



**Monroe County Community College
Institutional Review Board**

FULL REVIEW PROTOCOL SUMMARY FORM

Research activities involving human subjects that do not meet the criteria for exemption or expedited review by Monroe County Community College's Institutional Review Board must be subject to a full board review process. The principal investigator/project director is authorized to make the first determination of eligibility for exemption or expedited review; 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 federally-approved Categories of Full Board Review are:

1. Projects for which the level of risk is determined by the IRB Chair to be greater than minimal.
2. Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
3. Projects that involve sensitive or protected populations (such as children or cognitively disabled individuals).
4. Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

As with exempt and expedited review activities, research that is under full board review requires investigator(s) to ensure 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 is ineligible for exemption or expedited review and, therefore, subject to full board review may 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

FULL IRB REVIEW 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: _____

Please answer the questions below, attach all supporting documents, and return with this form for the IRB to proceed with full review process. Applications without all required supporting documentation will be returned to the principal investigator.

I. Project Information:

A. Project Activity Status:

- New Project**
- Periodic Review of Continuing Project**
- Revision to Previously Approved Project**

B. This project involves Monroe County Community College students

- Yes** **No**

C. Human Subjects from the following populations will be involved in this study

- Minors** **High School Students**
- Mentally Disabled** **Prisoners**
- Elderly** **None of the above**

D. Total number of subjects to be studied: _____

II. Attach the following supplemental documents with this application:

- 1. Abstract Describing Project and Purpose** (Include a description of all experimental methods to be used and design and program activities; what measures or observations will be taken in the study? If any questionnaires, tests or other instruments are to be used include a brief description and a copy of such instrument.)
- 2. Protocol** (Who will be the research subjects? How will they be solicited or contacted? Include any recruitment letters or other recruitment materials with this document; How much time will be required of each subject? Describe procedures to which humans will be subjected – use additional pages if necessary.)
- 3. Precautions** (What steps will be taken to insure that each subject's participation is voluntary? What, if any, inducements will be offered to the subjects for their participation?)
- 4. Confidentiality of data** (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc.)
- 5. Informed Consent** (Attach a copy of all consent forms to be signed by the subjects and/or any statements to be read to the subject. An IRB-approved copy of this form is found on pages 5-6 of this application.)
- 6. Conflict of Interest and Financial Disclosure Form** (Attach a signed copy of the conflict of interest and financial disclosure form for each investigator involved in the research. An IRB-approved copy of this form is found on pages 7-9 of this 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 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.
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I certify that the protocol and method of obtaining informed consent as approved by the Monroe County Community College Institutional Review Board will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.

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

Signature of IRB Committee Chair:			Date: / /	
IRB Chair: Check 1 box:	<input type="checkbox"/> Approved	<input type="checkbox"/> Approved with Restrictions	<input type="checkbox"/> Tabled	<input type="checkbox"/> Disapproved



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.



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_____ 5) Other Significant Financial Interests

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