

 <b>Research Integrity Office</b>	<b>Human Research Protection Program</b> Regulatory Sheet	
Title: Exempt Research	Date Effective 3/20/08	Supersedes P&P dated: N/A
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**Background**

Certain categories of research involving human subjects qualify for exemption from the federal regulations for the protection of human subjects. Oregon Health and Sciences University (OHSU) is authorized by the federal government to determine whether studies qualify for this exemption.

**SCOPE**

This policy describes human subjects' research that is exempt from the requirements of 45 CFR 46 and 21 CFR 56. This policy does not cover non-human subjects' research or expedited review.

**I. Policy**

- A.** 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.
- B.** 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.
- C.** 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.
  - 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 o public behavior, unless:
    - a. information obtained is recorded in such a manner that 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 final standing, employability or reputation.
    - c. 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.
  - 3.** 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 I.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.

4. 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.
5. 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.
6. 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.
- D. 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:
  1. 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;
  2. 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.]
  3. The taste and food quality evaluation provided for in the exemptions for 45 CFR 46.
- E. The exemptions do not apply to research involving prisoners.
- F. 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.
- G. OHSU IRB requires annual continuing review of exempt studies to re-evaluate the exempt status of the study.
- H. Proposed changes to an exempt study, that could potentially affect the study's exempt status, must be submitted to the OHSU IRB for review.
- I. If proposed research involves Protected Health Information (PHI), HIPAA regulations still apply, even if the OHSU IRB has determined that the research is exempt.
- J. The IRB reserves the right to request a higher level of review at its discretion.

## II. Procedures

### A. Principal Investigators

#### 1. Initial Reviews:

- a. The PI makes a preliminary determination that a protocol is eligible for exempt review based on an assessment of the protocol establishing that it falls into one or more of the exempt categories.
  - b. All protocols must be submitted to the OHSU IRB using eIRB, the online submission system for IRB applications.
  - c. Complete the eIRB application, answering all relevant questions, completing the "applying for exemption from IRB review" page.
  - d. The protocol or complete grant should be uploaded if available, a lay language protocol summary and all research tools.
  - e. Special attention should be made to describe the recruitment, data collection and data coding methods. The ORIO analyst will request this information if it is missing. If applicable, include a release form or letter for obtaining existing data, documents, records or pathological or diagnostic specimens
2. Modifications: If the PI is anticipating a change to a previously approved exempt study that could potentially affect the study's exempt status, the PI must submit a

modification for review. These changes typically have to do with the identifiability of data, changes to recruitment or access to datasets.

3. **Continuing Reviews:** Exempt studies must be submitted and reviewed at least annually for an update and confirmation of continued exempt status. Submit by clicking on the “exempt/waived/NHS form” in the eIRB, answer the 3 questions as prompted and submit. If any changes have been made to the research they should be reported at this time, if they have not already been submitted via modification.

#### B. OHSU IRB

1. The IRB or a designee will review applications and determine if the proposed research qualifies for exemption under one or more of the exempt categories;
2. The IRB or designee will request additional information for review if it determines the information submitted is insufficient;
3. The IRB or designee will document the final action of the review, referring to the exempt category if satisfied by the research, or submit the proposed research for higher level review if no exempt category applies;
4. When the OHSU IRB has certified a research study as exempt, the IRB still conducts a review of the annual update.
5. When a research project is reviewed under exempt criteria, the review takes into consideration the level of risk involved as well as ethical concerns that may pose potential harm to a participant. If the reviewer finds that the ethical issues pose more than a minimal risk to the participant but the type of research falls within the exempt criteria, it is at the discretion of the OHSU IRB to determine that the project will be reviewed as either expedited or at a convened board meeting.
  - a. If a higher level of review is required, the reasons will be communicated to the PI.
  - b. The PI may appeal to the Chair for reconsideration.

### III. Definitions

- A. **Publicly available** means that the data are widely available. Data may still be considered publicly available when:
  - A fee is charged for obtaining the data.
  - Access to the data is limited to researchers, if any researcher with a standard academic or research affiliation has access.
- B. **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. 45 CFR 46.102(d)
- C. **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:
  - (1) Data through intervention or interaction with the individual, or
  - (2) Identifiable private information.
- D. **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- E. **Interaction** includes communication or interpersonal contact between investigator and subject.
- F. **Existing Data or Specimens** applies to retrospective studies of specimens or data that have already been collected. The materials must be “on the shelf” (or in the freezer) at the time the protocol is submitted to the OHSU IRB for exempt status. Research that involves the ongoing collection of specimens or data does not meet the criteria for Exemption 4.
- G. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of

the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. 45 CFR 46.102(f).

- H. Clinical Investigation** is any experiment that involves a test article and one or more human subjects, and that is subject to the FDA regulations. FDA regulations consider the terms “clinical investigation” and “research” to be synonymous.

#### **AUTHORITY**

45 CFR 46.101(b) Categories of Exempt Human Subjects Research

Office for Protection from Research Risks Guidance on Exempt Research:

[www.hhs.gov/ohrp/humansubjects/guidance/hsdc95-02.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc95-02.htm)

Office for Protection from Research Risks Guidance on 45 CFR 46.101(b)(5):

[www.hhs.gov/ohrp/humansubjects/guidance/exmpt-pb.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/exmpt-pb.htm)

Human Subject Decision Charts: [www.hhs.gov/humansubjects/guidance/decisioncharts.htm](http://www.hhs.gov/humansubjects/guidance/decisioncharts.htm)

National Institutes of Health FAQ about Research Using Human Specimens, Cell Lines or Data:

[http://grants.nih.gov/grants/policy/hs/faqs\\_specimens.htm](http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm)

Office for Human Research Protections Guidance on Research Involving Coded Private

Information or Biological Specimens: [www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf](http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf)