

Anoka Ramsey Community College
and
Minneapolis Community and Technical College
Joint
Institutional Review Board

Standard Operating Procedure Handbook

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I. Introduction

In 2013, Anoka-Ramsey Community College (ARCC) and Minneapolis Community & Technical College (MCTC) formed a joint IRB committee to support the expansion of undergraduate research at both colleges.

The federal government requires that all research involving human subjects conducted by an institution that receives federal funding be reviewed in advance by an IRB at the institution. Even if a specific research project is not funded by the government, the IRB is still expected to review it because ARCC and MCTC receive federal funding.

The Institutional Review Board (IRB) is responsible for overseeing all research (as defined below) that is conducted at ARCC or MCTC by faculty, students or staff that involves human subjects. The IRB is not a college committee in the usual sense; it is subject to the regulations of a federal agency: the Office for Human Research Protections (OHRP) within the Department of Health & Human Services (DHHS).

The federal definition of research includes only research activities that are “designed to develop or contribute to generalizable knowledge” (such as through a public presentation of data in a poster, at a statewide or national symposium or peer reviewed journal article). Research being conducted at ARCC or MCTC for educational purposes only is not subject to approval by the IRB. Likewise, research being presented within an investigator’s home college does not require IRB approval, as such presentations are not intended to contribute to the larger body of “generalizable knowledge.”

Note: the IRB does not replace FERPA. Projects that do not meet the definition of research must still comply with FERPA guidelines.

II. Institutional Authority

Once approved by both Anoka Ramsey Community College and Minneapolis Community and Technical College, the standard operating procedures outlined in this handbook establish and empower the joint Anoka Ramsey Community College and Minneapolis Community and Technical College Institutional Review Board, hereafter referred to as ‘the IRB’.

III. Purpose

The IRB exists to protect the welfare of human subjects used in research. To this end the goals of the IRB are to ensure that researchers understand and uphold the following two standards when conducting research:

1. Human subjects should not be placed at undue risk;

2. Subjects should give un-coerced, informed consent of their participation in the research.

Research procedures should minimize the risk of harm and maximize the possible benefits to the subject and to society.

IV. The Authority of the IRB

The IRB agrees to review all research involving the use of humans as research participants where any of the following apply:

- 1) The research is sponsored by either of the member institutions
- 2) The research is conducted by or under the directions of an employee or agent of either of the member institutions, or
- 3) The research involves the use of non-directory information to identify or contact prospective human research subjects.

The IRB is the definitive voice for the protection of human subjects in research at both colleges. While administrators of the Colleges might be able to restrict a research project that has received IRB approval, they may **not** overturn an IRB decision to disapprove a research project. However, it is the intent of the IRB to work with investigators to mutually agree on a protocol that will receive IRB approval.

V. Committee Members

The ARCC/MCTC IRB Committee is composed of employees at the colleges and representatives from outside the colleges. Members serve a three-year term. These terms are renewable. There are six seats on the board. Two are held, ex-officio, by the person from each college in charge of the institutional research functions, two are held by faculty members from each college and two are held by community members. Members are jointly appointed by the president of each college. In making appointments to the committee, the following guidelines must be observed: There must be both scientists (including social scientists) and non-scientists on the board. There must be at least one member who has no affiliation with either college (e.g., is not an employee or student and is not a member of the immediate household of an employee or student); there must be one non-faculty employee member of the committee. Efforts should be made to have a balance of gender, ethnicity, and disciplinary specialties on the Board.

The current committee members are:

Nora Morris, co-chair (Dean of Research & Evaluation, ARCC)

Gail O’Kane, Ph.D., co-chair (Associate Vice President of Strategy, Planning & Accountability, MCTC)

Kristen S. Genet, Ph.D. (Biology faculty, ARCC)

Jesse Mason, Ph.D (Psychology faculty, MCTC)
Joy Frestedt, PhD, RAC, CCTI, FRAPS (Community member)
Pamela Berry (Community member)

VI. Process of the IRB

During the academic year, applications are processed as received. Applications should be submitted to the co-chair for the respective college. The IRB would like to see a fully-developed plan and accompanying documentation (e.g. a questionnaire or scripts when the subjects are likely to be interviewed). In the case where students are the researchers, the applications must be reviewed by a **Faculty Research Advisor**, who will then serve as the principal investigator and submit the application to the IRB.

