

Proposed revisions for Use of Human Subjects in Research

New text:

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 be found by the IRB to be Exempt from Further IRB Review, but an IRB application and approval must still be obtained. Research by an investigator not affiliated with Ramapo College of New Jersey who proposes to involve Ramapo College of New Jersey 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 Ramapo 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.

Undergraduate and Master level student research projects that are being conducted in the context of learning research skills, 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 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 Ramapo College IRB Procedures. The Ramapo 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.

Current policy:

Use of Human Subjects in Research

No human research shall be conducted or authorized by Ramapo College of New Jersey unless the IRB has reviewed and approved the proposed human research project. Any research seeking financial support from within the college or release time that involves human research requires IRB approval to receive funding, and such applications should stipulate this requirement.

Purpose

This policy establishes a new Institutional Review Board (IRB) at Ramapo College of New Jersey. The IRB will oversee all human research at the college toward the purpose of protecting human subjects. The Institutional Review Board on the Use of Human Subjects in Research is an independent compliance committee mandated by the U.S. Department of Health and Human Services (DHHS) (See Title 45 Part 46 of the Code of Federal Regulations). The most recent version of these regulations, adopted in 1991, includes the adoption of the Federal Policy for the Protection of Human Subjects, generally known as the "Common rule."

Authority

The role of the IRB is to protect the rights and welfare of individuals recruited to participate in research activities conducted under the auspices of Ramapo College of New Jersey. The IRB has the authority to approve, require modifications in, or disapprove all research activities involving human participants that fall within its jurisdiction as specified by both federal and state regulations and elaborated upon in this document.

Definitions

Human Subject (from the Federal Policy for the Protection of Human Subjects—Section 102(f) of 45 CFR 46):

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Institutional Review Board (IRB)

The human research review committee at Ramapo College of New Jersey, which reports to the Provost.

Applicability

This policy applies to all research of any sort involving human research subjects that is conducted by any person who is a faculty or staff member or student at the college, regardless of where the actual research takes place. It also applies to research conducted

~~by individuals who are not faculty members or students at the college, if the human subjects are members of the college community.~~

~~Federal and state regulations require that individuals conducting research undergo training in the protection of human subjects in research. Ramapo College of New Jersey requires that all researchers complete a training course specified by the IRB committee, including students and their faculty advisors. This training will be coordinated by the Provost's Office.~~

Composition of the Institutional Review Board

See IRB membership Requirements at the following

URL: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.107>

- ~~Membership: The standing IRB committee will consist of at least eight members representative of a variety of professional disciplines including at least one external, non affiliated community member. One member of the standing committee should be a representative from the Office of Grants and Sponsored Programs. The external member(s) must not be affiliated with the college. The members will be appointed annually by the Provost upon recommendation by the IRB chair and the Provost's Office. Members will complete the training prescribed in 6.7 before serving.~~
- ~~Standing committee: The standing IRB committee will act as a pool, from which the IRB chair and co-chair select panel members as appropriate for each proposal. The standing committee and panels should be sufficiently qualified through their expertise. There should be consideration of the diversity of the standing committee and panel members in terms of race, gender, and cultural background in order to safeguard the rights and welfare of all human subjects.~~
- ~~Charge: The IRB provides for initial and continuing review of proposals involving human subjects. It assures that the rights of 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 Chair and co-chair should be tenured faculty, and their term should be two years. The chair's term should be staggered with a co-chair whose term should be two years. (The first appointment of these roles at the committee's inception should be two and three years, respectively.)~~
- ~~Every panel shall consist of either the IRB chair or co-chair, one non affiliated community member, and at least three faculty members from the standing committee. Panelists should be selected based on germane subject expertise. There should also be at least one scientist and one non-scientist on a panel.~~
- ~~Committee members and committee chairs shall not be allowed to sit on a panel for their own research proposals.~~

Categories of Research Subject to IRB Review

~~All research using human subjects must be reviewed and approved by the IRB prior to the initiation of the research project. Among the categories of human subject research which require direct IRB review are:~~

- ~~Faculty or staff research projects (including those which are funded).~~

- Research by an investigator not affiliated with Ramapo College of New Jersey who proposes to involve Ramapo College of New Jersey students, staff, or faculty as subjects in the proposed research project.
- Undergraduate student research within Honors and independent study projects.
- Graduate student research projects.
- Studies expected to result in publication, presentation outside the classroom, or public dissemination in some other form.
- Research conducted outside the college if it 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 women 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.
- Undergraduate research projects that have a low likelihood of being presented in a forum outside of the college do not need to undergo IRB review unless the risk exceeds minimal risk. However, all human subject research done by undergraduates is the responsibility of the course instructor, who is required to undergo the online training provisions listed in section 6.7.

Criteria Used for Review of Proposals

The IRB must review and approve the proposed human research project giving consideration to:

- The adequacy of the description of potential benefits and risks.
- Sensitivity to students' ability to give informed consent within faculty research while they are enrolled in that faculty member's course(s).
- The degree of risk and whether the benefits outweigh the risks.
- Protecting human rights and welfare.
- Obtaining voluntary informed consent.
- Providing debriefing about protocol and contact information for possible complaints, as appropriate.
- Whether researchers are competent and qualified.
- The overarching considerations stipulated by the Belmont report: Respect for persons, beneficence, and justice.

