MIDDLESEX Community College
BEDFORD • LOWELL

IRB QUICK START GUIDE FOR PRINCIPAL INVESTIGATORS

MIDDLESEX COMMUNITY COLLEGE IRB

QUICK START GUIDE FOR PRINCIPAL INVESTIGATORS

The Middlesex Community College (MCC) Institutional Review Board (IRB) reviews research protocols involving human subjects to evaluate and identify risks to those subjects. Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (intended for publication or public dissemination). MCC and the Principal Investigators (PI) are responsible for ensuring that high ethical standards are maintained for all research involving human subjects. Individuals seeking to conduct human subjects research may not solicit subject participation or begin data collection until they have obtained clearance by the Middlesex Community College Institutional Review Board.

Principal Investigators should review the MCC IRB Policies and Procedures before submitting an application. This Quick Start Guide is intended as a reference for PIs and does not substitute the requirements outlined in the MCC IRB Policies and Procedures.

- Determine if your project is considered human subjects research. Consult the OHRP Decision Charts in the MCC IRB Policies and Procedures and/or consult with the IRB Chair or a member of the IRB to determine if your project is considered research under the federal guidelines.

- If your project is considered human subjects research, consult with the IRB Chair to determine the level of review needed.

- Visit the IRB website (http://www.middlesex.mass.edu/irb) for forms, MCC IRB Policies and Procedures, and meeting dates and Frequently Asked Questions

- Complete the online human subjects protections training. The link to the training can be found on the IRB website. Include a copy of the training certificate with your IRB application.

- Review the sample informed consent forms and the Elements of Informed Consent in the MCC IRB Policies and Procedures. The IRB Chair and members of the IRB are available to assist you in the development of informed consent documents.

- If you have questions, share a draft of your application with the IRB Chair prior to submission.

- Submit your application electronically to the IRB Chair at irb@middlesex.mass.edu.

ELEMENTS OF INFORMED CONSENT

Unless otherwise authorized by the IRB, researchers are responsible to obtain informed consent of participants. This is to ensure that only those human subjects who have consented to participate are involved in the research. It is recommended that research be limited to individuals who are 18 years or older.

The informed consent must include the following (sequential order recommended) and in language that the participants can understand:

a) Study purpose and statement that the study involves research

b) Description of procedures, including duration and types of activities

c) Statement of any risks and benefits

d) Statement of data confidentiality

e) Statement that participation is voluntary and a person may withdraw from the study at any time without penalty or consequences

f) Description of incentives, if any

g) Contact information of the researcher, faculty advisor (if appropriate) & MCC IRB

h) Verification that participant is 18 years of age or older

i) Date and signature line for the participant or legally authorized representative

The informed consent document must be written in language that is understandable without using jargon or technical language. Writing it at a sixth- to eighth-grade reading level is suggested. The language should be written in the *second* person. The final Statement(s) of Consent, however, should be written in the *first* person. The degree of detail, and the length of the consent form, should reflect the level of risk that the project entails for the subject. If a study involves minors or participants with impaired decision-making ability, consent must be provided by the legally authorized representative and assent of the participants in addition to informed consent.

Separate forms may be required for different subject groups (e.g., parents, minors, non-English speakers), different types of activities and different kinds of information (photographs, audiotapes, videotapes). The signature of a participant or the participant's representative who may provide legally effective informed consent is required for signed informed consent.

In some cases requests for waivers for informed consent, or documentation of consent, may be considered depending upon the research protocol.

SAMPLE INFORMED CONSENT FORMS

Sample statement for exempt survey research conducted online, without identifiers, and not requiring documentation of informed consent

This online survey is part of a research study being conducted at Middlesex Community College in Bedford and Lowell, MA. The survey in its entirety should take less than 15 minutes to complete.

The purpose of this study is threefold: 1) to investigate xxx; 2) to develop an understanding of xxx and 3) to identify which services may contribute to xxx.

While it is generally agreed that xx services result in xx, the current economic climate, coupled with increasing mandates for student success, requires community colleges to make deliberate and considered choices about what resources can be directed toward student services. The results of this survey will provide important information about xxx.

Participation in this survey is anonymous. Your answers will go to a secure location without your name or any identifying information about you. Your responses cannot be linked to you, your specific school and results will only be reported in aggregate.

Completing the online survey will indicate that you've consented to participate. If you choose not to participate in this study simply close the survey browser window. You are free to exit out of the survey at any time you choose, and you should feel free not to respond to any questions with which you are uncomfortable.

Thank you very much for your consideration. If you have any questions you may contact the researcher at xxx or the Middlesex Community College IRB Chair, Kim Burns, at irb@middlesex.mass.edu or 781-280-3660.

Sample informed consent form for face-to-face interviews

Consent form for: *Integrating Faculty to Enhance Student Success*

Introduction and Contact Information:

You are being asked to participate in a research project that is exploring strategies for integrating faculty who teach developmental level courses. The researcher is xxx, currently a fellow in the Community College Leadership Academy. Please read this form and feel free to ask questions. If you have further questions later, xx will discuss them with you. You can reach xx at 781-280-xx or xx@middlesex.mass.edu.

Description of the Project:

The purpose of the study is to ascertain current level of integration and support of faculty teaching developmental courses. A literature review of best practices will be completed, along with a survey of adjuncts currently teaching developmental courses at Middlesex Community College as well as evaluation of data related to faculty and interviews with eight MCC staff who work directly with adjunct faculty teaching these courses.

The one-on-one interviews will be conducted by xxx, and will take approximately 30 minutes to complete. During the interview, you will be asked:

- what are the current practices for providing information, support and supervision for adjunct faculty with whom you work
- how satisfied you are with these current practices and why
- what you feel might further support adjunct faculty

The interviews will not be recorded. xx will take notes; you may ask to review xx notes and interpretations of your interview for accuracy.

Risks and Discomforts:

This research is of minimal risk. You may discuss any distress or other issues related to your participation with the researcher. Your name will not be used in any written reports of this study. While this study does not directly benefit participants, your participation may help other community college faculty in the future.

Confidentiality:

Xx will not ask you for any personal information that is not directly associated with the purpose of this study. The information gathered for this project will not be published or presented in a way that would lead to your identity. Only xx xx will have access to the notes taken during the interview, and these notes will be destroyed by July 1, 2010.

Voluntary Participation:

Your participation in this study is entirely voluntary. If you decide to take part in this study, you may terminate participation at any time without consequence. You may decline to answer any of the interview questions without consequence. If you wish to terminate participation, please contact xxx.

Rights:
You have the right to ask questions about this research before you sign this form and at any time during the study. You can reach the researcher xx at 781-280-xx or xxx@middlesex.mass.edu. If you have any questions or concerns about your rights as a research participant, please contact the Middlesex Community College Institutional Review Board (IRB) which oversees research involving human subjects. The IRB Chair, Kim Burns may be reached at 781-280-3660 or irb@middlesex.mass.edu.

Signatures:
I HAVE READ THE CONSENT FORM. MY QUESTIONS HAVE BEEN ANSWERED. MY SIGNATURE ON THIS FORM MEANS THAT I CONSENT TO PARTICIPATE IN THIS STUDY. I ALSO CERTIFY THAT I AM 18 YEARS OF AGE OR OLDER.

_____ _____
Signature of participant Date

_____
Printed name of participant

_____ _____
Signature of researcher Date

_____
Printed name of researcher