

**3358: 14-5-14 Protection of human subjects research.**

- (A) Northwest state community college will comply with the federal provisions of the protection of human subjects in research policy in accordance with 45 CFR 46 and 21 CFR 56. Research proposals must be reviewed and approved prior to any research activity.
- (B) Certain types of research may be designated as exempt under 45 CFR 46.101. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt from the review process. Research that meets the following requirements will not require a full institutional review board (IRB) review.
- (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, survey procedures, interview procedures or observation of public behavior, unless:
- (a) Information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects;
  - (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 use of educational tests, survey procedures, interview procedures or observation of public behavior, is not exempt if:
- (a) The human subjects are elected or appointed public officials or candidates for public office;

- (b) Federal statute(s) requires(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
  
- (4) 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.
  
- (5) 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;
  
  - (d) Possible changes in methods or levels of payment for benefits or services under those programs.
  
- (6) Taste and food quality evaluation and consumer acceptance studies:
  - (a) If wholesome foods without additives are consumed;
  
  - (b) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe.

Effective: 03/19/2015

CERTIFIED ELECTRONICALLY

---

Certification

03/09/2015

---

Date

Promulgated Under: 111.15  
Statutory Authority: 3358  
Rule Amplifies: 3358