

Research that Qualifies for Exemption from Federal Regulations for the Protection of Human Subjects - Code of Federal Regulations, Title 45 CFR 46.101

Exempt status *may* apply to research activities in which the only involvement of human subjects will be in one or more of the following categories. The IRB will make the final determination regarding exemption.

45 CFR 46.101(b)(1) Research Conducted in Educational Settings: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula or classroom management methods.

45 CFR 46.101(b)(2) Survey, Interview, Observational Research (Video/Audio Taping) or Educational Testing: Research involving the use of survey procedures, interview procedures or observation of public behavior including educational tests (cognitive, diagnostic, aptitude, achievement), **unless:** (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects **and**; (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be harmful* to the subjects' financial standing, employability or reputation.

45 CFR 46.101(b)(3) Survey or Interview Research not Exempted in (2) Above: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior not exempt under category (b)(2), **if:** (i) the human subjects are elected or appointed public officials or candidates for public office; **or** (ii) federal statutes require, without exception, that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

45 CFR 46.101(b) (4) Use of Existing Data or Biological Samples: 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 linking identifiers such as codes, that can lead back to the subjects.

45 CFR 46.101(b)(5) Evaluation and Demonstration Projects: Research and demonstration projects that are conducted by or subject to the approval of [federal] department or agency heads, and that are designed to study, evaluate or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- DHHS guidance for category #5:
 - The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
 - The research or demonstration project must be conducted pursuant to specific federal statutory authority.
 - There must be no statutory requirement that the project be reviewed by an IRB.
 - The project must not involve significant physical invasions or intrusions upon the privacy of participants.
 - The exemption should have authorization or concurrence by the funding agency.

45 CFR 46.101(b) (6) Taste and Food Quality Studies: Taste and food quality evaluation and consumer acceptance studies, (i) **if** wholesome foods without additives are consumed, or (ii) **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 containment at or below the level found to be safe by the FDA or approved by the EPA or the Food Safety and Inspection Service of the USDA.

Research Activities That DO NOT Qualify for Exemption

(The following list is not all-inclusive)

Special Populations - Interventions or Manipulations

- Prisoners, pregnant women, children, the cognitively or mentally impaired, in-vitro fertilization or other "vulnerable" subjects.
- Research involving human ova, the products of in-vitro fertilization or human fetuses.

Survey, Interview or Observational Procedures, Video or Audio Recording and Sensitive Questionnaires

- Recorded audio or taped data that presents potential harm to subjects if revealed or disclosed.
- Whenever a subject's name, demographic or other private information is revealed and release of that data may cause harm or embarrassment.

- Surveys or interviews collecting sensitive data such as illegal activities, undesirable work behavior or other data that may be painful or embarrassing to reveal, such as sexual orientation or behavior, death of a family member, memories of physical abuse or genetic information, etc.
- Surveys or interviews where sensitive information such as personal aspects of a subject's behavior, life experiences or attitudes has the potential to preclude a negative emotional reaction and/or seriously disturb or embarrass the subject.
- Survey or interview procedures using children or mentally disabled persons.
- Educational research where subjects can be identified directly or through identifying links and disclosure may place them at risk or prove embarrassing.
- Observation of minors when the investigator participates in or influences the observed activities.
- Observation involving sensitive aspects of subjects' behavior or in settings where subjects have a reasonable expectation of privacy.
- Observation of employees or workers in the conduct of their normal work performance if the results of their involvement in the research were revealed an could prove embarrassing or harmful (employability)
- Observation of public behavior when an investigator participates or influences the observed activities and subjects can be identified directly or through identifying links and disclosure may place them at risk.

Research Using Existing or Archived Data, Documents, Records or Human Biological Materials

- Data, documents, records or biological specimens labeled in such a manner that subjects can be identified, directly or indirectly, through identifying links (i.e., codes) back to the original source.
- Data, documents, records or biological specimens that are not "archived" prior to submission of the IRB application (samples obtained from FDA- or IRB-approved repositories may qualify for exemption).
- Data, documents, records or biological specimens obtained after the protocol is submitted for IRB consideration.
- Medical, academic or other personal records and, in some instances, biological materials obtained without consent.
- Products of in-vitro fertilization stem cells, human fetuses or embryos.
- Biological samples collected or used for genetic research.

Other

- Deception where an investigator does not disclose the true purpose of the research and/or the results of a subject's participation.
- Whenever the potential for coercion or undue influence exists.
- Whenever a serious potential for conflict of interest exists.

* "Harm to subjects" means that any disclosure of subjects' responses or private information outside the research could reasonably place them at risk of criminal or civil liability or could be damaging to their financial standing, employability, reputation or emotional well being, (i.e., genetic information that might prove harmful or embarrassing to a subject).

** "Existing" means collected (i.e., archived or on the shelf) prior to the research for a purpose other than the proposed research. It includes data or specimens collected in research and non-research activities. For NIH grants, "existing" refers to data or biological samples collected prior to the time the research was proposed. PNNL IRB policy allows that biological materials obtained from US FDA-licensed or IRB-approved commercial repositories may be considered to exist before the research is proposed and/or conducted, even though additional samples may be obtained from those repositories during the course of the research. Biological samples obtained from any other source during the conduct of research do not qualify for exemption. Archived or "off the shelf" data must exist prior to IRB review to qualify for exemption.

***NIH interpretation of "publicly available" means to the general public.