MONROE COUNTY COMMUNITY COLLEGE
enriching lives

Monroe County Community College
Institutional Review Board

EXPEDITED REVIEW OF RESEARCH FORM

Human subject research activities involving no more than minimal risk to the subjects may be eligible for expedited review by Monroe County Community College Institutional Review Board Chair. The principal investigator/project director is authorized to make the first determination of eligibility for expedited review; however, the College bears the responsibility for concurring in that determination based on information provided by the principal investigator.

Research activities eligible for expedited review:

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

(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 specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to 45 CFR 46.101(b)(4)).

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) 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. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to 45 CFR 46.101(b)(2) and (b)(3)).

Expedited review may also be used to review minor changes in previously approved research.

Questions about whether a research activity may be appropriate for expedited review can be directed to the Coordinator of Institutional Research, Evaluation and Assessment located in the Office of Institutional Research.

___/___/____ **Monroe County Community College Institutional Review Board** _____

Date Submitted **File Number**

Expedited Review of Research 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: _____

Expedited Review Category (see categories on page 1–check one) 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐

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 4-5 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 6-8 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

- 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.

_____ __/__/__ _____ __/__/__

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

Signature of IRB Committee Chair:			**Date:** __/__/__
IRB Chair: Check 1 box:	☐ **Approved**	☐ **Approved with Conditions**	☐ **Refer to Full Committee Review**

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 REESARCH; 1-2 SENTENCES).** In this study, you (your child/ward) will be asked to **(FILL IN THE DATA COLLECTION PROCEDURES THAT PARTCIPANTS WILL BE EXPECTED TO PARTICPATE 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 PARTCIPANTS 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 PARTICPANTS 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

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