When an application is submitted, the co-chairs ask a member of the board to be **Primary Reviewer**. This reviewer reads the application and the supporting materials. Then, he/she prepares an analysis and a recommendation for distribution to other IRB members. If they agree with the recommendation, the reviewer sends an e-mail message to the applicant explaining the finding. The normal findings are:

Doing research that involves human subjects is a privilege, not a right. The IRB will work with applicants on meeting the federal requirements. However, the IRB cannot approve projects submitted after the fact (prior review is necessary to insure compliance with federally defined criteria for ethical treatment of human subjects, particularly when the intent is to contribute to generalizable knowledge. Thus, research done without IRB approval **MUST NOT BE USED IN ANY PRESENTATION OR PUBLICATION**. Please be aware that IRB approval is critical for both College related work, as well as professional endeavors outside of the college. In fact, increasing restrictions are being placed on publication in professional journals of research conducted without IRB approval. Thus, we urge you to plan ahead and consider possible future uses of the data to be collected (e.g. class projects that do not require IRB approval would require IRB approval if used for publication); and obtain necessary approval in advance. If you have collected data without IRB approval for a class project or other non-research purpose and later decide to pursue research that might build on or potentially use this data, you must contact the co-chair of the IRB at your respective institution to discuss restrictions and possible ramifications.

Procedures for Securing Approval for Research

The Principal Investigator: is responsible for (1) determining whether the project involves research with human subjects and (2) submitting a complete application for approval with all supporting documents. After reviewing the application and its supporting materials, the IRB may ask the investigator to explain some elements of the protocol and may require revisions in the protocol. When the investigator revises a project, the IRB must review the amended protocol to see whether its concerns have been adequately addressed. To fully protect subjects, the IRB must approve a project

before investigators start to work on it—even before they begin to recruit subjects, since recruitment strategies are part of the review. Research projects are reviewed at one of three levels, depending on the IRB's interpretation of the project's risk to the human subjects and on the federal guidelines that define the categories of review, which are:

- screening for exemption from full IRB review
- expedited IRB review
- full IRB review

The level of review can be determined only by the IRB.

Exempt Research

Investigators do not have the authority to determine whether research involving human subjects is exempt from full review (45 CFR 46.101(b) and (c)). Hence, while research that involves only minimal risk to human subjects is sometimes exempt from full IRB review, that does not mean that it is exempt from peer review. Researchers must file an application requesting that a project be classified as exempt. In general, the federal guidelines for research on human subjects allow a project to be exempt from full review only if the research involves no risk to the subject.

Criteria of exempt research include:

1. Routine Instructional Research:

Research on instructional strategies conducted in educational settings, involving normal educational practices (such as research on regular and special educational strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods).

2. Anonymous Survey and Public Behavior Research (on adults):

Research involving the use of educational tests (cognitive, diagnostic aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless:** (a) the information obtained is recorded in such a manner that human subjects can be identified; **and** (b) any disclosure of the human subjects' responses outside the research could place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. This exemption does not apply to research involving children, **except for** research involving observation of public behavior in which the investigator does not interact with the child.

3. Survey and Public Behavior Research on Public Officials:

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior **if:** (a) the human subjects are elected or appointed public officials or candidates for public office **or** (b) federal statutes(s) require(s) without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.

4. Research on Existing Data and Specimens:

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified (i.e., so-called "blinded" data sets). Investigators should note that a survey is anonymous when there is no possible way to identify the participants from the data collected. In most cases, the omission of names or other specific identifiers, such as social security numbers or student id numbers, is sufficient to qualify a study as anonymous.

NOTE: Observational research involving sensitive aspects of subjects' behavior, or in settings where subjects have a reasonable expectation of privacy, is not exempt. Similarly, sensitive survey research is seldom exempt from review. A sensitive survey includes questions about illegal activities or highly personal aspects of the subjects' behavior, life experiences, or attitudes. Examples include chemical substance abuse, sexual activity or attitudes, sexual abuse, criminal behavior, sensitive demographic data, detailed health history, etc. The potential for provoking a negative emotional reaction from subjects is a principal determining factor of sensitive survey research. Additional consideration for exemption includes whether there is a risk associated with a possible breach of confidentiality (i.e., accidental disclosure of drug use to law enforcement personnel or disclosure about a subject's mental health state where such information might harm the person's reputation). In surveys with potential psychological risk, review for exemption includes risks associated with surveys about sensitive topics as well as those resulting from a breach of confidentiality. When confidentiality is an issue, the presence or absence of subject identifiers may be a decisive factor. Questionnaires or surveys covering sensitive topics may qualify for a Claim of Exemption if they fulfill the following:

- anonymity of the subject is guaranteed,
- potential subjects are informed of the sensitive nature of the topics prior to their participation, and
- the study does not exceed minimal risk.

