MIDDLESEX Community College
BEDFORD • LOWELL

Institutional Review Board
Application for Expedited or Full Board Review

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:

B. CATEGORY CLAIMED (45 CFR 46.110)
( ) Request for Full IRB review (Research with prisoners REQUIRES Full Review.)

OR

( ) Request for Expedited Review-Research reviewed under this category must involve no more than minimal risk and be described by one or more of the allowed categories. Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 Code of Federal Regulations (CFR) 46.102(i)]. Check those that apply:

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

( ) a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

( ) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

( ) (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

( ) (b) From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

( ) **4**. Collection of data through noninvasive procedures (not involving anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

( ) **5**. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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 participants. 45 CFR 46.101(b)(4).

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

( ) **7**. Research on group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identify, 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 participants. 45 CFR 46.101(b)(2) and (b)(3).]

( ) **8**. Continuing review of a previously approved protocol by a convened IRB. (Note: (If this applies, submit an Annual/Continuing Review form instead of this application.)

( ) **9**. Continuing review of research not conducted under an investigational new drug application or investigational drug exemption where categories 2 through 8 do not apply, but the IRB has determined at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. (Note: If this applies, submit an Annual/Continuing Review form instead of this application.)

C. OTHER REQUIRED INFORMATION

1. 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):

2. Are you working with a researcher from an institution with their own IRB? ( ) Yes ( ) No
If yes, please provide the name and contact information for each:
Do you intend to file an agreement to assign oversight to one IRB? ( ) Yes ( ) No
If yes, contact IRB@middlesex.mass.edu for assistance.

3. Will the research be conducted with collaborators outside of MCC? ( )Yes ( )No
a. Will collaborators be involved in interventions or interactions with the participants?
( ) Yes ( ) No If yes, please list names under personnel and include training date(s).

b. If yes, describe the collaborator's role in the research (include details as to whether they are serving as a study site, providing support, or engaged in the research activity by intervening or interacting with the participants):

c. Provide letters of support from each collaborator.

D. RESEARCH ACTIVITIES

1. Check all that will apply to your participants for this research:

( ) Analyze data previously recorded
( ) Contact by mail, email, or telephone
( ) In person interview
( ) Internet survey
( ) Medical Record Review
( ) Photographs
( ) Incentives
( ) Transcription Services(interview, focus group)
( ) Test or record physiological measures
( ) Observe or record spontaneous behavior
( ) Manipulate participants
( ) Collecting tissues or fluids
( ) Questionnaires/survey
( ) Audiotapes/Videotapes/Recordings
( ) Using control group and study group
( ) Other, explain:

2. Do you intend to recruit from any of the following special populations? ( )Yes ( )No
If yes, **c**heck the type of participants and be aware that Full IRB Review may be required if greater than minimal risk:

( ) Minors under the age of 18
( ) Prisoners (Full review required)
( ) Economically/Educationally Disadvantaged
( )Other:
( )Pregnant Women
( ) Non-English Speaking Participants
( ) Cognitively Impaired.

3. Categorize the risk of the research:

( )No more than minimal risk.
( )Greater than minimal risk.

E. RESEARCH SUMMARY (Complete all sections on this form. Do not attach full proposals!

Summarize the proposed research using language understandable to committee members whose primary concerns are nonscientific.

1. Describe the research purpose and objectives:

2. Describe the research methods:

3. Describe the participant population:

4. Recruitment Information
   a. Describe who you intend to recruit. Check all that apply:
   ( ) MCC students ( ) MCC Faculty and Staff ( )Other:
   b. Describe how you will recruit the participants:
   c. Indicate the anticipated number of participants (range of Min. to Max is fine):
   d. Indicate the type of recruitment materials used (and submit to the IRB):
   ( )flyers ( )newspaper advertisements ( ) posters ( ) email) ( )Other:
   e. Are enough participants being recruited to achieve the objectives of the research (e.g., to provide for statistical analysis or to achieve saturation of a topic)?
   Explain:
5. Incentive Information:: Will you be providing any incentives to the participants?
   ( )Yes ( )No (go to question 7)
   a. If yes, check the type: ( ) Cash ( ) Gift Card, to where:
   ( ) Academic Credit ( ) Lottery Chance

( ) Other, list:

b. Specify the amount provided:

c. Provide justification for why the incentive is necessary:

d. Indicate when the incentive will be issued and how you will handle payment if the participant withdraws part way through the study:

7. Estimate the anticipated Start Date (This must be after IRB approval):
Estimate the anticipated End Date:

7. Does research involve the use of publicly available or currently existing data?
( ) Yes ( ) No

a. If yes, list source of the data or specimens:

b. Indicate whether the data is currently de-identified or how it will be de-identified:

8. Check all supporting materials submitted with the application:
( ) Questionnaires, surveys, interview/focus group questions, etc.
( ) Training Certificates
( ) Recruitment Materials
( ) Consent Documents
( ) Letters of Support
( ) Other, list:

F. INFORMATION FOR RESEARCH WITH SPECIAL POPULATIONS (Check all that apply)

( ) For research with participants under the age of 18, complete F.1.
( ) For research with participants with English as a SECOND language, complete F.2.
( ) For research with all other protected categories, complete F.3.
( ) If no special categories apply to your research, skip to section G.

