Use of Human Subjects in Research

Policy and Procedures Manual

For Faculty, Staff, and Student Researchers

(2026)

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USE OF HUMAN SUBJECTS IN RESEARCH POLICY

The Institutional Review Board (IRB) oversees human subjects research at the college for the purpose of protecting the rights and welfare of human subjects recruited to participate in research activities. The IRB is an independent compliance committee mandated by the U.S. Department of Health and Human Services (See Title 45 Part 46 of the Code of Federal Regulations). The most recent version of these regulations includes the adoption of the Federal Policy for the Protection of Human Subjects, generally known as the “Common Rule.”

In accordance with 45 CFR 46.102i, research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Without regard to methodology, all Ramapo affiliated researchers (including faculty, staff, and students) conducting research with human subjects are required to submit an application to the IRB and gain approval before beginning their study. Secondary analysis of data which does not include interactions with human subjects may or may not be found by the IRB to be Exempt from Further IRB Review.

Research by an investigator not affiliated with Ramapo College of New Jersey (the “College”) who proposes to involve College students, staff, or faculty as subjects in the proposed research project must also be reviewed and approved.

The IRB performs critical oversight functions to ensure applicable scientific, ethical, and regulatory standards are met. The IRB reviews and monitors research conducted by College faculty, staff, and students. It is charged with the responsibility and authority of reviewing research study proposals and granting approval, denying approval, or granting approval subject to modifications or conditions for those proposals. The IRB is responsible for establishing and administering College policies and procedures related to the implementation of or compliance with federal, state, and local regulations that govern the protection of people participating in research. Researchers should consult the IRB procedure manual on the IRB website, which outlines the procedures of the IRB.

Undergraduate and Master level student research projects that are being conducted in the context of learning research skills in an academic course, and that will not be presented outside of the College do not need to undergo IRB review unless the risk exceeds minimal risk. However, human subject research conducted by students in such a context is the responsibility of the course instructor or faculty sponsor, who is required to undergo the online training provisions listed in HUMAN SUBJECTS RESEARCH ETHICS TRAINING (for researchers) of the College’s IRB Procedures. The College IRB requires that the instructor or faculty sponsor use a course-based research approval form and that the instructor or faculty sponsor act as the research review chair with responsibility for reviewing the proposed project, overseeing the research, and ensuring that students adhere to human subjects policies in their activities.

INTRODUCTION TO PROCEDURES MANUAL

NOTE: For IRB purposes, the terms researcher and investigator are interchangeable. In keeping in alignment with the regulations the manual will use the term investigator going forward.

The purpose of this procedures manual, (herein referred to as 'the Manual'), is to provide guidance and procedures to all faculty, staff, students, and others who propose to conduct research involving human subjects under the jurisdiction of the College. This Manual applies to all research involving human subjects that is conducted by any person who is a faculty, staff member, or student at the college, regardless of where the actual research takes place. It also applies to research conducted by those who are not affiliated with the college, if the human subjects are members of the College community.

This Manual is based on IRB Policies and Procedures 300-D pre 2025 and expands upon the original policy and guidelines.

NOTE: Research involving animals is overseen by the College's Institutional Animal Care and Use Committee (IACUC). The College's IACUC is a committee, composed of both scientists and non-scientists, who oversee a wide range of issues related to the use of animals at the College. The IACUC assures that the institution operates in accordance with the Animal Welfare Act and Public Health Service Policy on Human Care and Use of Laboratory Animals (S2.C1:PHS Policy on Humane Care and Use of Laboratory Animals).

STATEMENT OF PRINCIPLES AND PURPOSE UNDERLYING PROTECTIONS OF HUMAN SUBJECTS

The IRB oversees all human research at the College toward the purpose of protecting human subjects. The role of the IRB is to protect the rights and welfare of individuals involved in research activities conducted under the auspices of the College. The three basic ethical tenets of respect for persons, beneficence, and justice, and the application of these tenets set forth in the Belmont Report, issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research shall guide the IRB. They will apply these tenets to all human subjects research, regardless of funding.

DEFINITIONS

Common Rule (from the Federal Policy for the Protection of Human Subjects): The Common Rule was published in 1991 and codified in separate regulations by 15 Federal departments and agencies. It is The Federal Policy for the Protection of Human Subjects.

Human Subject (from the Federal Policy for the Protection of Human Subjects--Section 102(e) of 45 CFR 46): means a living individual about whom an investigator (whether

professional or student) conducting research: (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Institutional Review Board (IRB):(from the Federal Policy for the Protection of Human Subjects--Section 102(g) of 45 CFR 46) means an institutional review board established in accord with and for the purposes expressed in policy 45 CFR 46.

Minimal risk (from the Federal Policy for the Protection of Human Subjects--Section 102(j) of 45 CFR 46) means that 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.

Office for Human Research Protections (from Office for Human Research Protections): The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

Principal Investigator (PI): the lead researcher responsible for the scientific, technical, and administrative direction of a research project. PIs ensure compliance with regulations, manage funds, supervise the team, and uphold ethical standards for participant safety.

