

EXEMPT CATEGORIES - The DHHS regulations identify certain activities that may be exempt from compliance with the regulations. WIU policy requires that an exemption determination be made by the IRB Administrator and may not be an independent determination made by an investigator. Only the activities listed below qualify for exemption.

Note: Exemptions do not apply for research involving prisoners, nor for FDA- regulated research (except category 6).

Exemption 1: Evaluation/Comparison of Instructional Strategies, Techniques or Curricula –

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. (This category may include children.)

Exemption 2: Educational Tests, Surveys, Interviews or Observation –

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.

When research in this category involves children, this exemption must be limited to the following activities:

- Educational tests (cognitive, diagnostic, aptitude achievement)
- Observation of public behavior where the investigator(s) do not participate in the activities being observed.

Note: Research with children that involves survey or interview procedures, or observation of public behavior where the investigator(s) participate in the activity being observed cannot be granted exemption.

Exemption 3: Tests, Surveys, Interviews, Observation – Public officials/candidates or federal statutes apply

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 the category 2 above 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 thereafter.

Exemption 4: Research with Existing Data/Samples – Publicly available or de-identified

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. (This category may include children.)

- To qualify for this exemption, the data, documents, records or specimens must be in existence before the project begins.
- Under this exemption, an investigator may inspect identifiable records, but may only record information in a non-identifiable manner.

Exemption 5: Public Benefit or Service Programs –

Research and **demonstration projects** which are conducted by or subject to the approval of Department or Agency heads, and which 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. (This category may include children.)

- This category applies to federally funded projects only and requires authorization or concurrence from the funding agency. Specific criteria must be satisfied to invoke this exemption. The category does not apply if there is a statutory requirement that the project be reviewed by an IRB or if the research involves physical invasion or intrusion upon the privacy of subjects.

Exemption 6: Taste and Food Quality Evaluation and Consumer Acceptance 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 contaminant at or below the level found to be safe, by the FDA or approved by the EPA or [USDA Food Safety].

(This category may include children. This category may be FDA regulated.)