Middlesex Community College
Institutional Review Board

Submit documents electronically to burnsk@middlesex.mass.edu

Date Submitted _____ **File Number** _____

FULL BOARD or EXPEDITED APPLICATION REVIEW FORM

Type of Review Requested: ☐ **FULL BOARD;** **or** ☐ **EXPEDITED**
If unsure, please contact the IRB Chair at X3660 or irb@middlesex.mass.edu

Project Information:

_____
Title of Research Project

Status of Project: ☐ New Project; ☐ Periodic Review of Continuing Project; ☐ Revision to previously approved project

Project Personnel:

_____	_____	_____	_____
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 in months: _____ Projected Starting Date: _____

Other organizations and/or agencies, if any, involved in the study:

_____

Participants covered under another IRB:
If Middlesex Community College is being requested to rely on the IRB of another institution with an approved Federalwide Assurance (FWA), please attach the Authorization Agreement form and related documentation.

☐ N/A

☐ IRB Collaborating Institution Agreement form is attached with appropriate signatures. List other institution and location. _____

For Expedited Review only. The Federally approved categories for Expedited Research found in 45 CFR 46.110 are listed below. Check one of the nine boxes below to identify the appropriate category. Expedited review is for certain types of research that involve no more than minimal risk and meet one of the categories below or for minor changes in approved research. See MCC IRB Charter and Standard Operating Procedures pages 7-9 for full detailed descriptions.

☐ Collection of blood samples by typical methods and within allowable amounts

☐ Noninvasive collection of biological specimens (hair and nail clippings, deciduous teeth, placenta, dental plaque, excretion such as sweat or saliva, etc.)

☐ Study of existing data, documents, records, or specimens or data analysis of previously approved research

☐ Research on individual or group behavior using survey, interview, focus group, etc. (studies of perception, cognition, game theory, or test development) where the PI does not manipulate subjects' behavior and research involves no more stress than in daily life

☐ Collection of data from voice, video digital, or image recordings for research purposes (e.g. investigations of speech defects)

☐ Continuing review of previously approved research with no subject enrolled and no additional risk identified

☐ Research on investigational new drug/device exempt drugs or devices

☐ Research involving materials (data/records/specimens) collected for non research (treatment or diagnosis)

☐ Collection of data from subjects 18 years of age or older using noninvasive procedures (e.g. by MRI, EEG, moderate exercise, etc.)

For both Expedited and Full Board Review

Study Summary
Summarize the proposed research using language understandable to committee members whose primary concerns are nonscientific. **Do not attach full proposals to meet the requirements for this section!** The summary must be inserted here and include (1) a statement of the purpose, study objective(s) and goal(s) background, significance, research design, and methods, (2) a brief description of the procedures(s) involving human subjects; (3) a brief description of any questionnaires, tests or other instruments to be used; how they will be used, and a copy of such instruments.

Selection of Participants
Anticipated number of participants to be enrolled (number of subjects needed to get adequate data set):

_____

Describe how study participants will be identified, recruited, and screened for eligibility.

Will recruitment advertising materials (e.g. flyers, newspaper advertisements, posters) be used?

☐ Yes; ☐ No If yes, please submit these materials to the IRB with this application)

Are the subjects being offered any incentives such as academic credit, monetary compensation, or thing of value, including the chance to participate in a lottery for a prize? ☐ Yes ☐ No

If yes, please justify. _____

Does this project involve Middlesex Community College students? ☐ Yes ☐ No

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

☐ Subjects under 18 years of age; ☐ Non English Speakers; ☐ Prisoners; ☐ None of the above

Check all the relevant activities that will apply to your subjects:

☐ Analyze data previously recorded
☐ Contact by mail, email, or telephone
☐ Meet face-to-face
☐ Interview
☐ Medical Record Review
☐ Surveys (Questionnaires/interviews)
☐ Record physiological measures
☐ Test physiological measures
☐ Record "spontaneous" behavior
☐ Manipulate "subjects" behavior
☐ Manipulate psychological treatment/conditions
☐ Manipulate physiological treatment/conditions
☐ Other, explain: _____

Risk Information

Describe any potential risks or discomfort that could result to human subjects as a result of this research.

_____

How will you try to minimize these risks or discomfort?

_____

Are there alternative methods to acquire the information that could avoid the risks? ☐ Yes ☐ No
If yes, explain:

_____

Could the information be obtained from animals or other laboratory models? ☐ Yes ☐ No
If yes, explain why these alternatives were not chosen:

_____

Confidentiality of data

Will you be recording any private information that identifies the subjects? ☐ Yes ☐ No
If yes, describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc.

_____

Consent
What steps will be taken to assure that each subject's participation is voluntary?

_____

Attach a completed copy of all consent forms to be signed by the subjects and/or any statements to be read to the subjects.

Waiver Requests

Do you intend to apply for any Waivers of the Informed Consent Requirements? ☐ Yes ☐ No
If yes, contact the IRB Chair.

PRINCIPAL INVESTIGATOR ASSURANCE AND SIGNATURE PAGE

Each item must be read and each box must be checked. Then, submit the original by intercampus mail with PI signature.

☐ I agree to personally conduct or supervise the described investigation(s).

☐ I understand that Middlesex Community College students will be recruited by public announcement and not by personal solicitation.

☐ I understand that any medical procedures or treatments of human subjects will be performed by or under the supervision of a person who is licensed or certified to perform that particular procedure.

☐ Once the project has begun, I will communicate any problems connected with the use of human subjects to the IRB Chair.

☐ I agree to maintain adequate and accurate records in accordance with the regulations and to make those records available for inspection in accordance with the regulations. (Records including informed consent documents will be kept on file for a period of three years from the project completion date.)

☐ I (and all associated investigators) have completed the required human subject research training and certificates are on file or have been sent to the MCC IRB (LC312).

☐ I certify that the protocol and method of obtaining informed consent as approved by the Middlesex 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 written review and approval prior to implementation.

☐ I am responsible for submitting the materials for continuing review a minimum of once per year.

☐ I agree to insure that all associates, colleagues, and employees assisting in the conduct of the study(s) are informed about their obligations in meeting the above commitments and confidentiality requirements.

☐ I understand that the research may not begin until this signature page has been received by the IRB and I have received the official notice of approval from the IRB.

Principal Investigator/Project Director Signature		Co-Investigator/Student Signature (if appropriate)	
Printed Name of PI		Printed Name of Co-Investigator	

Signature of IRB Committee Chair:				**Date:** _____
IRB Chair: Check 1 box:	☐ **Approved**	☐ **Approved with Modifications**	☐ **Tabled**	☐ **Disapproved**