Rochester Community and Technical College

Institutional Review Board

Standard Operating Procedure Handbook

Table of Contents

I. Introduction

To be compliant with the Code of Federal Regulations (CFR) 45, Part 46, Protection of Human Subjects, all research proposals involving human subjects by an institution that receives federal funding must be reviewed and approved by the Institutional Review Board (IRB or the Board) prior to beginning the research. This is consistent with Rochester Community and Technical College's mission and values of safeguarding the rights and welfare of all human participants.

The IRB is responsible for overseeing all research (as defined below) and performing an ethical review of proposed research that is conducted at Rochester Community and Technical College (RCTC) by faculty, students or staff that involves human subjects.

- A human subject means a living individual about whom an investigator (whether faculty, staff, or student) conducting research obtains data or private information (45 CFR 46.102).
- Research means a systematic investigation, including research development, testing and evaluation, "designed to develop or contribute to generalizable knowledge" (45 CFR 46.102), such as through a public presentation of data in a poster, at a statewide or national symposium, or in a peer-reviewed journal article. Research being conducted at RCTC for educational purposes only is not subject to approval by the IRB. Likewise, research being presented within an investigators home college does not require IRB approval, as such presentations are not intended to contribute to the larger body of "generalizable knowledge."

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).

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 Rochester Community and Technical College, the standard operating procedures outlined in this handbook establish and empower the RCTC 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 and indicate their understanding of their rights.

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 the institution,
2) The research is conducted by or under the directions of an employee or agent of the institution, 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 the college. While administrators of the College 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 RCTC IRB Committee is composed of faculty and administrators that are representative of a mix of disciplines. There are five seats on the Board. One is held by the AVP – Academic Operations and Institutional Effectiveness, and four are held by faculty members who are appointed by the President of the 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. Efforts should be made to have a balance of gender, ethnicity, and disciplinary specialties on the Board.

The current committee members are:

- Alissa Oelfke, PhD, IRB Chair – AVP Academic Operations and Institutional Effectiveness
- Onalee Finseth, EdD, MSN – Nursing faculty
- Ruth Casper, PhD – Psychology faculty
- Casandra Dennison – Early Childhood Care and Education faculty
- Suzanne Szucs – Photography faculty

VI. Process of the IRB

During the academic year, applications are processed as received. Applications can be found on the IRB website and should be submitted to the chair. 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.

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 ensure 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 PUBLIC PRESENTATION OR PUBLICATION outside of RCTC.** Please be aware that IRB approval is critical for 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 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 chair of the IRB 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 subjects.

Criteria of exempt research include:
The federal code of federal regulations regarding human subjects research defines several categories which are exempt from IRB review. The Principal Investigator should review the following categories and complete the attached **Exempt Research Categories Information Sheet** to request a determination. The IRB will then determine whether the research qualifies as exempt, or if it should move on to full IRB review.

Category 1: Investigational Strategies in Educational Setting; 45 CFR 46.101(b)(1)
Research conducted in educational settings, involving normal educational practices.

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
1. research on regular and special education instructional strategies, or
2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Note: This category may be applied to research involving children.

Examples of exempt research:
- Evaluating the use of accepted or revised standardized tests
- Testing or comparing a curriculum or lesson

Category 2: Surveys/Interviews, Standard Educational Tests, Observations of Public Behavior; 45 CFR 46.101(b)(2)
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, ***unless***:
1. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

2. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Note: Surveys on sensitive or personal topics which may cause stress to study participants are not exempt from IRB review.

This category may apply to research with children only when the investigator observes public behavior but does not participate in that behavior or activity; it is not applicable to survey or interview research involving children.

Examples of exempt research:

- Surveying college students on homework practices
- Interviewing shoppers at a farmers' market about local food preferences

Category 3: Public Officials, Surveys/Interviews, Educational Tests, Observation of Public Behavior; 45 CFR 46.101(b)(3)

Research involving the activities in category 2 and the human subjects are elected or appointed public officials or candidates for public office.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:

1. the human subjects are elected or appointed public officials or candidates for public office; or
2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Examples of exempt research:

- Interviewing public officials about a local or global issue

Category 4: Existing Data: Records Review, Pathological Specimens; 45 CFR 46.101(b)(4)

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic 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, directly or through identifiers linked to the subjects.

Examples: Existing Data, Records Review, Pathological Specimens

All records or specimens included in research under exempt Category 4 must exist at the time of IRB submission. If you are collecting data prospectively, this study does not qualify for exemption.

If the dataset or specimens being researched have been de-identified, or if the data is coded and the researcher does not have access to a link to identifiers, the research does not meet the federal definition of human subjects research and does not need to be reviewed or approved by the IRB.

Examples of exempt research:

- Analyzing existing tissue samples labeled with identifying data, or containing a link to identifying data, when the researcher does not record identifying data or link to identifying data.
- Reviewing existing medical or educational records when the researcher does not record identifying data or a link to identifying data.

Category 5: Reserved for Federal Government Research; 45 CFR 46.101(b)(5)
Not available for local IRB exemptions.

Category 6: Food Quality and Consumer Acceptance Studies; 45 CFR 46.101(b)(6)
Taste and food quality evaluation and consumer acceptance studies.

Taste and food quality evaluation and consumer acceptance studies,

1. if wholesome foods without additives are consumed or
2. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: This category may be applied to research involving children.

Examples of exempt research:

- Taste testing whole grain food products
- Comparing taste or smell of molasses, cheese or milk
- Sampling texture of ice cream

If the principal investigator believes the research project may qualify as exempt research, they should complete the **Exempt Research Categories Information Sheet** and submit it to the IRB chair for consideration. Screening for exempt status streamlines IRB procedures with no diminution of protection of human subjects. **The chair of the IRB or other designated IRB member decides whether the project qualifies as exempt**, and the decision is confirmed in writing. If the project does not qualify as exempt, it will be considered for expedited or full review.

Expedited review

Federal criteria for risk assessment make some studies eligible for Expedited Review (c.f. 45 CFR 46.110 and 21 CFR 56.110). Expedited Review and Exemption are not one and the same. Expedited Review is a complete review that does not require the convening of the full IRB, while Exemption is reserved for research that is not IRB reviewable under 45 CFR 46. For additional information on Exemption, consult "Exempt Research Categories Information Sheet".

Studies eligible for Expedited Review must meet the federal definition of minimal risk which is:

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

To qualify for expedited review, a research project (a) must involve one of the activities that are federally approved for expedited review and incur no more than minimal risk for participants, or (b) must 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 through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis, educational records, etc.).
6) Collection of data from voice, video, digital, or image recordings made for research purposes.
7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note: Categories 1 through 4 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.

Generally, research at RCTC will fall into categories 5, 6, and 7. Expedited Review Categories 1, 2, 3 and 4 deal with the collection of biological samples of any kind through invasive and noninvasive means, as well as research involving treatments, drugs, and medical devices. If you believe your research falls into categories 1, 2, 3, or 4 contact the IRB for more information.

The IRB chair verifies 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, in which case a full review is 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 chair of the IRB. If the research is ongoing, 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 chair.

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.