04.22 Institutional Review Board Policy and Procedures

Purpose of the IRB: Protect the welfare, rights and privacy of RVCC students, faculty, and staff who might be asked to participate in research studies as subjects of those studies. Specifically, the IRB must ensure that human subjects are aware of their rights, and are informed of any risks arising from their participation in research studies. Assurances must be provided that risks are minimized and anticipated benefits are maximized.

Making Application: All principle investigators (the individual with primary responsibility for the research project), whether they be RVCC employees or students, or employees or students of an external organization or institution, who are planning research involving RVCC human subjects, are responsible for initiating the review process. All research, including that which the investigator believes is exempt from review, must be submitted to the initial reviewer for confirmation of the relevant review category. After completing the preliminary assessment of risk, the initial reviewer will refer the application to the Chair of the IRB with his/her recommendations.

For members of academic departments, the initial reviewer shall be the Senior Vice President for Academic Affairs, or his/her appointed proxy. For RVCC administrative employees, the initial reviewer shall be the immediate supervisor. Students will have their requests initially reviewed by the department chair for their major.

Categories of Review status: Applications should be placed into one of three categories, chosen initially by principle investigator. S/he must make the election based on personal knowledge of research activities.

Exempt – Proposals involving no foreseeable risk to research participants will be considered exempt. Anonymity of human subjects is guaranteed. Proposals can be submitted to the IRB Chair at any time. Projects granted this status will not require further review by the IRB. The determination may be made by the Chair of the IRB acting independently. Final clearance must still be granted regarding the project's FERPA status by the Registrar. Other criteria apply and are noted below.

Expedited Review – Proposals involving no more than minimal risk. Assurances of confidentiality must be clear. These proposals can be sent to the Chair of the IRB at any time during the academic year. The Chair will distribute copies of the proposal to the IRB membership for independent review, with project status determined by vote at the next meeting. FERPA review is also required.

Full IRB Review – Research involving greater than minimal risk to participants and collection of data that can be linked to research subjects. Proposals must be submitted to the Chair of the IRB two weeks before the first IRB meeting of the fall or spring semester. The proposal will be discussed and a determination made at a meeting of the full board, scheduled by the Chair. FERPA review is also required.

What type of research is covered by this policy?

According to the Common Rule (Federal Document 45 CFR 46), research is technically defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". The distinction between the conduct of basic or applied research is applicable in this instance, but the definitions of each are not self-evident in reviewing research proposals. The task of identifying the characteristics of "generalizable knowledge" falls to the IRB. Often the use of the results determines whether a project is research. The intent to publish or make a presentation at a conference, with the results of the study made public, suggests IRB review as a research project. There are other characteristics also.

Interaction or intervention with the individual for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Intervention* includes both the physical procedures by which the data is gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Conducting interviews, collecting survey responses, or observation of behavior, even if unobtrusive, are examples to be considered.

Obtaining or accessing individually identifiable private information for research purposes. The term *identifiable private information* is subject to determinations made by the IRB, with proper regard for the protections provided students by FERPA legislation. Accessing students records in the Banner system or collecting oral histories are relevant examples. Sensitive data, connected to the individual, that may be embarrassing to reveal, suggests more than minimal risk and requires a review by the board, even if the research subjects are faculty or staff.

Not all projects are research, and not all research is subject to IRB review. In the first instance, as an example, when data collection by students occurs in a classroom, for the purpose of learning some aspect of research methodology, the educational process is not considered research, as the results of the process may be of little importance. In the second case, considerable activity occurs on our campus that follows accepted research procedures, but the results are not viewed as contributing to "generalizable knowledge". Examples of such an activities include administration of the IDEA course evaluation, the CCSSE survey, and the PACE questionnaire. All of these are research instruments, but the individuals completing them can not be traced their responses, they are anonymous, and the results are used to directly benefit the college, not a body of educational or social science literature. There is a legitimate educational purpose and the researcher is acting as an agent of the college.

Exempt Status

The Common Rule lists six categories of research that are exempt from review. Three of them are particularly relevant to our purposes. They are:

(1) research in education settings on instructional techniques, curricula, or classroom instructional techniques, and

(2) research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior, unless

(a) the subject can be identified and disclosure of the subject's responses could put the individual at risk of criminal or civil liability or
(b) the results could damage the subject's financial standing, employability, or reputation, and

(3) research involving the use of existing data, documents, records,… if these sources are publicly available or if the information is recorded by the investigator in such a way that subjects cannot be identified, directly or through identifiers linked to the subjects.

