



**Institutional Review Board
Continuing Review Form**

Instructions

- This form should be submitted 30 days prior to the anniversary of the last approval date for projects exceeding one year in duration. If your project is complete you must submit a final report.
- This form is for projects that occurred over the past year with only minor or no changes to an approved protocol. Changes that are more than minor require filing a new Full or Expedited Application Review Form.
- Training certifications must be current before approval is renewed.
- Exempt status research projects do not require Continuing Review.
- Send the completed form to the IRB Chair at irb@middlesex.mass.edu

Project information

Date

File No.

Principal Investigator Name and Department

Principal Investigator Email and Phone

Title of Research Project

Funding sources

Other organizations or agencies, if any, involved in the study

Initial MCC IRB Approval Date

Last Annual Review Date

Co-investigator and/or study staff information

Include: Name, role, email, training provider, training completion date

Project status (check all that apply)

Project is proceeding on schedule

No subjects are enrolled to date

Subject recruitment is ongoing with a projected end date of recruitment of:

Subject recruitment is completed as of (date)

Subject recruitment needs to be expanded. Request increase from original approval of _____ to _____

Intervention and data collection completed as of (date)

Data analysis is ongoing with a projected end date of

Data analysis is complete as of (date)

Other

Project summary

1. Study abstract

2. Summary of activities during past approval period

3. Were any manuscripts, publications, or conference presentations related to this study completed during the past approval period? Yes No

If yes, list here:

Research procedures

Protocol has not been altered since original approval or last continuing review.

Protocol has been modified and a summary of the changes are provided. Provide a brief description of the research procedures, incorporating elements of all approved amendments to date for the research.

Subject numbers (Enter N/A for questions that are not applicable)

Number of subjects proposed and approved by the IRB:

Number of subjects screened:

Number of subjects enrolled/consented to participate:

Number of subjects who voluntarily withdrew:

Number of subjects excluded by the PI: Reason for exclusion:

Subject safety (check at least one)

Not applicable – there is nothing to report

Describe any problems encountered that involved risk or harm to subjects or others since last annual review:

Describe any unexpected benefits to subjects or others since the last annual review:

Are you aware of new information from other sources that affect risks/benefits from participating in this study? Yes No

If yes, please explain and/or provide copies of literature that provides new information on this study's risk/benefit ratio.

Amendments

None requested at this time.

Minor changes requested (e.g., personnel changes, elimination of a tool, etc.). If checked, please provide a summary of the changes.

Study materials

Informed consent forms (check all that apply)

If informed consent forms were used, are they on file and available upon request for the IRB to review?

Yes No

If no, please explain.

Have any changes been made or need to be made to the informed consent form? Yes No

If yes, what changes have been made?

Please submit any project materials that have changed since initial review. This may include 1) recruitment materials such as letters, brochures or flyers that have been updated; 2) survey or interview tools and other documents.

PI Assurances

I certify the accuracy of the information provided and I agree to abide by Middlesex Community College policies and procedures governing research with human subjects.

This form has been submitted electronically from my email account.