Rock Valley College

Conducting Institutional Research

RVC Administrative Procedure (2:30.010)

Background

Rock Valley College has legal and ethical responsibility to protect the rights and welfare of human subjects used in research efforts conducted at the College or by college faculty, staff or students. Consistent with regulations established by the Department of Health and Human Services (DHHS) through the Protection of Human Research Subjects (45 CFR 46), the College has established an Institutional Review Board to develop appropriate procedures for review of research involving the use of human subjects.

All efforts meeting federal definitions of research involving human participants must be reviewed by the Director of Institutional Research. If the research is not exempt, the Director will forward the research request to the College's Institutional Review Board for review and approval prior to initiating data collection.

The procedures guiding the efforts of the College's Institutional Review Board are framed by the ethical principles established in the report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report) of the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research. These ethical principles include the following:

1. Respect for persons
    a. Human subjects should be treated as "autonomous agents."
    b. Human subjects with "diminished autonomy" should be treated with respect.
    c. Human subjects must enter research "voluntarily and with adequate information."
2. Beneficence
    a. Beneficent actions do not harm.
    b. Beneficent actions "maximize possible benefits and minimize possible harms."
3. Justice
    a. Risk and benefits of research should be distributed fairly.
    b. Selection of subjects should be equitable.

Definitions

Autonomous Agent – A person that can execute tasks or make decisions independently with direct human intervention.

Diminished Autonomy – A person who is, but not limited to, minors, persons with illness or mental disability and prisoners.

Research - Per federal regulations, research is defined as, "a systematic investigation designed to develop or contribute to generalizable knowledge." The following proposed efforts would not meet the federal definition of research involving human subjects in the collection or study of data:

- involves existing data and artifacts that are publicly available and human subjects that are not identifiable;
- are from the records of deceased individuals;
- benefit only participants involved and results are shared only within the participant group of study (e.g., members of an organization, stakeholders, or funding agent);
- is intended only for internal evaluation of programs (i.e., for quality improvement) (e.g., assessment for student learning, end-of-course evaluations by students, employee evaluation);
- involves anonymous evaluation or assessment component of a training session, workshop, or event, for adult participants.

Research Involving Human Subjects - This type of research effort involves collecting data from or about living human subjects. It includes scholarly research of faculty and staff, as well as student research (e.g., student dissertation or thesis and other student-initiated research for class or club activity). Evaluation or assessment activity at the College does not meet this definition of research; therefore, such activities do not require IRB review or approval.

Approval – A research proposal is approved if all review criteria are met. A project must be completed within one year of approval or the request needs to be resubmitted to the IRB. Any changes to the project also must be submitted to the IRB.

Approval with Revision – A research proposal is approved with revision if the IRB requests changes before research can begin.

Rejection – If a research proposal is rejected, the researcher cannot collect data. Researchers may appeal this decision.

Appeal – The appeal process may allow a researcher to collect research if an appeal is granted after initial rejection of the project.

Membership

Consistent with guidelines provided in federal regulations, efforts are made to maintain an IRB with members of varied background and sufficient expertise to address research issues. Therefore, at RVC, the IRB is made up of the following members:

- Director of Institutional Research, Chair and Primary Reviewer;
- Vice President of Student Affairs or designee;
- 2-4 Faculty (3-year, renewable term):
    - At least 1 faculty member whose primary academic background is within a scientific area;
    - At least 1 faculty member whose primary academic background is within a nonscientific area;
    - One of the faculty members will be a co-chair
- Community member (not affiliated with RVC)

Any IRB member with a conflict of interest must disclose it to the Chair and recuse themself from discussion and decision making. A conflict of interest involves situations in which an IRB member has personal, financial, or non-financial interest in the research that could potentially bias the review process.

IRB members must maintain confidentiality of all aspects of research proposals reviewed, including, but not limited to, applicant names, project topics, human subject data and information collected.

Review Process

The IRB is responsible for reviewing all proposed research involving human subjects at Rock Valley College. In doing so, the IRB is charged with protecting the rights and welfare of human subjects. Each proposed research project will require completed research request documentation and all associated forms, as directed. No research request will be reviewed until all required documentation is completed and submitted to the IRB. Research request documentation can be found on the Institutional Research & Effectiveness page of the RVC website.

The primary reviewer of the IRB within the Office of Institutional Research & Effectiveness will review research request documentation for thoroughness and accuracy of completion.

The chair of the IRB, the Director of Institutional Research, will further review the proposal to determine if the research falls into the exempt category. If not, the full IRB will review research request documentation submitted and make one of the following recommendations:

- Approved

- Approved with Revisions
- Rejected

Categories of Review

Federal regulations distinguish among types of research and define three categories of review – exemption, expedited review, and full review. While some research will need to go through full review, certain minimal risk projects may be exempt from review requirements or eligible for expedited review. The Chair of the IRB will use decision charts provided by the federal government to assist in category identification of proposed research involving human subjects.

Exemption

Federal regulations identify eight categories for research involving human subjects that can be classified as exempt. The IRB may not alter these categories. At RVC, determination of exempt classification is done by the IRB through the primary reviewer. As such, even if the researcher believes that the proposed research involving human subjects meets exempt classification, research request documentation must be completed and submitted for primary review. Upon primary review, the proposed research will be categorized as exempt, recommended for revision, or submitted to expedited or full review.