Research (from the Federal Policy for the Protection of Human Subjects--Section 102(l) of 45 CFR 46) means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

1. Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely

situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

IRB COMMITTEE CHARGE AND MEMBERSHIP CHARGE

The IRB provides for initial and continuing review of proposals involving human subjects research participants. It assures that the rights of self- determination, privacy, and confidentiality are maintained through its procedures, and it strives to protect subjects from undue harm by upholding the minimum risk requirement. The IRB is charged with the authority to approve, require modifications in, or disapprove of all research activities involving human participants that fall within its jurisdiction as specified by both federal and state regulations and elaborated upon in this Manual. No human subjects research shall be conducted or authorized by the College unless the IRB has reviewed and approved the proposed human research project, even if previously approved at another institution. Retroactive approval for research studies is not given. Any research seeking financial support from within the College, extramural funding, or release time that involves human research requires IRB approval to receive funding, and such IRB applications must designate that there is the possibility of funding. Additionally, the IRB is responsible for handling complaints concerning human research projects and making recommendations on sanctions.

The authority to interpret these policies rests with the College's President, and is generally delegated to the College's Provost and the IRB Chair.

The responsible office for the IRB and all of the requirements of the Federal wide Assurance for the Protection of Human Subjects and the Office for Human Research Protections is the College's Provost's Office. The Provost serves as the signatory on federal assurance documents and is the Senior Officer responsible for overseeing the activities of the IRB. The IRB Chair and Provost review updates to the Federal policies and implement these changes in a timely fashion as dictated by OHRP.

Membership: In accordance with the Federal Policy for the Protection of Human Subjects--Section 107 of 45 CFR 46, the standing IRB committee will consist of a minimum of five members representative of a variety of professional disciplines including at least one external Community Member. The external member(s) must not be affiliated with the College. One member of the standing committee is a representative from the College's Office of Grants and Sponsored Programs. Members will complete the training prescribed in the Human Subjects Research Ethics Training section of this Manual before serving.

Standing committee: The standing IRB committee acts as a pool, from which the IRB Chair selects panel members as appropriate for each proposal. The standing committee and panels should be sufficiently qualified through their expertise. There is

consideration of the diversity of the standing committee and panel members in terms of race, gender, cultural background, and other relevant identity categories in order to safeguard the rights and welfare of all human subjects.

If the IRB regularly reviews research that involves vulnerable populations, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

Every Full IRB review panel shall consist of either the IRB Chair or Co-Chair, one Community Member, and at least three faculty members from the standing committee. Panelists are selected based on germane subject expertise. There should also be at least one scientist and one non-scientist on a panel.

If external funding has been secured to conduct the research, a representative from the Office of Grants and Sponsored Programs will serve on the panel.

Committee members and committee chairs shall not be allowed to sit on a panel for their own research proposals.

The IRB Chair and Co-Chair are tenured faculty members and their terms are two years. The Chair's term is staggered with the Co-Chair's terms as follows:

- Co-Chair year 1: During the first year, a faculty member who accepts appointment as Co-Chair begins in a learning position. They serve as Co-Chair under the Chair and observe processes and procedures for one year.
- Chair year 1: During the second year, the faculty member serves as Chair, with the previous Chair serving as mentor and Co-Chair.
- Chair year 2: During the third year, the faculty member serves as Chair with a new faculty member as their Co-Chair. The Chair mentors the Co-Chair.
- Co-Chair year 2: During their fourth year, they serve as Co-Chair, consulted as needed.

ROLES AND RESPONSIBILITIES

PROVOST

The responsible office for the IRB and all of the requirements of the Federal wide Assurance for the Protection of Human Subjects and the Office for Human Research Protections is the Provost's Office. The Provost serves as the signatory on federal assurance documents and is the Senior Officer. The Provost oversees all of the actions of the IRB and ensures that all regulations are followed and requirements are met. The Provost is responsible for ensuring that procedures and forms are updated and training is provided to all personnel. The Provost, in consultation with the Chair and Co-Chair, appoints Chairs and Co-Chairs.

CHAIR

The Chair serves as the main point of contact for IRB applications and inquiries and reviews all materials for completeness. The Chair determines the type of IRB review

and coordinates between applicant and reviewers. The Chair keeps records of applications, correspondence, and approvals. The Chair coordinates the maintenance of the IRB website and necessary documentation for the Federal registry with the office of the Provost. The Chair recruits IRB members, manages their onboarding, and manages and verifies their training. The Chair coordinates updates and revisions to the Manual as needed with oversight of the Provost. The Chair consults with the Co-Chair and the Provost as needed. The Chair coordinates convened IRB panel meetings and records minutes. The Chair provides informational sessions and outreach to the college community. The Chair provides mentoring to the Co-Chair who is preparing for the Chair role. The Chair maintains records regarding members' review of applications and provides service letters at the end of each academic year and as requested. The Chair ensures that there are enough members that no particular member is over burdened with application reviews. The Chair has the authority to interpret and apply the procedures in this Manual as needed. The Chair is the point of contact for the Research Integrity Officer if research misconduct of a College faculty, staff member, or student is suspected or reported.

CO-CHAIR

The Co-Chair may serve as the Chair on an as needed basis, as determined by the Chair, in consultation with the Co-Chair or Provost. Reasons may include the absence of the Chair, or if the Chair recuses themself to avoid the appearance of a conflict of interest. The Co-Chair is the first point of consultation for the Chair when ethical or other consultation is needed. The Provost and other experts as appropriate to the application may be called in as needed. The Co-Chair in preparation for the Chair role learns policies and procedures from the Chair. The Co-Chair that has already served as Chair is available for consultation as needed.

MEMBERS

Both College affiliated and non-College affiliated Community Members of the IRB are contacted by email on an as needed basis. Members let the Chair know if they are available or not to review an application, and members review applications and provide feedback within 2 weeks.

