

## Exempt Research

### OHSU Policy

1. A determination of eligibility for exemption under 45 CFR 46.101(b)(1-6) or exemption from the requirements of 21 CFR 56 must always be made by the OHSU IRB or its designee.
2. When a study is exempt, the OHSU IRB will ensure that the approved research is not contrary to the ethical principals of the Belmont Report. Exempt does not mean that the research activity is exempt from state laws, and it does not mean that the research need not conform to the principles of sound research ethics.
3. Research with human subjects is exempt from the requirements of 45 CFR 46, including informed consent, when it is determined that the involvement of human subjects is limited to one or more of the six "exempt" categories listed below: Although consent is not required by law, the OHSU IRB reserves the right to request an information sheet.
  - a. 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
  - b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    - information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects; and
    - 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 final standing, employability or reputation.
    - This exemption does not apply to research involving children, except for research involving observation of public behavior when the PI does not participate in the activities being observed.
4. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under 1.2 above if:
  - a. the human subjects are elected or appointed public officials or candidates for public office; or
  - b. federal statute(s) require(s) without exception that the

confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

5. Research involving the collection or study of existing data, documents, records, pathological specimen or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects.
6. Research and demonstration projects which are conducted by or subject to the approval of (federal) department or agency head 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.
7. Taste and food quality evaluation and consumer acceptance studies, if:
  - a. wholesome foods without additives are consumed; or
  - b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
8. Research is subject to FDA regulation if it involves a drug, medical device, food, or other product regulated by the FDA. FDA regulated research with human subjects is exempt from the requirements of 21 CFR 56 when it is determined that the involvement of human subjects is limited to:
  - a. Research which started before July 27, 1981, and either did not require FDA approval before that date, or, was subject to requirements for IRB review prior to that date, and remains subject to review by an IRB which meets FDA requirements;
  - b. Emergency use of a test article, provided any such use is reported to the IRB within 5 working days AND any future use of the test article at OHSU is subjected to IRB review; [NOTE: Exemption 56.104(c), the emergency use of a test article, is covered in a separate policy Emergency Use of an Investigational Drug, Device or Biologic.]
  - c. The taste and food quality evaluation provided for in the exemptions for 45 CFR 46
9. The exemptions do not apply to research involving prisoners.
10. If the proposed research does not meet one or more of the criteria for

exemption, the protocol will be reviewed at a convened meeting of the OHSU IRB or using the expedited review procedure, whichever is appropriate for the research activity.

11. OHSU IRB requires annual continuing review of exempt studies to re-evaluate the exempt status of the study.
12. Proposed changes to an exempt study, that could potentially affect the study's exempt status, must be submitted to the OHSU IRB for review.
13. If proposed research involves Protected Health Information (PHI), HIPAA regulations still apply, even if the OHSU IRB has determined that the research is exempt.
14. The IRB reserves the right to request a higher level of review at its discretion.

Effective: 3/20/2008