# Title: IRB Review of Exempt Research SOP #7

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**Subject:** IRB Review of Human Subjects Research - Exempt

# Policy:

Research studies involving human subjects may be determined to be exempt from the requirement that they receive expedited or full committee review, under 45 CFR 46.101(b)(1)-(6), 45 CFR 406.301(a), 45 CFR 46.401(b) and 21 CFR 6.104(d). An exempt research study may not begin until the study receives IRB approval. Research subjects enrolled in a research study that has been determined to qualify for exemption are entitled to the same human subjects protections and ethical standards as outlined in *The Belmont Report*. This SOP refers to studies submitted in Cayuse through the standard initial submission process and are determined by the IRB office to qualify as exempt. The process for studies submitted under the Self-Exemption Tool are addressed in SOP #15, Self-Exemption Determination.

The categories of research that are exempt from expedited or full committee review are listed below. Note: These categories do not apply to research involving prisoners or research regulated by the Food and Drug Administration.

Exemption Categories

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   1. Research on regular and special education instructional strategies; or
   2. 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 of public behavior (including visual or auditory recording), unless:
   1. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   2. Any disclosure of the human subjects’ responses outside of 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.

If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement), and observation of public behavior when the investigator(s) do not participate in the activities being observed. Research that uses survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed cannot be granted an exemption.

1. 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 category 2 above, if:
   1. The human subjects are elected or appointed public officials or candidates for public office; or
   2. Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
2. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

To qualify for this exemption, data, documents, records, or specimens must have been collected before the research project begins.

1. Research and demonstration projects, which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   1. Public benefit or service programs.
   2. Procedures for obtaining benefits or services under those programs.
   3. Possible changes in or alternatives to those programs or procedures.
   4. Possible changes in methods or levels of payment for benefits or services under those programs.

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 under the Older Americans Act):

* The research or demonstration project must be conducted pursuant to specific federal statutory authority.
* There must be no statutory requirements that the project be reviewed by an IRB.
* The project must not involve significant physical invasions or intrusions upon the privacy of participants.
* This exemption is for projects conducted by or subject to approval of Federal agencies and is most appropriately invoked with authorization or concurrence by the funding agency.

1. Taste and food quality evaluation and consumer acceptance studies:
   1. If wholesome foods without additives are consumed; or
   2. 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.

Procedures:

1. Investigator
   1. Investigators will submit the protocol to the IRB administration office through the Cayuse system
2. IRB Administration Office
   1. Upon receipt of a protocol application form, the IRB administration office will conduct an initial review to determine if the protocol is Exempt, Expedited, or requires Full Board review
3. Final approval
   1. Final approval of exemption applications will be made by the IRB Committee Chairperson and will be good for five years minus one day from the date of approval.

References:

21 CFR 56.104(d)

45 CFR 46.101(b)(1)-(6)

45 CFR 46.301(a)

45 CFR 46.401(b)

SOP #15