Informed Consent

No human subject research may be conducted without informing the human subject (or subjects) or the legally authorized representative of the subject of the risks, procedures, and discomforts of the research. Subjects should be clearly informed that their participation is voluntary. When appropriate, a statement illustrating the voluntary nature of the project should be included on written questionnaires. When research involves the use of minor participants, consent must be obtained from a parent or legal guardian. In addition, the 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, responsible explanation of procedures and purpose in language appropriate for the subject group (with experimental procedures specifically identified).~~
- ~~A description of expected risks or discomforts.~~
- ~~A description of expected benefits.~~
- ~~A disclosure of alternative procedures available.~~
- ~~An offer to answer any questions raised by a subject regarding procedure, concerns, complaints, etc.~~
- ~~Freedom to withdraw/discontinue participation at any time, especially when the subjects are students enrolled in a class. Discontinuing participation will be without penalty and without loss of benefits which the subject is otherwise due.~~
- ~~Appropriate contact information for the researcher.~~
- ~~Maintenance of anonymity of subjects.~~
- ~~Maintenance of the confidentiality of subjects.~~
- ~~An explanation that any concerns regarding rights of the research subject should be directed to the chairperson or co-chairperson of the IRB.~~

~~Procedures for Submitting Research Proposals to the IRB and Gaining Approval to Commence the Project~~

~~A researcher must submit a proposal to the IRB and receive approval prior to initiation of the research project. Each human subject research project proposal should abide by the following steps:~~

~~Protocol for all IRB applications:~~

- ~~The IRB chair (or co-chair in the absence of the chair), and not the researcher, will make the determination of whether a project is exempt from full review.~~
- ~~Applicants will submit an application to the IRB chair electronically when possible.~~
- ~~Research application will include an abstract detailing methodology, the research instrument(s), a risk assessment statement, general time frame of the research, and proof of completion for the IRB training. Additional relevant research materials (i.e. letter of consent, questionnaire, survey, observation protocol) must be provided where appropriate.~~
- ~~Notification of approval from the IRB is required prior to conducting the research.~~
 - ~~There are three possible outcomes of the IRB deliberation:~~
 - ~~Rejection~~
 - ~~Conditional approval: Resubmission necessary with modifications.~~
 - ~~Approval~~
 - ~~Researchers must notify the IRB of any substantial departures from the original protocol before continuing the research and significant departures require IRB approval.~~
 - ~~The normal calendar for IRB approval is:~~

- The IRB normally reviews applications monthly, September through June.
- The committee may convene outside of the normal schedule if the IRB chair approves and a panel can be constituted.

Initial IRB approval is granted for the duration of the project dates indicated on the approval form. Researchers must submit to the chair of the IRB a research renewal notification once per year. Researchers must also notify the IRB committee at the conclusion of their research.

Statement of Concern/Complaint

Any person who has a complaint about a human research project shall submit in writing to the Chairperson of the IRB a statement of complaint and a brief description of the events that document the complaint. The Chairperson shall refer the complaint to the IRB to determine if there has been a violation of protocol. Before or after the interaction with the researcher, subjects should be informed clearly whom to contact for concerns or complaints if such disclosure is appropriate.

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 researcher.

Training

Individuals with projects subject to IRB review (see 6.2 above) must complete a training course and successfully pass a certification exam. The training and test can be found on the IRB web page located on the Provost's Office website.^[1] Training is required regardless of whether the project is internally funded, externally funded, or unfunded. Training must include key foreign and domestic personnel on subcontracts and consultants, and it applies whether or not these individuals are compensated. Although subject to modification based on changing federal guidelines, training is currently required annually for each student investigator and recommended every 3 years for faculty/staff.

The link to the web-based training program required of research personnel may be found on the IRB home page under the Provost's Office website. A report detailing the results of the training should be included in the application.

IRB and Provost Responsibilities

The IRB is responsible for reviewing research protocols concerning human research, evaluating those proposals to determine if they meet the requirements, and approving or disapproving such proposals in a timely fashion. Additionally, the IRB is responsible for handling complaints concerning human research projects and making recommendations on sanctions.

The Office of the Provost is responsible for updating procedures, forms and providing training for researchers through the web based program in section 6.7 above.

~~The Provost's Office will maintain all records and proceedings of the IRB committee (per section 46.115(b) of Code of Federal Regulations 45 CFR 46).~~

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 severity and/or frequency of the offense and may include termination of employment.~~

Exemptions

~~In certain cases, the IRB chair may approve a project application as being eligible for exemption from full IRB review. Exemption requests must be submitted to the IRB, and approval received prior to conducting the research, using the procedure described in 6.5. Research that is exempt from full IRB review does not negate the need for subjects' informed consent where appropriate. Federal guidelines detailing such exemptions can be found here:~~

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c2>

Interpretation

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

Post-Implementation Review

~~Two years after the implementation of these IRB policies, the Provost shall conduct a review of the committee and its procedures with the intention of improving the protection of human research subjects at Ramapo College of New Jersey.~~

~~Appendix: Points of reference addressed in the document in need of creation or implementation:~~

- Approval Form
- IRB website, located on Provost website and maintained by Provost's Office and IRB chair/co-chair
- Repository for the business of the committee in Provost's Office.

~~[1] The link to the University of Montana's IRB training is: http://ori.dhhs.gov/education/products/montana_round1/research_ethics.html~~