SECONDARY ANALYSIS OF EXISTING DATA SETS

The IRB recognizes that some research projects involving existing data sets and archives may not meet the definition of "human subjects" research requiring IRB review; some may meet definitions of research that is exempt from the federal regulations at 45 CFR part 46; and some may require IRB review. This section is intended to provide guidance on IRB policies and procedures and to reduce burdens associated with IRB review for investigators whose research involves only the analysis of existing data sets and archives.

Although projects that only involve secondary data analysis do not involve interactions or interventions with humans, they may still require IRB review, because the definition of

“human subject” at 45 CFR 46.102(f) includes living individuals about whom a researcher obtains identifiable private information for research purposes.

In general, the secondary analysis of existing data does not require IRB review when it does not fall within the regulatory definition of research involving human subjects. This includes public use data sets, and datasets have been stripped of all identifying information and there is no way the data could be linked back to the subjects from whom it was originally collected.

Restricted use data sets frequently contain identifiers or extensive variables that combined might enable identification, even though this is not the intent of the researcher. Research using these data sets requires IRB review.

INSTITUTIONAL RESEARCH

Institutional research and surveys of students required by state or federal funders such as for program evaluation or quality improvement generally do not require IRB approval. When it is unclear whether a survey is being conducted for research purposes or program evaluation or quality improvement, the responsible party should consult with the IRB Chair.

SECURITY FOR RESEARCH INVOLVING ELECTRONIC DATA

- All data collection and storage devices must be password protected.
- Non-College devices for use in research should have up-to-date antivirus and protection software.
- Identifiers, linking codes or keys should be placed in separate, password protected or encrypted files.
- Identifiers should not be stored on mobile devices, flash drives, or other portable devices [excluding laptops]. If the protocol deems use of a portable device as necessary then the data files should be encrypted. The Principal Investigator (“PI”) is responsible for consulting with the College’s Information Technology Services to determine the most secure method(s) for portable devices.
- No protected health information or highly sensitive information should be transmitted via email.
- All data should be transferred onto the PI’s College computer and should not be stored permanently on flash drive devices or portable devices.
- If the protocol mandates destruction after a set period (e.g., 3 years), the PI or Faculty Advisor is responsible for ensuring this is carried out using secure shredding or digital wiping.
- For student PI’s, upon completion of the degree program or any change in affiliation from the College, the student must ensure a formal hand-off of the data; All raw data and consent forms must be transferred to the Faculty Sponsor. The student may retain a de-identified copy of the dataset for future publication, provided this was disclosed in the original IRB application. If the protocol mandates destruction after a

set period (e.g., 3 years), the Faculty Sponsor is responsible for ensuring this is carried out using secure shredding or digital wiping.

- The IRB standards and regulations require maintaining original data for three years after project completion. However, if the risk to the participant is primarily breach of confidentiality through an identifiable data record then the PI should consider, as part of the protocol, a method of deleting or destroying identifiable information (i.e. video files). Data destruction prior to the regulatory requirement must be approved by the IRB.
- Standard security measures like encryption and secure socket layer (SSL) must be considered. Additional protections may include certified digital signatures for informed consent, encryption of data transmission, and technical separation of identifiers.
- The College has a site license for the Qualtrics survey system. This cloud-based tool has been vetted and authorized by the College's Information Technology Services. Other survey tools may be used but it is the responsibility of the PI to understand the "terms of service" and how data may be accessed by the vendor.
- When using Qualtrics (or other survey tools), check the option to anonymize the data collection process and do not collect the IP address. If IP addresses are necessary to the research, include in the consent process that you will be recording this information.
- Use of mobile apps for data collections is permissible. However, it is the PI's responsibility to understand the "terms of service" and how app data will be used by the vendor or shared with third-parties. The PI must relay those terms to the participant and monitor terms for updates.
- The data file used for data analysis should be free of IP addresses or other electronic identifiers. If IP addresses are collected by the survey tool, the addresses should be deleted from the downloaded data file.

APPLICATION SUBMISSION REQUIREMENTS

A PI must submit a proposal to the IRB and receive approval prior to the initiation of the research project, even if previously approved at another institution. Retroactive approval for research studies is not provided.

Applications are submitted as an email attachment to IRB@ramapo.edu. Applications are accepted on a rolling basis from the first day of Fall semester until the last day of the Spring semester. Applications that are submitted after the last day of the Spring semester as indicated on the Academic Calendar are reviewed in the Fall.

The IRB Application, Application Checklist and other relevant resources can be found on the IRB website and in the appendices.

Applications should include all relevant documentation which may include:

- Completed IRB Application for Review of Research with Human Participants form

- Informed Consent Form and/or Assent Form and Parental Consent Form, as applicable
- CITI Program research training certificate for PI and all staff that will interact with subjects or data (no more than three years old)
- Copies of all questionnaires/surveys, interview scripts, etc.
- Debriefing form in the case of deception or sensitive topics that may make debriefing appropriate
- Copies of all solicitation letters, recruitments flyers, emails, phone scripts, etc.
- On-site approval letter and/or IRB approval letter (for research at a non-Ramapo College site, for example, at a hospital, school, clinic, etc.)
- Approval of IRB from an institution outside of the College
- Financial Conflict of Interest Form

Even if a project has been approved by an IRB at another institution, an IRB application must be submitted at the College. However, the College will comply with federal single IRB (sIRB) requirements when applicable.

Applications are approved for one calendar year from the date of approval. If project implementation is delayed, the approval date may be adjusted if no changes are made to the application contents. The PI emails the IRB Chair to make such a request, and if approved the Chair will provide an updated approval letter.

CRITERIA FOR IRB REVIEW

College affiliated members may choose to review the IRB Member Handbook (additional copies are always available from the Chair) in their review process. All IRB members may consult the Study Review Checklist in their review process.