It is significant to note that it is the IRB who determines the presumed level of risk for research participants, and not the principle investigator. While any researcher may apply for exempt status, granting that status is the IRB's responsibility.

In IRB rulings on other campuses, the definition of risk has been extended beyond the cryptic statement contained in the Common Rule noted above (in section (a)). If research subjects might be adversely affected by their participation in a study and as a result become angry, stressed, embarrassed, or depressed, an exemption from review should not be provided. In addition to the exceptions just noted, research involving the collection of sensitive data, such as sexual behavior or drug and alcohol use, cannot be exempt from review. Nor can research involving special populations, including prisoners, pregnant women, the seriously ill, the mentally compromised, or subjects under the age of 18. In all cases the subjects must be given notice of their rights, in an informed consent document, unless otherwise noted in section (1) or (2) above.

In a sense, the term "exempt from review" is a misnomer. All research proposals must be reviewed. The "exempt" status does mean the review process need not be conducted by the entire IRB. It also means the project need not follow continuing review procedures, an annual process for studies not "exempt". If the project is not granted "exempt" status, then it must be submitted for review according to either the "expedited" or "full-review" protocol.

Criteria for Expedited Review

Proposals that are deemed ineligible for exempt status can apply for further consideration by the IRB. Research activities that present no more than minimal risk, with assurances that reasonable and appropriate protections will be implemented to prohibit breaches of confidentiality, qualify for expedited review. Another criterion is that the participants must not be recruited from special populations, as noted previously. The research proposal must also meet standard principles of informed consent, so as to also satisfy the

requirements for FERPA. The results of the independent judgments of the IRB members are presented at the next regularly scheduled meeting of the IRB.

Full Review

Research that involves more than minimal risk, recruits from special populations, seeks waivers from informed consent procedures, or lacks the guarantees of confidentiality, must apply for full review. Studies in which a guarantee of anonymity cannot be provided, will require participants be provided with the opportunity to sign an Informed Consent Statement. The review process can only occur at regularly scheduled meetings of the IRB, and the application must fully address all the requirements for submissions prior to consideration.

Mandatory Full Review

There are two instances where a research proposal must undergo a full IRB review. If the research is funded by external monies, especially from federal sources, a full review must be completed. Also, if the research is conducted by an outside investigator, they must submit the results of their own institution's IRB approval and complete an RVCC Request for Research Approval.

How to Apply

A complete application is necessary for all categories of research proposals. Each proposal should indicate the purpose of the project, a description of the subjects, including how they will be recruited, a full description of all procedures, and copies of all instruments.

The principle investigator must make the initial decision regarding the category of review for which s/he is applying. If there will not be any information collected that can be used to identify the subjects, and if the study involves no possible harm to subjects, application can be made for the ***exempt*** category. If there is any uncertainty, it is better to err on the side of caution. If subjects can be identified with their responses, then apply for an ***expedited*** review. If the subjects might be adversely affected by their participation, then apply for a ***full review***. Use of subjects from vulnerable populations also requires a ***full review***.

When applying for an exemption, the PI should provide sufficient information to help the IRB determine if the proposal meets the criteria for exemption. The application should include the following:

(a) A brief description of the study.

(b) A brief description of how subjects will be recruited.

(c) A copy of the data collection instrument(s).

(d) A copy of the consent form which will be given to the subjects.

Application for Expedited or Full Review

An application for review of human subject's research proposals should include the following elements:

(1) A statement of the purpose of the research written in a language understandable for a person unfamiliar with that field of study.

(2) A list of the questions the research is designed to address.

(3) A summary of the literature search with sufficient detail to provide assessment of the level of risk associated with such studies.

(4) A clear rationale for doing the research.

(5) A description of the subject pool, noting especially members of vulnerable populations.

(6) An explanation of how subjects will be recruited.

(7) A chronological outline of the specific procedures to be followed during the course of the study.

(8) An explanation of the possible risks or discomforts that subjects may experience.

(9) An explanation of the potential benefits to the subject for participating in the study.

(10) An explanation of who will have access to the data during and after the study, how the data will be stored, and what will happen to the data once the study is completed.

(11) A detailed list of all instruments used in the study, including copies of all tests, surveys, questionnaires, etc.