Screening for exempt status streamlines IRB procedures with no diminution of protection of human subjects. **The co-chair of the IRB at your respective institution or other designated IRB member decides whether the project qualifies as exempt**, and the decision is confirmed in writing, typically within one week. If the project does not qualify as exempt, it will be considered for expedited or full review.

Expedited review

To qualify for expedited review, a research project must involve one of the activities that are federally approved for expedited review and incur no more than minimal risk for participants, or be a minor change in previously approved research that involves no additional risk to the research subject. Activities approved in the federal regulations for expedited review include:

- 1) Collection of small amounts of blood from healthy adults;

- 2) Collection of biological specimens (like hair or nail clippings) through noninvasive means;
- 3) Research on existing data or specimens (note: some research in this category is exempt);
- 4) Collection of data from voice, video, digital or image recordings;
- 5) Research on individual or group characteristics or behavior or involving surveys, interviews, oral history or focus groups (note: some research in this category is exempt);
- 6) Continuing review of non-exempt research previously approved by the IRB, where no new subjects will be enrolled or where the research involves no greater than minimal risk.

Note: There are a few other categories eligible for expedited review, but they involve clinical studies seldom performed at community colleges. These additional categories are listed in 45 CFR 46. The researcher must show on the application how the proposed project activities fall into one or more of these categories.

The IRB co-chair of your respective institution assures that all of the elements essential for review, including consent forms and supporting information, have been submitted. The application is then forwarded to a designated committee member for review and decision. Either the research is approved by the committee member or it is forwarded for full review.

Full review

A project that involves greater than minimal risk requires approval by the IRB committee. Any survey or interview that is likely to be stressful for the subject requires full review. Full review means that a convened meeting of a majority of the IRB members occurs, during which discussion of the proposal occurs. Among the members present there must be at least one scientist and one non-scientist, and the member who is otherwise unaffiliated with the Colleges. Because of scheduling issues, investigators should expect that full review of a proposal can take up to several weeks.

Continuing Oversight:

All non-exempt research is subject to at least annual review and renewal. If research involves extreme risk to subjects, the IRB may require more frequent review and may ask to be kept apprised of all research activity. The investigator is responsible for re-applying for approval after the initial IRB approval expires. The IRB will conduct an expedited review of these applications, unless the research protocol has been modified or new subjects are to be added and full review is otherwise appropriate.

Procedure for Addressing Complaints from Research Subjects

If possible, subjects must be told that they can direct complaints about the conduct of the research to the co-chairs of the IRB. If the research is on-going, the IRB will document complaints and review research procedures. If the research is completed, the IRB will investigate

the complaint, including discussing it with the investigator, and prepare a report. The report will be forwarded to the investigator and to the appropriate college administrator.

VII. Investigator Responsibilities

Investigators are responsible for the ethical conduct of their research and the conduct of participating faculty, students, and staff. Investigators ensure that research involving human subjects is reviewed and that this review takes place **before** the research is initiated.

The investigator must also

- Seek approval for making changes in the research protocol
- Report to the IRB unanticipated problems or adverse events
- Reapply for approval when approval expires (at least annually)
- Retain copies of IRB approval documents
- Retain copies of signed consent forms for three years after the completion of the research. Should the Investigator leave the institution, the consent forms must be transferred to the IRB co-chairs of your respective institution.

VIII. Record Requirements

The IRB maintains adequate documentation of IRB activities including the following:

- 1) Copies of all research proposals reviewed, approved sample consent documents and continuation reports
- 2) Minutes of IRB meetings
- 3) Copies of all correspondence between the IRB and Investigators or Project Directors including updated consent documents.
- 4) Records of continuing review activities including summaries of ongoing activities.
- 5) Copies of all project information that Investigators provide to research subjects such as fact sheets, statements of significant new findings, unanticipated adverse reactions or risks, etc.
- 6) Adverse reaction reports

The IRB shall retain these documents for at least three years after completion of the research project. The IRB shall also maintain a record of all IRB members and a current Standard Operating Handbook.