The Chair of the IRB makes determinations on approval in consultation with the Federal Policy for the Protection of Human Subjects--Section 111 of 45 CFR 46 and other guidelines and regulations as appropriate to the proposed study, Co-Chair, IRB members, and the Provost as needed.

LEVELS OF IRB REVIEW AND REVIEW PROCESSES

EXEMPT RESEARCH

In certain cases, the IRB Chair may approve a project application as being eligible for exemption from further IRB review. The determination of exemption is made by the Chair, not the PI. Exemption requests must be submitted to the IRB, and approval received prior to conducting the research, using the procedure described in the APPLICATION SUBMISSION REQUIREMENTS section of this Manual. Research that is exempt from full IRB review does not negate the need for subjects' informed consent where appropriate. See the Federal guidelines detailing such exemptions at the Federal Policy for the Protection of Human Subjects--Section 104 of 45 CFR 46.

An application that is eligible for exempt review requires review by the Chair. Exempt reviews are typically managed via email.

EXPEDITED REVIEW

While the name of this review type implies a quick review, the term “expedited” has nothing to do with the speed of the review. Federal regulations allow certain types of applications to be reviewed by a single reviewer instead of a full committee, and the term for this type of review is “expedited”.

A research study may undergo expedited review if it involves:

- No more than minimal risk,
- Identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation or be stigmatizing, OR reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal, AND
- Only involves procedures in one or more of the federally approved categories.

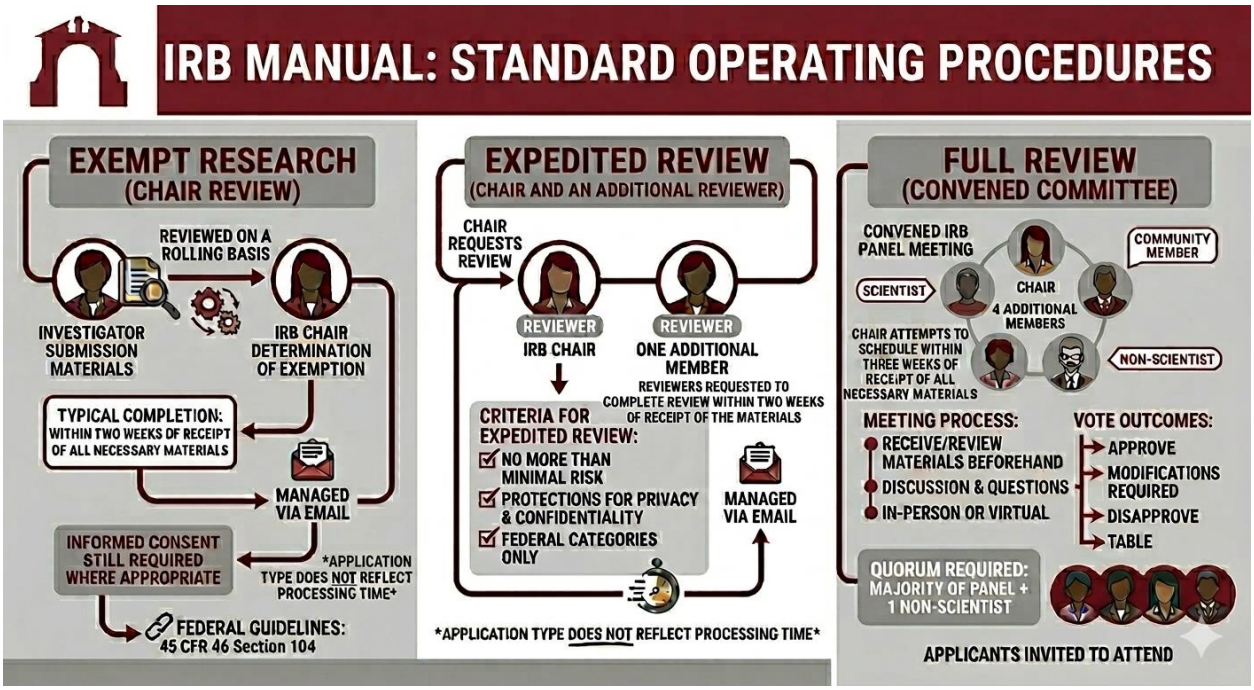
An application that is eligible for expedited review requires review by the Chair and one additional member. Expedited reviews are typically managed via email.

FULL REVIEW

Applications that indicate any more than minimal risk to human subjects require full IRB review. An application that requires full review is reviewed by the Chair and four additional members, one of whom is a Community Member. At least one member who is a scientist, and one who is not a scientist must be part of the review panel.

For applications that require a full IRB review, a convened meeting of an IRB panel must occur. IRB panel members should receive and review application materials before the meeting. The meeting is an opportunity for discussion and asking of questions. Meetings can be held virtually or in person. Minutes of the meeting must be kept. During the meeting, the IRB votes to; approve, require modifications in order to approve, disapprove, or table the discussion until a later time. When a meeting is required, there must be a quorum. Federal regulations require a majority of the panel plus one nonscientist. For a 5-person panel (4 college affiliated and one nonaffiliated member), three members (one chair, one college affiliated IRB member and one community member) constitutes a quorum. Applicants are invited to attend the meeting, but their attendance is not required.

Figure 1. An overview of application types and review processes.



