

Institutional Review Board

New Protocol Application

PROTOCOL:

Please include a narrative document that addresses the following:

1. Purpose of the Study
 - Specific Aims and Hypothesis to be Tested
2. Study Procedures
 - Describe the Research to be conducted. Include all interventions, and data collection procedures.
3. Participant Selection
 - Recruitment
 - Inclusion/Exclusion Criteria
 - Study Withdrawal / Discontinuation
 - Compensation
 - Costs to the Subject
4. Risks
 - Detail the Risks to the Subject of any
5. Benefits
 - Detail the Benefits to the Subject/Participant. Compensation should not be listed as a benefit in participating in the research project.
6. Data Analysis and Monitoring
 - Describe the Statistical/Analytical/Qualitative Methods to be Used
 - List the Process of Reporting of Anticipated Adverse and Serious Adverse Events.
7. Data Storage and Confidentiality
 - Describe how Research Data will be encrypted for storage and transfer to ensure Confidentiality
8. Informed Consent Process
 - Detail the informed consent process

APPLICATION FOR FULL COMMITTEE REVIEW

PART A: PROTOCOL INFORMATION

1. Please check one:
2. Date: _____
3. Protocol Title: _____
4. Funding Source: _____
5. MassBay Principal Investigator (PI): General Information
Please complete this section for the person responsible for this research at MassBay.
Complete question 6 for any other PI at another institution.

PI's Name		
PI's Department and Division		
Phone number on campus		
Alternative/cell phone number		
Email address		
Office Mailing Address		

6. Complete this section **only if there is PI named at a partner institution**.
All principal investigators that are not a MassBay employee must designate a responsible MassBay faculty member below. The MassBay faculty member should be added to the IRB Application as a Co-Investigator.

PI's Name		
PI's Institution		
PI's Department and Division		
Phone#/Extension		
Cell phone #/		
Email address		
Office Mailing Address		

7. *Research Staff and Personnel*

List all personnel involved in study; PI, Co-PI, Research Assistants, etc., who are recruiting, obtaining consent, collecting data, providing data analysis, etc. Personnel listed here must have a Human Subject Training Certificate on file in the IRB office.

Name	Division or Affiliation	Project Role	Human Subjects Training Completed	
			☐ Yes	☐ No
			☐ Yes	☐ No
			☐ Yes	☐ No
			☐ Yes	☐ No
			☐ Yes	☐ No

8. Has this proposal been submitted to another Institutional Review Board (IRB)?
☐ No ☐ Yes If yes, list the name of institution(s): _____

If approval granted, attach a copy of the approval notice.

PART B: SPONSOR INFORMATION

Complete this section **only if the research is funded by MassBay or an external institution.**

- Title of Grant Application: _____
- Name of Funding Source: _____
☐ Federal (*) ☐ State ☐ Foundation
☐ Industry ☐ MassBay Internal
☐ Other _____
- If more than one is checked (from above), please describe collaboration.

- Please check as appropriate. MassBay Community College is:
☐ The primary institution
☐ Receiving a subcontract and the primary institution is: _____
☐ Other, please specify: _____
- Please provide a contact name at the funding source: _____
☐ Business ☐ Scientific Phone number: _____
- Type of Study:
☐ Life Science/Biotechnology/Genetic
☐ Program Project Grant (Several Protocols under one Grant)

- ☐ Survey / Questionnaire / Interview / Focus Groups
- ☐ Observational
- ☐ Case Study
- ☐ Longitudinal Study
- ☐ Course Activity
- ☐ Other: Specify

7. Performance Site: Location where the study/research procedures will be conducted:

Other MassBay Location(s):

Off Premises: (i.e. schools, other hospitals, home, private practices, etc.)

