

Institutional Assurance Concerning Human Research
Victor Valley College Institutional Review Board (VVC-IRB)

Guiding principles

In compliance with the Department of Health and Human Services (DHHS), Victor Valley College (VVC) is committed to safeguarding the health and safety of VVC's students and staff who participate as subjects in research activities, as defined below. The intent of the VVC-IRB is to protect the rights of participants including the right to informed consent and protection from undue risk as stated in federal regulations (45CFR46.102). The VVC-IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by local institutional policy.

The primary questions for the investigator are:

- 1) Does the activity involve **Research**?
 - Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable* knowledge (45CFR46.102 (d)).
- 2) Are **Human subjects** involved?
 - Human subjects are defined as living individual(s) whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (45CFR46.102 (f) (1), (2)).

Any investigator who is unsure of whether his/her proposal constitutes "human subjects research" should contact the VVC-IRB. The IRB committee will make this determination and if IRB regulations are not warranted, correspondence will be provided stating that the project does not require IRB approval.

What constitutes a review?

- **Exempt**

These assignments are usually not intended to contribute to *generalizable* knowledge. Therefore, they would not be considered "research" since they are being conducted for educational purposes and only used in Victor Valley College classes. In most cases these assignments include educational testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation; and research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded that can link subjects to the data.

The federally-approved Categories of Exemption are:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: (a) research on regular and special education instructional strategies; (b) research on the effectiveness of or the comparison among instructional techniques curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the

investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

4. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

Exempting an activity from review does not absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

- **Expedited**

The VVC-IRB must review projects which are considered to be “research” and involve human subjects. Because these projects may consist of obtaining information through interaction or intervention with individuals for the purpose of **generalizing** the results (e.g. publication or presentation), care must be taken to safeguard the participants as defined in VVC’s guiding principles.

Expedited review may be granted if the following conditions are met:

- The protocol consists only of the administration of a written survey or questionnaire.
- Participants will NOT be audio- or videotaped.
- No members of at-risk populations (e.g. minors, pregnant women and prisoners) will be enrolled in the study.
- The survey instrument will include the appropriate statement of voluntary participation provided in the consent form.
- There are no foreseeable risks or discomforts (physical, emotional or psychological) associated with participation in the study.
- Participants will not receive monetary compensation.
- The survey instrument will ensure participant privacy by being distributed in such a way as to leave no public record of participation.
- No personally identifiable information will be reported in any published or unpublished work.
- Access to the data generated by this survey will be restricted to the investigators listed in this proposal.

- **Full**

If significant errors are noticed on the VVC-IRB application or the items as discussed in the expedited review are not met, a full review is warranted. This entails the gathering of board members to meet in person in order to further review the application. Amendments to approved protocols will be reviewed and IRB recommendations will be provided to the applicant via the VVC-IRB change matrix. Only until all recommendations are satisfactorily met by the applicant, will approval be granted.

Composition of the VVC-IRB

The VVC-IRB will consist of the following constituencies: Full and/or Part-time faculty, Classified, and Management employees. The VVC-IRB Chair, convenes VVC-IRB meetings, and is responsible for maintaining minutes of these meetings and records of VVC-IRB actions.

- **Essential elements:**

- 1) Members must obtain OHRP certification for “[Protecting Human Research Participants](#).”
- 2) Members will be qualified through their experience, expertise, and diversity.
- 3) Membership will total at least five individuals, 4 of whom will be from the college.
- 4) Membership will consist of diverse backgrounds and professions.
- 5) Members will not be entirely men or women.
- 6) Members will not be entirely from one profession.
- 7) At least one member will have primary expertise in a non-scientific area.
- 8) At least one member will be unaffiliated with the college.

Submission to VVC-IRB

Application forms are available from the VVC Research Office. Completed applications receive a preliminary review by Research Office staff and are forwarded to the VVC-IRB chair who is responsible for convening the IRB meetings. Applications will be reviewed on an as needed basis. Requestors must complete the “Application to Institutional Review Board for Review and Approval of Research with Human Participants”

Timelines for Submission

It is recommended that research proposals be submitted to the VVC-IRB at least two months before the research is to begin in order to allow sufficient time for the review process.

(These timelines are only recommendations. Protocols may be processed more quickly if the VVC-IRB does not require revisions or additional information.)

Additional Resources

United States Department of Health and Human Services: Office for Human Research Protections (OHRP) <http://www.hhs.gov/ohrp/>

US HHS Office of Human Research Protections (OHRP) **decision chart to assist in determining whether a project is human subjects research.**

www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm select: Chart 1: Is an Activity Research Involving Human Subjects?

US HHS Office for Human Research Protections (OHRP) **Engagement of Institutions in Research**
<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>

United States Food and Drug Administration <http://www.fda.gov/>

Federal Policy for the Protection of Human Subjects (Common Rule)

<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>