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CONTINUING REVIEW

In general, if data collection will not continue, studies will not require continuing review. All studies with an IRB approval that continue data collection beyond the initial one-year approval period must be reviewed by the IRB. Applications for continued review include an application, additional relevant research materials, a progress report, and a description of any design changes. The request must be submitted at minimum 4 weeks before the expiration date of the prior approval. In their consideration of the application, the Chair reviews the Federal criteria for renewal/continuing review.

Continuing review of research previously provided with an IRB Exempt approval with no changes and no unanticipated problems is not in need of IRB review.

Continuing review of research previously provided with an IRB Exempt approval with changes can be considered as in need of Exempt review.

Continuing review of research previously approved in an IRB Expedited review with no changes and no unanticipated problems can be considered as in need of Exempt review.

Continuing review of research previously approved in an IRB Expedited review with any changes or unanticipated problems can be considered as in need of Expedited review.

Continuing review of research previously approved in a Full IRB review where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for

long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis can be considered as in need of Exempt review.

Continuing review of research previously approved in a Full IRB review where the research involves no greater than minimal risk and no additional risks have been identified can be considered as in need of Expedited review.

Continuing review of research previously approved in a Full IRB review where the research involves greater than minimal risk can be considered as in need of Expedited review.

APPLICATION REVIEW PROCESS AND RECORD KEEPING

The Chair and Co-Chair both maintain full access to the IRB@ramapo.edu email address and Google Drive. All correspondence that includes IRB applications or materials is only sent via College email address. The Chair monitors the IRB email address on a daily basis. Occasionally investigators will send the Chair or Co-Chair correspondence to their own email addresses, but all emails received at other email addresses are forwarded to the IRB email address in order to maintain IRB records.

All applications are processed as follows:

- Application is received via email
- Chair logs application on Google sheet
- Chair creates a Google file and files all materials under the applicant's last name
- Chair reviews application for completeness
- Chair reviews supplemental materials for completeness
- Chair adds additional materials as received
- Chair emails applicant to confirm receipt of application, noting any missing required materials
- Chair determines level of review (exempt, expedited, full, continuing review)

EXEMPT APPLICATIONS

Further processed as follows:

- Chair reviews application and materials
- Chair emails feedback to applicant
- Chair monitors receipt of revised and additional materials
- Chair works with applicant and reviewer(s) until an outcome can be determined
- There are three possible outcomes of the application review:
    - Rejection
    - Conditional approval: Resubmission necessary with modifications.
    - Approval
- When approved, Chair creates an approval letter
- Chair logs the outcome in the Google sheet

- Chair emails a PDF of the approval letter to the applicant and maintains the original in APPROVAL LETTERS folder
- Investigators must notify the IRB Chair of any substantial departures from the original protocol before continuing the research and significant departures require IRB approval

EXPEDITED APPLICATIONS

Further processed as follows:

- Chair emails application and materials relevant to the review to one relevant IRB member to request review
- Chair replaces reviewers who are not available for a particular application
- Chair receives feedback from reviewer and anonymizes feedback
- Chair emails feedback to applicant
- Chair monitors receipt of revised and additional materials, and communicates back to reviewer as needed
- Chair works with applicant and reviewer until an outcome can be determined
    - There are three possible outcomes of the IRB deliberation:
        - Approval
        - Conditional approval: Resubmission necessary with modifications
        - Rejection
- When approved, Chair creates an approval letter
- Chair logs the outcome in the Google sheet
- Chair emails a PDF of the approval letter to the applicant and maintains the original in APPROVAL LETTERS
- investigators must notify the IRB Chair of any substantial departures from the original protocol before continuing the research and significant departures require IRB approval.

FULL REVIEW APPLICATIONS

Further processed as follows:

- Chair emails application and materials relevant to the review to relevant IRB members to request review and convened meeting; three college affiliated members and one community member
- Outside members are unlikely to check their College email address on a regular basis, so when inquiring about availability, the Chair emails the community member indicating that there is a request for review and asking the member to check their College email address for more details
- Chair replaces reviewers who are not available for a particular application
- Chair schedules meeting with panel and invites applicant
- Convened IRB meeting occurs
- Chair records minutes and outcome of IRB panel vote:
    - Conditional approval: Resubmission necessary with modifications

    - Approval
    - Disapprove
    - Table the discussion until a later time
- When approved, Chair creates an approval letter
- Chair logs the outcome in the Google sheet
- Chair emails a PDF of the approval letter to the applicant and maintains the original in APPROVAL LETTERS
- Investigators must notify the IRB Chair of any substantial departures from the original protocol before continuing the research and significant departures require IRB approval
- If the IRB approves a study, continuing review should be performed at least annually if data continues to be collected
- Investigators must notify the IRB at the conclusion of their research

(CONTINUING REVIEW APPLICATIONS are further processed as designated above in LEVELS OF REVIEW AND PROCESSES FOR CONTINUING REVIEW)

APPLICATION REVIEW TIMELINE

Applications reviewed on a rolling basis from the first day of Fall to the last day of Spring semesters. The type of application does not necessarily reflect the processing time. Review timelines are estimates, and are based on when all necessary materials are received.

TYPE	TIMEFRAME
Exempt	Reviewed by the chair within 2 weeks
Expedited	Sent to reviewers, who are asked to review and respond within two weeks
Full	Chair will attempt to schedule convened IRB panel meetings within three weeks

CONFLICTS OF INTEREST

IRB Members and investigators must notify the IRB Chair during the initial review phase if there are any potential conflicts of interest (COI).
COI typically includes:

- Financial interests
- Personal relationships
- Professional ties that may affect impartiality

If an IRB member has a COI related to a specific study, they must recuse themselves from the deliberation of that application.

