# 1000.250 PROTECTION OF HUMAN SUBJECTS PROCEDURE

## A. PURPOSE

The purpose of this procedure is to ensure that the rights of human subjects in research are appropriately protected and that Wenatchee Valley College and its authorized representatives are in compliance with applicable regulations for the protection of human subjects, including [Title 45 of the Code of Federal Regulations, Part 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) and [RCW 42.48.020](https://apps.leg.wa.gov/rcw/default.aspx?cite=42.48.020).

## B. INSTITUTIONAL REVIEW BOARD MEMBERSHIP

The membership of the institutional review board (IRB) shall include college faculty and staff with relevant experience and training and at least one external member as defined in [45 CFR § 46.102](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102). Board members must have completed DHHS compliant human subjects review training in the past two years to serve on the IRB.

## C. REVIEW PROCESS

The researcher or investigator responsible for the research study shall contact the IRB prior to initiating any contact with students or employees that are intended as research subjects. The contact person shall be the WVC Executive Director of Institutional Effectiveness. The researcher or investigator will provide, in writing, the following information:

### 1. A complete, signed IRB request for review and approval form (available on the HR webpage).

### 2. A brief statement describing the intent/purpose of the research project and the question under investigation.

### 3. A description of the intended participants in the research (employees; students; specific programs or courses, etc.).

### 4. A copy of the informed consent information to be provided to participants.

### 5. A copy of any advertisements or recruiting materials and/or a description of participation incentives to be offered (if any).

### 6. A statement describing how confidentiality of data will be maintained, if personal information is to be collected. Statement should include a description of measures to be taken to protect anonymity of response for non-personal information to be collected.

### 7. A copy of the instrument/s to be used, or a summary of the research procedures as experienced by the participants.

### 8. If the researcher or investigator is a WVC faculty or staff member, a statement of support from the appropriate administrator/supervisor. If a WVC student, a statement of support from the supervising faculty member. Faculty/staff statements should address workload and/or release time if applicable.

### 9. Evidence that the principal researcher(s) or investigator(s) have completed training in the protection of human research participants that addresses principles of ethical research and federal regulations.

## D. REQUEST FOR EXEMPTION

Some research with human subjects is exempt from the requirements of this procedure if it meets the following criteria (taken from the Code of Federal Regulations, [45 CFR § 46.101](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1101)).

### 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, or

#### 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 or observation of public behavior, unless:

#### a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

#### b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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

If the researcher or investigator believes that the project meets one of the above criteria for exemption, this must be indicated in the space provided on the IRB request for review and approval form. The IRB will make a final determination of eligibility for exemption; research may not proceed until verification of the exemption is received by the researcher or investigator from the IRB.

## E. IRB DEFERMENT TO PRIOR REVIEW

A researcher or investigator may ask WVC’s IRB to defer to the ruling of a prior Institutional Review Board of another institution. That institution’s IRB must meet WVC’s standards for review and be compliant with federal and state regulations on human subjects’ research and review. The researcher or investigator will indicate a request for deferment on their request for review form (available on the HR website) and provide all documents related to the prior institution’s IRB’s actions. If WVC’s IRB grants deferment, it may later choose to withdraw this different at any time.

## F. IRB DECISIONS

The IRB will review all requests and will contact the investigator with a decision to approve the project; approve with modifications or restrictions; grant an exemption from review; defer to a prior IRB of another institution, table the request pending receipt of additional information; or disapprove. To ensure adequate time for review, requests should be submitted with complete documentation at least six weeks prior to the intended start of the research.

Approved by the president’s cabinet: 2/7/12, 1/7/14, 6/4/2019

Presented by the board of trustees: 2/15/12, 2/26/14, 6/16/2019

Last reviewed: 5/7/20

Procedure contact: Institutional Effectiveness

Related policies and procedures

 000.250 [Protection of Human Subjects Policy](https://www.wvc.edu/humanresources/policies-procedures/000-general/000.250-protection-of-human-subjects.html)

 300.330 [Use of Human Subjects in Instructional Activities Policy](https://www.wvc.edu/humanresources/policies-procedures/300-instruction/300.330-use-of-human-subjects.html)

 1000.255 [Surveys Procedure](https://www.wvc.edu/humanresources/policies-procedures/000-general/1000.255-surveys.html)

 1300.330 [Use of Human Subjects in Instructional Activities Procedure](https://www.wvc.edu/humanresources/policies-procedures/300-instruction/300.330-use-of-human-subjects.html)