

Human Subject and Exemption Determination Checklist For USD(P&R) Institutions

Are human subjects involved?

- _____ 1. The activity involves collecting data about living people through an interaction or intervention with people. For example, an intervention can involve physical procedures or a manipulation of the subject's environment. An interaction includes surveys, interviews, focus groups, etc.
- _____ 2. The activity involves identifiable, private information. Private information is information provided for specific purposes which the individual can reasonably expect will not be made public (e.g., medical, personnel, and student records), or information about behavior that occurs in a context in which the individual can reasonably expect no recording or observation is taking place. Identifiable information includes both direct identifiers and indirect identifiers. Direct identifiers include name, address, SSN, registration numbers, etc. Indirect identifiers include general demographic information when combinations of specific non-identifiable data can lead to individual identification (e.g., female, marine officer, limited geographic area).

If yes to 1 **or** 2, the activity involves human subjects; otherwise, it is not subject to the human subjects regulation.

If yes to 2, and the information is protected health information (PHI), then privacy review is required in addition to any human subjects review.

Is it research?

- _____ 3. The activity is a systematic investigation. For example, if the activity includes a hypothesis or clearly stated research question, utilizes research methodology, and has a plan for data analysis, then it is probably research.
- _____ 4. The activity is designed to contribute to generalizable knowledge. Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature.

If yes to both 3 **and** 4, it is human subjects research subject to regulation. If no to **either** 3 **or** 4, the human subject regulation doesn't apply; however, P&R requires that the activity be conducted in a manner consistent with the ethical and professional standards embodied in the regulations and policies.

If a project has multiple components and at least one of those components is research, the entire project is classified as research unless the components are separable.

Is it exempt?

To be exempt, the research must not involve (target) prisoners*. Exemption 2, except for procedures only involving observation of public behavior, may not be used with children.

*Prisoners of war may not be used as human subjects in research.

_____ This research does NOT involve (target) prisoners.

Category 1 Exemption (see attachment):

_____ The research is in an educational setting, involving normal educational practices.

Category 2 Exemption (see attachment): **Subjects must be adult except as noted above.**

_____ The research procedures **only** involve educational tests, survey or interview procedures, or observation of public behavior. **AND**

_____ The data are non-identifiable [either directly, indirectly, or by a coding procedure linked to subjects' identity] **OR**

_____ Disclosure poses no risk of criminal or civil liability, or will not be damaging to subjects' financial standing, employability or reputation.

Category 3 Exemption (see attachment):

_____ The research procedures only involve educational tests, survey or interview procedures, or observation of public behavior (that is not exempt under Category 2). **AND**

_____ The subjects are elected or appointed officials or candidates for public office. **OR**

_____ Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4 Exemption (see attachment):

_____ The research involves the collection or study of existing data, documents, records, or pathological or diagnostic specimens. **AND**

_____ The sources are publicly available **OR**

_____ The information is recorded in such a manner that subjects can't be [readily] identified [either directly, indirectly, or by a coding procedure linked to subjects' identity].

Category 5 Exemption (see attachment):

_____ The research is a federal demonstration project. **AND**

_____ The research is studying the cost and utilization of a particular benefit change [but **NOT** assessing clinical outcomes in comparison to the clinical outcomes of the standard covered therapies].

Category 6 Exemption (see attachment):

_____ Taste and food quality evaluation of wholesome foods without additives **OR**

_____ Taste and food quality evaluations of foods with ingredients at or below the level found to be safe by FDA, EPA or USDA.

If it is not exempt, then it requires IRB review.

Attachment: Exempt Categories

Reference	Description
§219.101(b)(1)	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.
§219.101(b)(2)	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, 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 damaging to the subjects' financial standing, employability, or reputation.
§219.101(b)(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 paragraph (b)(2) of this section, if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and hereafter.
§219.101(b)(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.
§219.101(b)(5)	Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designated 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.
§219.101(b)(6)	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 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.