Federal guidelines and College policies require that an actual, perceived, or potential conflict of interest (COI) in research be eliminated or mitigated. Research personnel involved in the design, conduct, or reporting of research have an institutional responsibility and must disclose any financial interests or relationships that could result in a COI. Investigators must report an actual, perceived, or potential conflict of interest on their IRB application. They must also share their proposal to mitigate the actual, perceived, or potential conflict. If an investigator has a COI, the IRB Chair determines whether to approve, disapprove, or require modifications to reduce the conflict and potential harm to study participants. A PI may appeal the decision after taking steps to mitigate the COI, which the IRB will review.

Failure to comply with disclosure requirements or adhere to the decision made by the IRB may constitute research misconduct.

If a COI arises during the research process, the PI must notify the IRB Chair, who will make a decision on the course of action to be taken.

COMPLAINTS OR ISSUES DURING RESEARCH

Consent forms must indicate the IRB Chair's email address, IRB@ramapo.edu and include a statement indicating the IRB Chair is the contact for concerns or complaints. In cases where consent forms are not required, subjects can be provided this information at the conclusion of the study session verbally or in writing.

Projects may be reevaluated if a complaint is filed with the IRB or if the investigator reports issues with the research. In such cases, the IRB may choose to review the data collected and interview both the research staff and human subjects.

If the IRB determines that this policy has been violated or that the project was conducted in violation of protocol, it shall recommend to the Provost the course of action the College should take, including the possibility of a sanction to be imposed against the investigator. If research misconduct is suspected to have occurred, refer to the College's Policy on Research Misconduct.

SANCTIONS

Sanctions for IRB policy violations shall be recommended by the IRB and submitted to the Provost for action. Sanctions will be commensurate with the type, severity and/or frequency of the offense.

REPORTING REQUIREMENTS

The Vice Provost, who is the College's Research Integrity Officer, or Provost may be required to report violations to the Office for Human Subject Research Participation. For more information, see Reporting Guidelines.

HUMAN SUBJECTS RESEARCH ETHICS TRAINING

Federal and state regulations require that investigators undergo training in the protection of human subjects in research.

INVESTIGATORS

The College requires that all investigators complete the CITI Program Social and Behavioral Researcher Basic training course, successfully pass the certification exam, and include the completion certificate with their application materials. The current training consists of 14 modules with a quiz at the end of each module. This training is funded by the Provost's Office.

Training is required regardless of whether or not the project is funded, and regardless of level of IRB review. Training must include all personnel who will interact with human subjects or data, and it applies whether or not these individuals are compensated.

Although subject to modification based on changing federal guidelines, CITI Program certification must be renewed every three years.

PROVOST

The Provost is required to complete the CITI Program Institutional/Signatory Officials Basic Course.

IRB CHAIR

The Chair is required to complete the CITI Program IRB Members Basic Course, IRB Chair Basic Course, and IRB Administration Basic Course.

IRB MEMBERS

College affiliated IRB members are required to read the *Institutional Review Board: Member Handbook 4th Edition* by Robert J. Amdur and Elizabeth A. Bankert. The IRB Chair distributes handbooks to members upon on-boarding, and the IRB member must read the handbook before reviewing any applications and returning the handbook. The IRB Chair maintains a lending library of handbooks that IRB members can borrow whenever needed as a reference. The IRB Chair keeps a record of members and dates of training completion.

COMMUNITY MEMBERS

Community members of the IRB must complete the CITI Program IRB Community Member Course and include the completion certificate during on-boarding. The IRB Chair keeps these records.

STUDENTS LEARNING RESEARCH METHODS IN A COURSE

College faculty looking for a less intensive educational classroom activity can have students complete the free 5 module course offered by the HHS Office for Human Research Protections (OHRP). Students can complete a quiz at the end of each

module. https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html

The IRB Chair holds the authority to accept alternate training on a case-by-case basis, for example, when investigators are affiliated with institutions other than the College.

ACCESSING CITI PROGRAM TRAINING

CITI Program training is funded by the Provost's office, and is required for investigators and IRB Non-Ramapo affiliated Community Members.

Directions for accessing the researcher training:

1. Go to https://about.citiprogram.org/ click on Register
2. Click on Select Your Organization Affiliation
3. Type on Ramapo College of New Jersey into the search field to find our institute
4. Check off both of these below
    a. I AGREE to the Terms of Service and Privacy Policy for accessing CITI Program materials
    b. I affirm that I am an affiliate of Ramapo College of New Jersey
5. Then click Create a CITI Program Account
6. On the next screen please use the Ramapo Gmail for the Email address
7. Next, you'll create a login and password to your CITI Program account. You don't need to use the same password and username as the Ramapo Gmail
8. Follow through with completing the rest of the registration screens, clicking Social & Behavioral Research investigators for Question 1. Leave Question 2 blank and click Not at this time for Question 3
9. You should now be able to access the Social & Behavioral Basic course. The modules can be completed across multiple sessions.