8. Proposed Population Included: Check all that apply

- ☐ Fetuses in utero/non-viable fetuses/abortuses
- ☐ Newborns / Infants
- ☐ Children (between 2-12 years) Specify ages
- ☐ Adolescents (between 13-17 years) Specify ages
- ☐ Adults (18 years & Over) Specify age range
- ☐ Males
- ☐ Females
- ☐ Pregnant Women
- ☐ Mentally Handicapped/Challenged Specify ages:
- ☐ Prisoners
- ☐ Employees / Staff (you cannot recruit employees/staff under your direct supervision)
- ☐ Students (specify where from)

9. Project Timeline: *(The start date cannot precede the IRB Approval Date)*

Anticipated Start Date of Project: Anticipated End Date:

PART C: RECRUITMENT METHODS

Please note: you must submit written and/or oral interview scripts, questionnaires, surveys, tests, etc., with your application. The material cannot be used until the IRB approves it (the IRB will stamp the material "approved") prior to implementation.

1. Check if the following will be used in Data Collection:

☐ Audio Recording ☐ Video Recording ☐ Other methods

2. Specify how and where the data will be stored, in a manner that the subject's confidentiality is maintained.

3. Specify for how long, the data will be retained after the completion of the study.
Please Note: Legally, data must be retained three years from date of completion of project, although MassBay specifies five years.

PART D: ADVERSE / SERIOUS ADVERSE EVENTS

Check the boxes to verify that this information has been read and to certify that you will comply with the necessary requirements for reporting Adverse (AE) / Serious Adverse Events (SAE).

- ☐ I will report SAE(s) to the IRB within 10 days of the occurrence of the event.
☐ I will report AE(s) in the annual continuing review application to the IRB.

PART E: GENETIC ANALYSIS

1. Does this study involve genetic analysis?
☐ No ☐ Yes If no, skip to PART F
2. What genetic material will be studied?
☐ Blood ☐ Tissue ☐ DNA
☐ Other:
3. Please specify whether:
☐ Stored samples already exist
☐ Stored samples already exist from a previously approved study
☐ Samples will be collected specifically for this study
☐ Samples collected are part of a routine clinical procedure
☐ Other:
4. If stored samples are to be used was informed consent obtained?
☐ Yes ☐ No

☐ Was the consent prospective to collection of the sample; or
☐ Was the consent retrospective to collection of the sample?
5. Will identifiers be maintained?
☐ No ☐ Yes If Yes, please specify:
4. When will samples/data be discarded?

Note: All of the above must be disclosed in the Informed Consent Form.

PART F: AGREEMENT OF COMPLIANCE AND SIGNATURES

If the Institutional Review Board approves this project, I agree to (please check all boxes):

- ☐ Execute the research plan as described in this application.
- ☐ Report to the IRB any changes in the approved research plan.
- ☐ Report to the IRB within 7 business days any unexpected serious adverse events that arise with human subjects.
- ☐ Report progress annually (Continuing Review) unless the IRB requires the report earlier.
- ☐ Submit a three-year rewrite if the research is still active.
- ☐ Report to the IRB any conflict of interest that already exists or arises.
- ☐ Notify the IRB when the study terminates.
- ☐ Maintain records of research, including signed informed consent documents, for a minimum of five (5) years beyond the termination of the study. However, in some instances you will need to save information indefinitely. Please note: funding agencies/sponsors of a project may specify a longer time for documents to be saved.
- ☐ Comply with all Federal, State, and Institutional regulations governing this research.
- ☐ Provide to the IRB proof of Human Subject Certification.
- ☐ Cooperate with the IRB on all issues pertaining to this research.

Signature of Principal Investigator ¹

Date

The IRB will forward, along with the approval letter, a copy of this signed page. The PI is responsible for maintaining a complete copy of the fully executed protocol on file. The IRB has the right to audit the research project at any time.

For IRB use only:

Approved: _____ **Requires Modifications:** _____

Reviewer's Signature: _____ **Date:** _____

¹ The PI is responsible for ensuring that all personnel (those directly involved in the research, including CO-PIs, Research Assistants, Data Analysts, etc.) mentioned in this protocol are certified in human subject research. Please submit the certificate when you submit this application. If you have need Human Subject certification, please click on the following link for online training and certification: <http://phrp.nihtraining.com/users/login.php>