Expedited Review

Some research may be reviewed by one or more designated members of the IRB through the expedited review process. To be eligible for expedited review, the research involving human subjects must meet both of the following criteria:

- Present no more than minimal risk - per federal regulation, minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
- Involve procedures within expedited categories per federal regulations found on the US Department of Health and Human Services website

In addition, minor changes to already approved/ongoing research can be reviewed through expedited review if the changes do not affect the risk-benefit ratio or substantively change the previously approved study design.

The outcome of expedited review can include approval, request for revision or additional information, or request for full review. Consistent with federal regulations, the primary reviewer will communicate with the full IRB about those research requests approved through expedited review.

Full Review

Research not meeting criteria for exemption or expedited review must be submitted to the IRB for full review as described above.

Timeline

After submitting all relevant documentation, Principal Investigators (PIs) can expect to be notified on the status of their request via email. After a week, the PI will either receive a request for more information on the research proposal, a notification that the proposal is being sent for full review, or be told that it qualifies as exempt human subjects research. If the request is sent to full IRB review, results can be expected within three weeks.

Review Criteria

As stated previously, the ethical principles of autonomy, beneficence, and justice as outlined in the Belmont Report will guide the review of all proposed research involving human subjects. In addition, criteria set forth in federal regulations define conditions which must be met. These criteria are articulated in the Research Proposal Review Checklist found on the Institutional Research & Effectiveness page of the RVC website. Per regulation, all of these conditions must be met for proposed research involving human subjects to be approved.

Federal regulations indicate that approvals may be granted for no longer than a one-year period. Research extending beyond a one-year period will need to go through continuing review.

Informed Consent

Researchers must obtain legally-effective, informed consent of the subject or the subject's legal guardian/authorized representative prior to the start of data collection. When research involves a minor, the researcher(s) must obtain informed consent of any subject under the age of 18 who is capable of reading and understanding the consent form, in addition to their legal guardian/representative's informed consent. For informed consent to be legally effective, it must be in language understandable to the signee and obtained in circumstances that allow signee ample opportunity to consider participation. Furthermore, legally-effective, informed consent should not include language that would have the signee waive or appear to waive legal rights or release the researcher from liability for negligence.

Research that involves video or audio taping of subjects requires separate consent to participate in such recording activities.

Informed consent forms given to human subjects of research must be submitted to and approved by the IRB during the request to conduct research process. An

informed consent template is available on the Institutional Research & Effectiveness page of the RVC website.

If the researcher modifies consent forms that have previously been approved by the IRB during the initial request to conduct research, the researcher must notify the Director of Institutional Research as Chair of the IRB and submit revised documents for IRB approval. Documents that need to be submitted include the following:

- The original, IRB approved version of the consent form
- The original, IRB approved version of the consent form with revisions highlighted
- The revised copy of the consent form as it would appear to the research subjects

Additional Protections for Children and Other Special Populations

In compliance with Subparts B-D of 45 CFR 46, as amended, the IRB gives special consideration to proposed research involving potentially vulnerable groups including, but not limited to, pregnant women, prisoners, and children.

Of particular concern is research involving children or minors as subjects. In addition to IRB approval, parental permission must be obtained prior to beginning any research involving children, including classroom-based research. Parental permission may be waived when the child is legally identified as an emancipated minor or in cases where the IRB determines parental permission is not a reasonable requirement to protect the subjects. In addition, minors must also agree to participate in the research (verbally or in writing) unless the IRB determines that their capacity to do so is too limited.

Compliance with IRB Decisions

Researchers must comply with all IRB requirements and decisions.

If the IRB becomes aware of research involving human subjects being conducted without an IRB review and decision, a full review will be conducted to determine the level of risk and harm of subjects. Based on this review, the IRB will make recommendations to the Vice President of Institutional Effectiveness & Communications as to the following:

- whether or not the researcher(s) should be allowed to make use of the data;
- whether or not to notify the funding agency, publication outlet, and/or thesis/dissertation chair that data were collected without IRB approval;
- whether or not any additional action needs to be taken to document or respond to the incident

Rock Valley College

Appeals Procedure

The primary investigator (PI) will be notified if the IRB rejects, suspends, or terminates a project by written correspondence which will include instructions for the PI to respond in writing to the decision. If clarification is needed, the PI will be instructed to contact the primary reviewer.

PIs may appeal an IRB decision if one or more of the following circumstances are met:

- Conflict of interest of IRB members(s)
- Timeliness of committee response
- Perceived bias of IRB member(s)
- Decision is beyond the scope of an IRB (i.e., respect for persons, beneficence, and justice)

Submission of Appeal

Appeals should be made in writing to the IRB Chair, who will instruct the investigator to provide the rationale and supporting documentation/materials for full IRB review.

Appeal Review Process

The primary reviewer will forward the appeal documents/materials to the IRB for discussion at the next full committee meeting. The Vice President of Institutional Effectiveness and Communications will be notified of the appeal and attend the meeting.

The primary reviewer will notify the PI in writing of the IRB final decision regarding the current appeal. In this notification, PIs will be informed that they can direct additional unresolved questions, express concerns, and convey suggestions to the Vice President of Institutional Effectiveness & Communications. The decision of the IRB to reject, suspend, or terminate a protocol may be overturned by the Vice President of Institutional Effectiveness & Communications if at least one of the following conditions are met:

- The research met conditions for exemption from full IRB review
- A conflict of interest or personal bias of IRB members(s) impacted the decision
- The decision to reject research was beyond the scope of an IRB (i.e., respect for persons, beneficence, and justice)

The Vice President of Institutional Effectiveness & Communications will provide a written rationale for the decision to both the PI and the IRB.

Reference: Board Report #6201

Rock Valley College