

### Institutional Review Board (IRB) Application for the Use of Human Subjects in Research

The IRB reviews **all research** involving **human subjects.** The Code of Federal Regulations (45 CFR 46.102) defines *research* as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. *Human subject* means a living individual about whom an investigator (whether a professional or student), in the process of conducting research, intends to either: (i) obtain information or biospecimens through intervention or interaction with the individual, and subsequently use, study, and/or analyze the information or biospecimens; or (ii) generate or obtain, use, study, and/or analyze identifiable private information or identifiable biospecimens. [For more information, see <a href="https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46.1">https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46.]</a>

**Instructions:** Submit your full IRB proposal package, including this completed form and required supporting documents, in a single email to <u>mcc\_ir@mcc.edu</u>. Submitting pieces of a proposal package in multiple emails may delay the review process.

Principal Investigator (PI):	CITI Cert. #:
Name of Institution:	CITI Exp. Date:
Email Address:	Phone:
Research purpose (dissertation, thesis, course number, etc.):	

Name, Contact Information, and Affiliation of all Co-PIs or assisting researchers:

#### **Status of Principal Investigator**

- □ MCC Student
- External Student
- Instructor or Supervisor Name:

If you are an MCC Student or Employee

□ MCC Faculty/Instructor

Instructor or Supervisor Email:

- $\Box$  MCC Staff
- □ Other:

Instructor or Supervisor Phone:

## Please complete the following sections as fully as possible. Date:

Note: Attach additional pages or submit the entire application as a separate PDF/DOCX file.

#### **Title of Study**

Anticipated Start/End Date (maximum approval is 12 months; new application required to renew)

Describe the research procedures. Include research design elements and major hypotheses.

To submit materials, or if you have any questions about this process or form, contact IRDS at mcc\_ir@mcc.edu.



**Is this study part of a larger study and/or have you received IRB approval from another institution? If yes, briefly describe the larger study and list all other institutions involved.** Please attach any relevant IRB approvals to this application.

# Describe the human subjects who will be recruited to participate in the study, including the selection or sampling criteria you will use.

Please attach examples of any recruitment materials, e.g., invitation letters, email messages, fliers, etc.

**Describe how your study will gain informed consent from participants.** Please attach a blank copy of the informed consent agreement that participants will be asked to sign.

Describe how you will ensure confidentiality of responses. Discuss any data coding and/or file management systems that you intend to use and whether these systems are cloud-based.

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<b>Describe how</b>	you will ensure	data security	y as data are	collected.	stored. a	and analyzed.
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Describe any potential benefits or harms to the research participants.

To what extent does your study protocol involve the intentional omission of key information or research in which a participant is purposely led to have false beliefs or assumptions?

Describe how you will disseminate the results and findings of your study to MCC. Include any relevant information about your plans to publish and/or present on these findings.

**Required Attachments** (provide the following information in attached PDF files):

- 1. Copy of letters, fliers, advertisements, emails, etc. used to solicit or recruit potential participants
- 2. Copy of all interview protocols, surveys, questionnaires, assessments, and/or pre-/post-tests
- 3. Copy of sample Informed Consent Agreement (blank)
- 4. Any additional information relevant to this study, including external IRB materials/approval(s)
- 5. Curriculum vitae/résumé and CITI Human Subjects Training Certification for each PI/Co-PI
- 6. Fully signed attestation (see next page) for each PI/Co-PI and any assisting researcher

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## **Attestation Form**

Instructions: Each researcher (PI/Co-PI) must initial all statements and sign the attestation at the bottom prior to submission.

Name:	Affiliation:				
	As the Principal Investigator, I am solely responsible for my proposed data collection. The MCC Institutional Research and Decision Support (IRDS) office may not have the resources available to provide me with requested data or administrate survey(s) on my behalf.				
	I will not begin any research involving participants who are MCC community members unless and until I receive final approval of my IRB application from MCC IRDS.				
	<ul> <li>(For research involving student participants from the MCC community in a classroom setting)</li> <li>I acknowledge that I must obtain consent from individual faculty members/instructors for access to their classroom and students. I will not attempt to obtain this consent unless and until I receive final approval of my IRB application from MCC IRDS.</li> <li>Check this box if you require assistance from IRDS to identify instructor(s) who may be willing to facilitate your research in their classroom.</li> </ul>				
	<ul> <li>(For research involving employee participants from the MCC community in a workplace setting)</li> <li>I acknowledge that I must obtain consent from the chair/director/head of each department (for faculty) and VP/AVP/head of each division (for staff) in order to access employees and campus offices during work hours. I will not attempt to obtain this consent unless and until I receive final approval of my IRB application from MCC IRDS.</li> <li>Check this box if you require assistance from IRDS to identify the appropriate department/division head to whom you should direct your request(s).</li> </ul>				
	As the Principal Investigator, I understand that I am responsible for assuring adherence to all approved research protocols by myself and all Co-PIs for the duration of the study. I will ensure that CITI Human Subjects Research (HSR) certification remains current for myself and all Co-PIs throughout the approved study period. I certify that I will contact MCC IRDS immediately if the need arises to amend or terminate an approved study or to report an adverse event.				
	I acknowledge that receiving IRB approval to conduct research involving members of the MCC community is not an endorsement by Mott Community College of my study nor the concepts that I eventually incorporate into my research output (dissertation, thesis, manuscript, working paper, poster, conference presentation, interview, etc., including any drafts or pre-publication versions), and that I will furnish these materials immediately to MCC IRDS if a review is requested.				
	, hereby attest that I have answered each question on this application				
-	In the best of my ability. I further attest that my initials on each of the statements above commitment to uphold the additional requirements set forth in this document.				
(signed)					
(dated)	Select date				

To submit materials, or if you have any questions about this process or form, contact IRDS at mcc ir@mcc.edu.