Note: CITI Program training completed at another institution may be transferred to Ramapo College by affiliating with both institutions. Do not remove your affiliation from past institutions as CITI Program will also delete training records acquired at that institution

Directions for accessing the Community Member training:

1. Go to https://about.citiprogram.org/ click on Register
2. Click on Select Your Organization Affiliation
3. Type on Ramapo College of New Jersey into the search field to find our institute
4. Check off both of these below
    a. I AGREE to the Terms of Service and Privacy Policy for accessing CITI Program materials
    b. I affirm that I am an affiliate of Ramapo College of New Jersey
5. Then click Create a CITI Program Account
6. On the next screen please use the Ramapo Gmail for the Email address
7. Next, you'll create a login and password to your CITI Program account. You don't need to use the same password and username as the Ramapo Gmail

8. Next, ADD A COURSE
9. One question offers the option to choose " I Have Agreed to be an IRB Community Member. Now What?" Please select that and leave all of the other questions unanswered
10. This will bring you to a set of materials that you can read through at your convenience
11. Once you verify that you have completed the reading you will be provided with a certificate of completion
12. Download and save this certificate and send it to IRB@ramapo.edu, you can officially be added to our board

EXTERNAL FUNDING

If external funding is being requested for a study, the applicant indicates this on the application and an IRB member from the Office of Grants and Sponsored Programs serves on the panel that reviews the IRB application.

STUDENT RESEARCHERS

IRB REVIEW NEEDED	IRB REVIEW NOT NEEDED	
Doctoral, Master's, Undergraduate Honors, and Independent Study projects that involve human subjects research that is not conducted in the context of learning skills in a research methods course. Student research projects that will be presented in a forum outside of the College. Student research projects that will be published in a thesis or dissertation.	Student research projects that are being conducted in the context of learning research skills in a course, if: • will not be presented in a forum outside of the College • will not be published in a thesis • does not exceed minimal risk	Course assignments where students are asked to collect information from people or to use real world data about humans (e.g., human subjects datasets) to learn skills or course-related content and are designed exclusively for the educational benefit of the student with no intent of contributing to knowledge (e.g., through publications/presentations or otherwise sharing the knowledge gained outside the classroom) Examples may include having students interview people to learn interviewing techniques in a research methods course, conduct Piagetian-style experiments for a child development course, or analyze datasets that include real information about people for a statistics course.

Student research projects that exceed minimal risk.		
Research conducted by students is reviewed by the IRB.	Research conducted by students in the context of learning research skills in a course is the responsibility of the course instructor. • Instructor is required to undergo the online training provisions listed in the HUMAN SUBJECTS RESEARCH ETHICS TRAINING (for investigators) • Instructor must use the Ethics Review Form for Course Related Research • Instructor acts as the research review chair with responsibility for reviewing the proposed project • Instructor oversees the research, ensuring that students adhere to human subjects policies in their activities	Research skills practiced in a course are the responsibility of the course instructor.

VULNERABLE POPULATIONS

The Federal Office for Human Research Protections identifies vulnerable populations, defined as groups who may be at increased risk of coercion or undue influence, as requiring additional protections under the federal regulations 45 CFR 46.

Research that involves minors (i.e. persons under the age of 18); a targeted population of adults whose ability to freely give informed consent may be compromised (i.e. persons who are socio-economically, educationally, or linguistically disadvantaged, cognitively impaired, elderly, terminally ill, or incarcerated); pregnant people and/or fetuses who may be put at risk of physical harm; a topic of a sensitive or personal nature, the examination or reporting of which may place the research participant at more than minimal risk, or any type of activity that places research participants at more than minimal risk must be reviewed by a full IRB panel.

PUBLICATIONS AND OTHER DISSEMINATION

Whether faculty, staff or student-led research, if the results of a study will be published, presented at a conference off-campus in a poster session or other form, included in a dissertation or thesis or disseminated in some other way, the project must be submitted to the IRB for review.

STUDENTS IN AN INVESTIGATOR'S CLASS AS SUBJECTS

While encouraging College faculty members to engage in scholarship of teaching and learning, additional measures are taken to ensure that students do not feel coerced to participate in research studies. This is particularly the case when the investigator is also the class professor. These guidelines are for using students who are enrolled in one of the classes an investigator is teaching and covers curriculum-based and non-curriculum-based research. Please note: if the faculty member is only using their students' data for internal evaluation purposes and has no plans to use the data for research purposes, IRB approval is not needed.

These guidelines are designed to assist investigators who wish to use their own current students as subjects in research protocols. An underlying principle of the regulations governing use of human subjects in research is that the subject's participation is voluntary, based upon full and accurate information. The relationship between teacher and student is inherently one that raises the issue of "voluntariness." No matter how well intentioned the instructor is, students may feel compelled to participate, believing that failure to do so will negatively affect their grades and the attitude of the faculty member (and perhaps other students) toward them.

The IRB recognizes, however, that in some research situations, use of one's own students is integral to the research. This is particularly true of research into teaching methods, curricula and other areas related to the scholarship of teaching and learning. The following are two models of research design that may be approved by the IRB for such circumstances which we believe strike a balance between the two interests.

Collection of Data by Third Party

The instructor/investigator should arrange to have the consent forms and data collected by an independent third party so that the instructor does not know who participated, and

does not have access to the identifiable data or identity of participants for any purpose until grades have been assigned and entered.

For example, if the faculty member wants to administer pre- and post- tests to determine the efficacy of a particular curriculum, the necessary consent forms could be obtained, and administration of the tests conducted, by a colleague at times when the instructor was not present. (Note: If anonymous data will be collected (e.g., online, anonymous survey via Qualtrics), a third-party is not required for data collection.)

Collection of Data by Instructor/investigator
In situations where the collection of identifiable data by a third party is not feasible, the IRB will require that the student's written consent to use their own data, e.g., test results, papers written, homework, etc., be obtained:

- By a third party at the beginning of the semester, where the third party holds onto the consent documentation until grades are entered; or
- By the instructor/investigator after grades are entered.

ON BOARDING IRB MEMBERS

The Chair is responsible for recruiting and on boarding new members.