(12) A comprehensive description of the informed consent process.

(12) A description of how confidentiality will be maintained, and, if anonymity is guaranteed, the procedures for gathering data.

(13) If the information gathered from the research will be shared with anyone, provide an explanation of who will have access, how it will be shared, and for what purpose.

Elements of Informed Consent

The most important element in the IRB review process is the requirement that the researcher obtain the informed consent of subjects who are asked to participate in research projects. This also includes, when appropriate, the consent of the subject's legally authorized representative, such as the parent or guardian of a student under age 18. Subjects must be given the right to decide what may or may not happen to them. The document must be written in language that is age- and culture appropriate. Points to be addressed for informed consent include:

(i) An explanation of the purposes of the research, the expected duration of the subject's participation, and a description of the procedures to be followed.
(ii) A description of any reasonably foreseeable risk or discomforts.
(iii) A description of any benefits to the subject that might be expected from the research.
(iv) A disclosure of any appropriate alternative procedures that might be advantageous to the subject.
(v) A statement describing the extent, if any, to which the confidentiality of records identifying the subject will be maintained.
(vi) An explanation of whom to contact for answers to pertinent questions about the research and the subject's rights.
(vii) Most importantly, a statement that participation is voluntary, refusal to participate does not incur a penalty, and the subject may discontinue participation at any time without penalty.
(viii) Finally, a line for the subject's signature, and the date of consent.

Provision of an Informed Consent document and attendant signatures, should not be misconstrued as a substitute for FERPA compliance. At the completion of the IRB procedure, the principle investigator must still seek a judgment from the FERPA officer on campus.

Composition of the IRB

The IRB shall have five members, with varying backgrounds, to promote complete and adequate review of research activities commonly conducted by the institution. The membership should be sufficiently qualified through experience and expertise, and sensitive to such issues as race/ethnicity, gender, and cultural differences. One member of the IRB should come from a non-scientific discipline, one from the health and biological sciences, one from sociology, one from psychology, and one other from a discipline that utilizes quantitative and/or qualitative research methods. The Director of Institutional

Research and an administrator from the Academic Affairs Division shall serve as *ex officio* members.

Responding to IRB Decisions

The IRB may render four opinions regarding proposals submitted. The first, **approved**, requires no further action from the principle investigator prior to initiating the study. The second, **conditional approval**, specifies certain conditions that must be met before conducting the research. The investigator is required to submit an explanation of how the conditions were met to the chair of the IRB, who can either accept the explanation as submitted, or refer to the full IRB for review. The third, **revise and resubmit**, requires that additional information be submitted to the IRB to clarify issues or provide additional documentation. Upon submission of the requested information, the full IRB shall rule at its next meeting. The final decision, **denial**, means the proposed research cannot be initiated. Reasons for the denial are provided in writing. The principle investigator may request a reconsideration by the IRB at its next meeting.

An investigator who receives an adverse ruling from the IRB may request a review of the decision. The PI's written arguments and supporting materials should be provided in advance of the next IRB meeting. If, after a final IRB judgment, the PI remains unsatisfied, s/he may request further mediation with the IRB and the Senior Vice President for Academic Affairs. If the IRB decision is not reversed once this mediation is concluded, there is no further appeal.

Following Approval

Final approval by the IRB is not the end of the review process. The research proposal must still be reviewed and approved by the campus FERPA officer before a project is initiated. The IRB cannot grant such approvals.

The IRB Chair will communicate all approved projects to the office of the Senior Vice President for Academic Affairs. The Senior Vice President, or designee, will ratify the IRB's approval, transmit the authority to begin the research project to the principle investigator, and serve as the official record keeper for all approved research projects.

For projects of short duration, those lasting less than one year, no further reviews are necessary. There are exceptions however. If the principal investigator needs to change an approved protocol, s/he needs to send a memo to the IRB Chair explaining why changes are needed and then attaches copies of documents highlighting the changes.

For projects of longer duration, beyond one year, continuation of the research is conditional. On the yearly anniversary of the project, the principle investigator must supply the IRB Chair with updates, noting any changes. PIs are notified of actions taken following the meeting of the IRB. Annual approvals are necessary for all categories of review.

RESPONSIBLE ADMINISTRATOR – Senior Vice President for Academic Affairs

REVISED AND REAFFIRMED

- April 2016