participant

Date



IF THE PARTICIPANT IS NOT OF AGE (NOT 18 YEARS OR OLDER), USE THE FOLLOWING SIGNATURE LINE, THE ASSENT SIGNATURE LINE BELOW, AND DELETE THE LINE ABOVE:

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

Signature of Parent/Guardian Date

FOR ASSENT FORM (CHILDREN), USE THE FOLLOWING SIGNATURE LINE, THE SIGNATURE LINE ABOVE FOR PARTICIPANTS NOT OF AGE, AND DELETE THE FIRST SIGNATURE LINE FOR PARTICIPANTS OF AGE:

I understand what I must do in this study and I want to take part in the study.

Signature of Child/Ward Date



**IRB Approved Conflict of Interest and Financial Disclosure Form
 Monroe County Community College**

To identify any potential financial or other conflicts of interest regarding the proposed research, any investigator to be involved in the research is to complete, sign, and return this form to the Office of Institutional Research at the Monroe County Community College. Research application submitted for Institutional Review Board approval will not be considered without the completion and submission of this form by each investigator. Each investigator must complete and return this form even if the research is unfunded (see the asterisk in the chart below). Please contact the Coordinator of Institutional Research, Assessment and Evaluation, Quri Wygonik, at qwygonik@monroeccc.edu or (734) 384-4723 with questions or further information.

Name	
Title	
Department	
Project Title	
Funding Agency*	
Role in the Project	
Project Dates (start-end)	

*Record "Unfunded" if the research is not funded by an agency or other source.

I have read the "Policy for Financial Disclosure to Avoid Conflict of Interest in Federally Funded Programs" and (check one):

- A. **Do not have any Significant Financial Interests** to report for myself, my spouse, or my dependent children which would reasonably appear to be affected by the project.
- B. **Do have Significant Financial Interest** to report for myself, my spouse, or my dependent children which would reasonably appear to be affected by the project.

If you checked A, simply sign the form and return.

If you checked B, check all that apply, attach requested documentation, sign the form, and return.

_____ 1) Salary or other payments for services (e.g., consulting fees or honoraria) anticipated over the next 12 months when aggregated for the Investigator and the Investigator's spouse and dependent children exceed \$10,000.

Attach information including:

- a) A description of the services to be performed.
- b) Name of the organization for which services will be performed.
- c) Date of service.
- d) Amount of payment expected.

_____ 2) Equity interests (e.g., stocks, stock options or other ownership interests) that when aggregated for the Investigator and the Investigator's spouse and dependent children exceed \$10,000 in value or represent more than a 5% ownership interest in any single entity.

Attach information including:

- a) A description of the type of equity interest.
- b) Name of the entity in which equity interest is held.
- c) Amount of the equity interest or percentage of ownership interest.

_____ 3) Intellectual property rights (e.g., patents, copyrights and royalties).

Attach information including:

- a) A description of the property rights.
- b) Amount of any payment received.

_____ 4) Participation (as an officer, director, partner, trustee, employee, advisory board member, or agent) in an entity funding or providing goods and services to a project.

Attach information including:

- a) A description of the type of participation.
- b) Name of the entity.

_____ 5) Other Significant Financial Interests



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Attach information including:

- a) A description of the interests.
- b) Names of organizations or entities involved.
- c) Amount of payment received or value of the interest.

I have answered fully and to the best of my ability and will update promptly if my circumstances change. This is page _____ of total of _____ pages that I am enclosing.

Signature _____ Date _____

Please return to MCCC Office of Institutional Research