

Manchester Community College Institutional Review Board (IRB) Procedures

I. WHAT REQUIRES REVIEW?

A. Research Requiring IRB Review

Research activities involving human participants will be reviewed by the Manchester Community College (MCC) Institutional Review Board (IRB) when one or more of the following apply:

The research:

1. is sponsored by Manchester Community College.
2. is conducted by or under the direction of any employee or agent of Manchester Community College in connection with his or her institutional responsibilities.
3. is conducted by or under the direction of any employee or agent of Manchester Community College using any property or facility of this institution.
4. involves the use of Manchester Community College records.
5. uses non-public information to identify or contact human research participants or prospective participants.
6. will be conducted on the grounds of Manchester Community College.
7. uses as subjects Manchester Community College students, faculty, or staff in their respective roles.
8. collects data which will result in an article, master's thesis, doctoral dissertation, poster session, abstract, or any other publication, presentation, or any dissemination of the collected data whether in aggregate form or otherwise.

B. No Review Required

In general data which will not be used beyond the classroom, is for internal institutional usage only, and/or is collected for the purpose of reporting to state or federal stakeholders do not require a review by the IRB. All other research activities require some level of review by the IRB. Examples of research efforts not requiring any IRB action include:

1. Data collection which will not result in an article, master's thesis, doctoral dissertation, poster session, abstract, or any other publication, presentation, or other dissemination of the collected data.
2. Simulations of human experimentation.
3. Data collection for educational purposes in which no data will be reported outside of the classroom and all data are properly destroyed by the end of the academic term (reporting and discussion of data within the class during a single term is acceptable).
4. Data collection for the purpose of reporting to state or national accrediting bodies or other agencies to which Manchester Community College is required to generate and submit reports as part of its regular operations.

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II. NON-AFFILIATED PERSONNEL AND APPROVAL TO CONDUCT RESEARCH

Non-affiliated personnel are defined as individuals not recognized as having a direct relationship to Manchester Community College (e.g., not a faculty member, staff member, or student of the college). For non-affiliated personnel, only research that is tightly aligned with the college's strategic goals will be considered for approval. If accepted, non-affiliated personnel must follow all of the same procedures as affiliated personnel (i.e., IRB approval processes), and in addition non-affiliated personnel are required to obtain approval to conduct research at MCC. Approval for conducting research at MCC is granted by the:

- Dean of Student Affairs, if the project involves collection of academic records or interaction with students outside of the classroom
- Dean of Academic Affairs, if the project involves interaction with faculty
- Institutional Research, if the project involves interaction with staff.

Approval from each administrator is required for interaction with each specific population / data type.

III. IRB LEVELS OF REVIEW

The IRB performs different levels of review based on the potential impact the study may have on participants. These levels of review are based on federal guidelines and are designed to ensure the safety of the participants. The general research conditions and level of IRB review they require are described below. Please note that the examples presented below do not constitute an exhaustive list. More detailed information can be found at the National Institutes of Health, Office of Human Subjects Research site <http://ohsr.od.nih.gov/index.html> and in the U.S. Department of Health and Human Services publication Guidelines for the Conduct of Research Involving Human Subjects at the National Institutes of Health <http://ohsr.od.nih.gov/guidelines/GrayBooklet82404.pdf> . If you are not sure which level of review applies to your particular research protocol please contact the MCC Planning, Research and Assessment office for assistance (DNielsen@mcc.commnet.edu)

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A. Exempt Review

Research involving data collected without any accompanying identifiers (e.g., name, date of birth, etc) is typically exempt and therefore the review is primarily to be certain the research protocol does not involve more than “minimal risk” to the participants. Examples that would qualify for an expedited review include those where:

1. Data are collected for the purpose of dissemination
2. No information is recorded in a manner where human subjects can be directly or indirectly identified. This includes but is not limited to name, address, date of birth, and email address.
3. The research will be conducted in an educational setting and involve typical teaching practices.
4. During observation of public behavior the PI is not an active participant in the activity being observed.
5. The collected data are publically available or were previously collected and in existence prior to the current proposal.
6. The research involves examination of a public service program and has been approved by the appropriate agency head.
7. The research involves the tasting and evaluation of wholesome foods.

B. Expedited and Full-Reviews

Projects which require that the participants’ identity be known but which do not involve any special circumstances typically require an Expedited Review. Finally, protocols which involve a “special circumstance”, such as those described below, require a full review, which means they can only be approved by a majority vote during an IRB meeting in which a quorum is present.

If the project requires that the participants’ identity be known, but does not fall under any of the special circumstances listed below then it follows an Expedited review.

Answering yes to ANY of the special circumstances listed below means that your project requires Full Review:

1. Does the protocol involve protected populations (e.g. prisoners, minors, pregnant women etc.)?
2. Are participants receiving compensation?
3. Are institutions other than Manchester Community College involved in this research?
4. Is there any risk beyond what participants would experience if they were not to participate in this project?
5. Is deception used in any way as part of this project (i.e., any time during the project in which information is withheld concerning the procedures and/or purpose of the project)?
6. Will the data collected be used in any way after the completion of this proposed work, other than for scholarly research presentations or publication (e.g., for a newspaper report, for posting to a website including personal websites, for adding to a national database other than institution-required federal and state reports, etc.)?

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IV. INFORMED CONSENT

Individuals wishing to perform research on human subjects are required to obtain consent from those participants by means of an informed consent document. One of the main ethical responsibilities of a Principal Investigator is to ensure that potential participants have been provided with all the information they might reasonably need to know about the research project before they begin participating.