1. Participants under 18 years of age.

a. Informed consent will be obtained from at least one parent or guardian. ( )Yes ( ) No

b. Describe the process for how parental informed consent will be obtained:

c. Will you also obtain assent from the participants? ( )Yes ( ) No
If yes, describe the process to obtain assent from the participants:

d. Justify why you must use this group of participants for the research:

2. Participants with English as a Second Language:

a. List the languages that materials will be translated to:

b. List the titles of all materials that will be translated (Do not translate materials until you have approval for the English version.):

c. I will submit an IRB Amendment Form with the translated and back translated materials in addition to a Translation Certification Form for each language. ( )Yes ( ) No

3. Other Protected Categories of Participants

a. Are any participants members of other protected populations? ( )Yes ( ) No

b. Describe the protected population category:

c. Justify why you must use this group of participants for the research:

d. Describe how this group of participants will be protected to meet all regulatory requirements:

e. Additional information:

G. PRIVACY AND CONFIDENTIALITY INFORMATION

1. Will you be collecting any information that identifies the participants? ( ) Yes ( ) No

2. If yes, indicate the type of identifying information to be collected:

3. Describe how this information will be protected and kept confidential:

4. Describe where the information will be stored:

H. RISK INFORMATION

1. What is your assessment of the level of risk? Federal guidelines state that risk "is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (Greater than minimal risk requires Full Review)

( ) No more than minimal risk.

( ) Minor increase (i.e., no significant threat to the person's health or well-being) over minimal risk.

( ) Greater than minimal risk
- ( ) **a.** Potential for direct benefit to participant.
- ( ) **b.** No potential for direct benefit to participants.

2. Describe any potential risks or discomfort that could result to human subjects as a result of this research and why you believe it to be of minimal risk:

3. Indicate what you will do to minimize these risks to participants:

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

I. BENEFITS INFORMATION (Compensation is not a benefit.)

1. Describe the direct or potential benefit of this research (Typically, there is no benefit to participants):

2. Explain the risk vs. benefit and how the risk is justified by the benefit for the participants in this study. (If using both a study group and a control group, more than one level of risk may be involved.):

3. Describe the potential benefits of the research to society as a whole. Include only those benefits that may result from the research (as distinguished from benefits of therapies participants would receive even if not participating in the research):

J. INFORMED CONSENT INFORMATION (Participation MUST be voluntary)

1. Are you submitting an informed consent document? ( )Yes ( )No

Note: After July 19, 2018, consent forms longer than one page must have a summary statement at the beginning to describe key activities, risks, and benefits.

a. List the title of each consent form submitted (ex. 'Focus Group Consent', 'Interview Consent):

b. Check one:
( ) Consent will be done in a group setting
( ) Consent will be done individually
( ) Consent will be embedded in a survey document or questionnaire.

c. Describe who will be obtaining consent for this study:

d. Where will this process and discussion take place:

e. Will any audio recordings, video recordings, or photographs be used (make certain the consent documents indicate recordings or photographs will be collected?
( )Yes ( )No If yes, complete the following:

i. Describe the purpose for collecting these materials:

ii. Indicate the date the materials will be destroyed:

iii. Will any of these materials be used for publication? ( )Yes ( ) No
If yes, also submit an IRB Video/Photo Release Form for approval.

iv. Is this a deception study? ( )Yes ( )No
If yes, explain how the participants will be debriefed at the end of their participation (For example, provide participants with a debriefing after a deception studies).

2. Are you applying for any type of Waiver or Alteration to the Informed Consent Requirement?
( )Yes ( ) No If yes, complete this section.

a. ( )Request to Waive Consent Entirely
i. Explain why this research involves no more than minimal risk to the participants or their privacy and why the waiver will not adversely affect the rights and welfare of the participants:

b. ( )Request to Waive Documentation of Consent (Consent process is completed with an IRB approved form, but no signatures are collected.) Check the option below and justify the waiver request that best meets the purpose.

( )The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality or discovery that they had participated in such research. Each participant will be offered a copy of the informed consent form but may refuse it. Explain:

OR

( )The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Explain:

K. PRINCIPAL INVESTIGATOR ASSURANCE AND SIGNATURE PAGE

Check each box to verify you understand and agree to the following

( ) I agree to follow the Middlesex Community College IRB Policies and Procedures

( ) I agree to conduct the study(s) in accordance with the approved protocol and will not modify or revise a protocol until an IRB Amendment Form is submitted and approval is received from the IRB and/or sponsor, except when necessary to protect the safety, rights, or welfare of participants.

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

( ) I agree to inform all research participants of the investigational nature of this project as required in 21CFR56 and 45CFR46.

( ) I will ensure that the requirements for obtaining informed consent are met per the regulations found at 21CFR56 and 45 and 45CFR46.

( ) I agree to immediately report to the Office of Institutional Compliance(OIC) any unanticipated events or adverse experiences that occur during the course of this research. OIC will assist in notifying the sponsor, FDA, OHRP or any other agencies as required.

( ) I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(s) are informed about their obligations to follow UML IRB Policies and Procedures and all confidentiality requirements.

( ) I agree to maintain adequate and accurate records, including copies of all consent documents, and to make those records available for inspection in accordance with the regulations. (Records must be kept on file 3 years from the project completion date.)

( ) I understand that UMass Lowell students must be recruited by public announcement and not by personal solicitation.

( ) I understand I must submit an IRB Annual/Continuing Review Form at a minimum of once per year, and an IRB Final Report Form at the conclusion of the study.

( ) I understand that any medical procedures or treatments of human participants will be performed by or under the supervision of a person who is licensed or certified to perform that particular procedure.
( )Check here if N/A.

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

( ) I understand that the research may not begin until I have received the official notice of approval from the IRB.

The signature page may be submitted electronically with this form by checking the box below and sending from your email account, send this page as a scanned document with your signature,, or sent by intercampus mail to the IRB@middlesex.mass.edu

ASSURANCE SECTION (Students are not eligible to submit 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:	

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