MIDDLESEX Community College
BEDFORD • LOWELL

Institutional Review Board
Application for Exempt Status Determination

NOTE: ONLY the IRB is authorized to determine exemption requests. Exemption categories may NOT apply if (a) deception of subjects may be an element of the research; (b) subjects are under the age of eighteen; (c) the subjects may encounter more risk than they may experience in daily life; (id) identifying information is collected; or (e) any vulnerable populations are subjects of the activity.

Research that meets the criteria for exempt status 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.

Submit documents electronically to irb@middlesex.mass.edu
File Number (provided by the IRB):

A. GENERAL INFORMATION

Project Title:	
PI:	Email:
Department:	
Phone:	Alt. Phone:
Co-PI(s):	Co-PI(s) Contact Info:
Date Submitted:	

1. Sponsor Information- Check One
( ) Not funded.
( ) Funded and Type (indicate sponsor):
( ) Government/Federal funding. List agency name:

2. Are any other organizations or agencies involved in the research? ( )NO or ( )YES
If YES, provide below the name, email and phone number for each and describe their involvement:

3**. Projected Start Date** (must be after IRB approval):
Projected Duration of Research (ex., 6 months, 1 year, etc.):

4. Project Personnel and Training Information (Note- training must be updated every 3 years and a copy of the human subjects training certificate must be provided with the application for each member of the research team):

Name: Date of Training Completion:
Name: Date of Training Completion:
Name: Date of Training Completion:
Name: Date of Training Completion:
Name: Date of Training Completion:
Name: Date of Training Completion:

5. Conflict of Interest Disclosure:

a. Do you or any family members have a financial interest in this research activity (such as an equity position or outside consulting arrangement with the company whose drug, procedure, device or product is used or tested in this study)? ( )Yes ( ) No
If **yes**, explain the nature of the relationship and the conflict(s):

b. Do other faculty or staff involved with this research have a financial interest in this research activity? ( )Yes ( ) No
If **yes**, indicate the nature of the relationship and the conflict(s):

c. To your knowledge, does the University have a financial interest in the company whose drug, procedure, device or product is used or tested in this study (such as patent rights, equity)?
( )Yes ( )No
If **yes**, indicate the nature of the relationship and the conflict(s):

EXEMPT CATEGORY CLAIMED under 45 CFR46.101. Many of these are NEW! Check all that apply:

( ) 1. Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

( ) 2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met (check those that apply):

__ (i.) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

__ (ii.) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

__ (iii.) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

( ) 3. Research involving benign behavioral interventions* in conjunction with the collection of information form an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of (i.), (ii), (iii) above is met.

* Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. They exclude medical test, procedures, and devices (e.g., EEG recording). Research participants must be prospectively informed if they will be unaware of or misled regarding the nature or purposes of the research.

__ (i.)
__ (ii.)
__ (iii.)

( ) 4. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

__ (i.) The identifiable private information or identifiable biospecimens are publicly available

__ (ii.) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

__ (iii.) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of 'health care operations' or 'research' as those terms are defined at 45 CFR 164.501 or for 'public health activities and purposes' as described under 45 CFR 164.512(b).

__ (iv.) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995. 44 U.S.C. 3501 et seq.

( ) **5**. Research and demonstration projects that are conducted or supported by a Federal department or agency*, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as se4ctions 1115 and 115A of the Social Security Act, as amended.

*These projects must be publicly posted by the Federal Dept. or agency BEFORE the research starts.

( ) **6**. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7***. Storage or maintenance for secondary research for which broad consent is required. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and Makes the determinations required by 45 CFR 46.111(a)(8).

*** NOT AVAILABLE TO USE AT MCC AT THIS TIME. Refers to material for which initial collection was not research-based, requires infrastructure to track consent, & limits subsequent use of waiver of informed consent.

( ) 8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with the regulations.
(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with the regulations.
(iii) An IRB conducts a limited IRB review and determines that the research to be conducted is within the scope of the broad consent
(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

RESEARCH SUMMARY:

1. **Describe the research purpose and objectives**.

2. **Describe the methods used and types of data to be collected using each method** (include types of demographic information to be collected so the IRB can verify the data will be anonymous):

3. **Recruitment information** (who you intend to use for the research such as students, faculty, etc., the number you hope to recruit, and how you intend to recruit them):

4. **Will any identifying information be collected?** ( )Yes or ( )No
   If yes, explain (An expedited or full review application may need to be submitted):

5. **Explain how data will be protected and disposed of and who will have access to the data.**

6. **Will all activities be conducted at MCC?** ( )Yes or ( )No.
   If no, describe where and how recruitment will occur:

7. **Describe how participants will provide consent**.

8. **Does the research involve the use of existing or publicly available data?**
   ( )Yes or ( )No.
   If yes, please describe source of data and whether it includes any identifiers.

9. **Describe any risk to participants and how you intend to minimize risk to them:**

10. Check all supporting materials submitted with the application:

( ) Questionnaires, surveys
( ) Standard Research Tools (published testing materials, etc.)
( ) Recruitment Materials
( ) Consent Documents
( ) Other, list:

PRINCIPAL INVESTIGATOR ASSURANCE AND SIGNATURE

( ) I understand that, as the PI, I am ultimately responsibility for the protection of the rights and welfare of human participants and the ethical conduct of research under this protocol. I agree to conduct the study in accordance with the approved protocol and ensure that all personnel involved in the research will do the same.

( ) I agree to follow the Middlesex Community College IRB Policies and Procedures for conducting human subject research. .

( ) I certify that the information provided in this application is complete and correct, and believe that my project qualifies as Exempt from the Federal Regulations.

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

( ) I agree to maintain copies of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human participants for three years following termination of the project,

( ) I understand all investigators associated with this research must renew their human participant research training every 3 years.

( ) I understand it is my responsibility to resubmit an application to the IRB if I need to make any changes that alter the exempt status determination and approval.

( ) I understand this project will be closed by the IRB one year from the date of approval and records will be retained in the IRB office for 3 years after that date.

Submit the entire application and supporting materials to irb@middlesex.mass.edu

SIGNATURE SECTION (Students are not eligible to sign this page.)

Printed name of PI: ( ) Check here if submitted electronically from your email account	Date:
OR Sign below: and fax or scan and email to IRB:	