Regardless of how innocuous the nature of the project may seem, potential participants have the right to:

- 1) Disclosure of all relevant information about the research,
- 2) their comprehension of the information, and
- 3) their voluntary agreement, free of coercion and undue influence

V. REQUESTING DATA FROM INSTITUTIONAL RESEARCH OFFICE

If the research involves MCC Banner data from IR or any other entity on campus a Request for Data form must be filed (see Appendix D). All data requests must be made to the office of Institutional Research (DNielsen@mcc.commnet.edu). Data requests which require the creation of new data sets will not be considered. Data requests which require the compilation of currently existing data set(s) for the purpose of research which is in-line with the strategic goals of MCC will be considered for approval. For Non-affiliated personnel, consideration of a data request must be accompanied by a document indicating that approval to conduct research at MCC has been confirmed (see II. above).

Data Delivery

If a data request is approved, all data will be provided in flat-table "raw" format. Aggregation of data files or any level of statistical modification of the data is solely the responsibility of the researcher(s). Requests to provide identifiers including but not limited to name, date of birth, address, or email require additional written justification for each identifying variable. The timeline for delivery of the data will vary greatly depending upon the magnitude of the data request and the current RAE workload. Primary Investigators should plan on a minimum of 6-weeks for delivery of data and up to 6-months from the time that the project is fully approved.

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Appendix A

Basic Procedures

- 1) Obtain approval to conduct research at MCC (non-affiliated personnel only)
 - a) Research involving MCC students is granted by the Dean of Student Affairs
 - b) Research involving academic records and/or interaction with faculty is approved by the Dean of Academic Affairs.
 - c) Research involving MCC staff is approved by the office of Institutional Research in consultation with appropriate staff supervisors.
 - d) Approval from each administrator is required if the project involves interaction with more than one of these specific populations / data types.
- 2) Complete the MCC IRB form (Appendix B)
- 3) Complete the Consent form (Appendix C)
- 4) Complete the Request of Data form (only if you are requesting data from Institutional Research)
- 5) Submit the MCC IRB form, the Consent form, the Request for Data form (if applicable) and a copy of all instruments being used (e.g., actual survey(s), list of interview questions, list of standardized tests, etc.) to the Institutional Research office. Additionally, individuals conducting research for the completion of graduate school requirements must submit an approved IRB notification from their degree granting institution.
- 6) Review process
 - a) Exempt reviews are reviewed by the Chair of the IRB and typically notification of the proposal's status can be expected within 5 business days of receipt of the proposal.
 - b) Expedited reviews are reviewed by a subset of IRB committee members and typically notification of the proposal's status can be expected within 30 days of receipt of the proposal.
 - c) Full reviews are done at IRB meetings. The final proposal must be submitted at least 10 working days prior to the scheduled meeting date. Notification of the status of the proposal will be given within 5 business days after the meeting at which the proposal was considered.

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Appendix B

IRB Form

Principal Investigator:

PI email:

PI Campus Phone:

Project Title:

1. Source of Funding (if any):

2. Dates of proposed project (cannot be retroactive):

Begin Date: _____ End Date: _____

3. Describe the Scientific Purpose of the Investigation:

4. Describe the research methodology in non-technical language (the IRB needs to know what will be done with or to all research participants):

5. What are the potential benefits of this research (either directly to the participants, or to the body of knowledge being researched):

6. What are the anticipated risks (risks include, physical, psychological, or economic harm)? What steps will be taken to protect participants from these risks?

7. Describe how participants will be recruited (must include total number and age range of all participants to be recruited and any compensation participants will be provided including extra credit in courses):

8. Is it necessary that the Primary Investigator(s) or other researchers know the identity of the participants? If so provide a detailed description of why:

9. Describe how data collected for this project will be securely stored and how and when it will be destroyed:

10. Describe the process you will use to obtain informed consent and complete the highlighted portions of the Consent Form Template found in Appendix C below.

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**Appendix C
Consent Form**

[Project Title]

***Introduction and Purpose**

[Briefly describe the study]

***Procedures**

[What will the participant be required to do?]

Potential Risk or Discomfort

[Describe any potential risks or discomfort – if there are none this section can be left off of the consent form]

***Confidentiality Information**

[How will data be stored securely and confidentiality insured]

***Voluntary Participation**

Participation in this research is voluntary. Declining to participate will in no way impact your relationship with [Primary Investigator], the [XXX Department], or Manchester Community College. If you decide to be in the study, you have the right to drop out at any time.

***Consent Statement (either statement A or B below is required):**

A: I understand the procedures described above. My questions have been answered to my satisfaction, I have been given a copy of this consent, and I agree to participate in this study.

Print Name: Date

Participant's Signature

B: I understand the procedures described above and all questions have been answered to my satisfaction. By returning this [questionnaire] I am agreeing to participate in this study.

*This project complies with the requirements for research involving human subjects by the MCC Institutional Review Board. If you have any questions or concerns about being a participant in this project feel free to contact the Primary Investigator [Investigator] by phone [999-999-9999] or by email [XXX@xxx.edu] or, the Director of Institutional Research at 860-512-3108.

* required items of consent form

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Appendix D

**Request for Data From
Institutional Research office**

IR OFFICE Use Only

Request received: _____

_____ Approved by _____

_____ Not Approved. Reason:

Date completed:

1. Date Submitted:
2. Project Title:
3. List of variables requested
4. Dates / Semester range for data
5. Any criteria (e.g., males only, Health Sciences majors only, etc.)
6. Requested date for delivery of data: