Research Involving the Use of Human Subjects

Updated: August 2013

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 CRF 46)[1], the College has established an Institutional Review Board to develop appropriate procedures for review of research involving the use of human subjects.

Board Policy (#105)
The College will develop procedures which ensure that research conducted at, for, or through Rock Valley College properly protect the rights of research participants and safeguard the College.

All efforts meeting federal definitions of research involving human subjects conducted by RVC faculty, staff, and students must be reviewed and approved by the College's Institutional Review Board 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 a 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."[2]
    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.

[1] Unless otherwise stated, federal regulations and guidelines in this document refer to 45 CFR 46.
[2] Per the Belmont Report, *autonomy* exists when an individual has the ability to deliberate and act on personal goals. Individuals often considered having *diminished autonomy* include, but are not limited to, minors, persons with illness or mental disability, and prisoners.

DEFINITIONS

Research

Per federal regulations, research is defined as, "a systematic investigation designed to develop or contribute to generalizable knowledge."

NOTE:
Evaluation or assessment activity at the College does not meet this definition of research; therefore, such activities do not require IRB review or approval.

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).

The following proposed efforts would <u>not</u> 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 human subjects involved and results are shared only within the human subject 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)
- involves anonymous evaluation or assessment component of a training session or workshop for adult participants

RVC INSTITUTIONAL REVIEW BOARD (IRB)

IRB 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:

- Executive Director of Institutional Research, Chair and Primary Reviewer
- Associate Vice President of Student Development
- 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
- Community member (not affiliated with RVC)

IRB 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

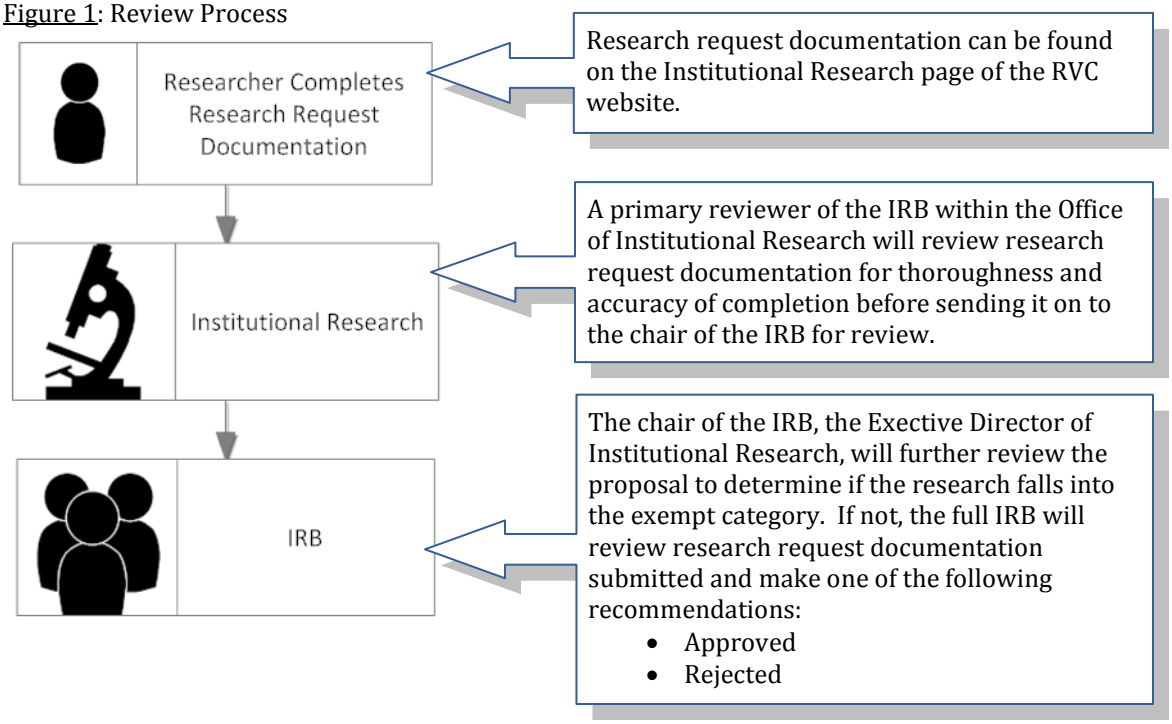
NOTE
Research request documentation can be found on the Institutional Research Page of the RVC website.

Executive Director of Institutional Research. Figure 1 outlines the process of review at RVC for proposed research involving human subjects.

Conflict of Interest
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. Any IRB member with a conflict of interest must disclose it to the Chair and recuse him or herself from discussion and decision making.

Confidentiality
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.

Figure 1: Review Process



CATEGORIES OF REVIEW

Federal regulations distinguish among types of research and define three categories of review – exemption, expedited review, and full review. While most 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 six categories[3] 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*[4]
- Involve procedures within expedited categories per federal regulations

In addition, minor changes to already approved 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 and outlined in Figure 1.

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 page of the RVC website. Per regulation, all of these conditions must be met for proposed research involving human subjects to be approved.

All documents approved by IRB (e.g., research request documentation, consent forms, and data collection tools) will be stamped as such, along with the date of the approval.

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 new review.

---

[3] Detailed information on these six categories can be found on the Institutional Research page of the RVC website.
[4] 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.*

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. The researcher(s) must also obtain informed assent of any minor subject who is capable of reading and understanding the consent form. In order 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.

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. Additional information about informed consent and sample consent forms are available on the Institutional Research page of the RVC website.

NOTE
Research that involves video or audio taping of subjects requires separate consent to participate in such recording activities. Information on this type of consent form can be found on the Institutional Research 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 Executive 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.

As mentioned previously, RVC IRB approval will be stamped, along with the approval date, on all consent forms.

Additional Protections for Children and Other Special Populations

In compliance with Subpart B of 45 CRF 46, as amended, the IRB gives special consideration to proposed research involving potentially vulnerable groups including, but not limited to, children, people with physical or mental handicaps, pregnant women, and prisoners.

NOTE
Sample consent forms, including those to be used in research involving minors, can be found on the Institutional Research Page of the RVC website.

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. Appeals should be made in writing to the IRB through the Office of Institutional Research.

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 Provost/Chief Academic Officer 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