Prospective Community Members will require a College email address and login credentials. The Chair coordinates this process with the prospective Community Member and IT Services.

The Chair provides the necessary training information to the prospective new member.

The Chair records the training completion information and files relevant documentation in the Google drive.

All IRB members must be listed on the IRB website and their information must be registered with the Office for Human Research Protections. The Chair gathers the required information (sex, earned degree, scientist or non-scientist, primary specialty, affiliation with the College Y/N) and provides it to the Provost's Office for submission.

COLLEGE AFFILIATED IRB MEMBERS

The Chair maintains a lending library of the IRB Member Handbook and distributes a copy to each prospective College affiliated member via campus mail. The member reads the handbook and confirms that they have read it, via email to the Chair. The Chair logs the training completion date on the Google Sheet.

COMMUNITY MEMBERS

Prospective Community Members complete the CITI Program Course for Community Members and submit their certificate of completion to the Chair, who files it in Google Drive.

ELEMENTS OF INFORMED CONSENT

No human subject research may be conducted without informing the human subject(s) or the legally authorized representative of the subject of the risks, procedures, and discomforts of the research. Subjects must be clearly informed that their participation is voluntary. When appropriate, a statement illustrating the voluntary nature of the project is included on written questionnaires. When research involves the use of minor participants, written consent must be obtained from a parent or legal guardian. In addition, minor participants over the age of 6 must provide their assent to participate, using a form appropriate for their age level.

Voluntary Informed Consent assures a person's right to exercise free power of choice regarding participation in research. The basic elements of information necessary for voluntary informed consent are:

- A clear explanation of the purpose of the in language appropriate for the subject group (with experimental procedures specifically identified)
- A description of what participants will be asked to do, including expected duration
- Names and appropriate contact information of investigators who are conducting the research
- A description of expected risks or discomforts for participants
- A description of expected benefits both to participants and society from the research
- A disclosure of alternative procedures available
- Description of compensation offered, if any
- Who to contact to answer any questions raised by a subject regarding procedure, concerns, complaints, etc.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
- A statement regarding the freedom to withdraw/discontinue participation at any time without loss of benefits which the subject is otherwise due (especially when the subjects are students enrolled in a class)
- A description of whether data will be collected anonymously, if applicable
- A description of how subjects' confidentiality will be maintained
- A statement that any concerns regarding the rights of the research subject or in the event of a research-related injury to the participant should be directed to the College IRB at irb@ramapo.edu. In cases where consent forms are not required, subjects can be provided this information at the conclusion of the study session verbally or in writing
- Statement of Consent: I am at least 18 years old and I have read the above information. I have had the opportunity to ask questions and receive answers. I consent to participate in the study. (Adjust for child studies where parents would give consent)
- Spaces for signatures and date, anonymous or online consent forms could include a checkbox along with the statement of consent or typing in name and date below the statement.

IRB RECORDS

All records and proceedings of the IRB committee will be maintained by the Provost's Office per section 115 of Code of Federal Regulations 45 CFR 46 and the College's Record Retention Policy. The below steps detail the IRB records process.

All records regarding a submitted study (regardless of whether it is approved) must be retained in an appropriate manner as required by regulatory requirements and/or institutional policy.

All protocol records are stored in the IRB Google Drive that is created and maintained by the Chair. The Chair and Co-chair have login access.

The IRB documentation of the IRB's activities including copies of all items reviewed, including, but not limited to:

- research applications
- recruitment materials
- scientific evaluations (if any) that accompany the proposals
- approved consent documents
- records of continuing review activities, including progress reports submitted by investigators
- any proposed amendments and the IRB action on each amendment
- reports of injuries to participants and serious and unexpected adverse events documentation of protocol violations
- documentation of noncompliance with applicable regulations
- statements of significant new findings provided to participants
- IRB membership roster(s)
- IRB meeting minutes
- copies of all correspondence between the IRB and the investigator

IRB records must also document any determinations required by the regulations and protocol-specific findings supporting those determinations, including:

- waiver or alteration of the consent process
- research involving pregnant women, fetuses, and neonates
- research involving prisoners
- research involving children

The IRB will retain the final approved records regarding an application (regardless of whether or not it was approved) for at least three (3) years. For all applications that are approved, and the research initiated, the IRB must retain all records regarding that research for at least three (3) years after completion of the research. Adequate documentation of each IRB's activities will be prepared, maintained, and retained electronically by the Office of the Provost.

Retained documents may include:

- All research protocols reviewed
- CITI Program certificates
- Recruitment brochures/materials
- Approved informed consent documents
- Continuing review/progress reports submitted by Investigators
- Reports of serious adverse events
- Reported deviations from the protocol and unanticipated problems involving risks to participants or others
- All correspondence between the IRB and the Investigators
- Reports of any complaints received from research participants
- Documentation of serious or continuing non-compliance

Access to IRB records is strictly governed by the "Principle of Least Privilege." Records are not public documents and are available only to:

IRB Members and Chairs: For the purpose of protocol review and administrative duties.

Institutional Officials: When necessary for legal or compliance oversight.

Regulatory Agencies: Including OHRP for audit purposes.

Investigators: Access is limited to their own specific protocol files only.

REVIEW OF THIS MANUAL

The Provost is responsible for the updating of this Manual, which should occur every five years or as may be needed. At minimum every link in the document must be checked to ensure it works and directs to the appropriate webpage.

APPENDICES

Links

Application
Application Checklist
Ethics Review Form for Course Related Research
Financial Conflict of Interest Form
Study Review Checklist