

Research that Qualifies for Exemption from Federal Regulations for the Protection Human Subjects
Code of Federal Regulations, Title 10 CFR 745.101

NOTE: The following exemptions **DO NOT** apply to research involving prisoners, fetuses, pregnant women, human in vitro fertilization, medical, academic or other personal records obtained without consent, or tissues obtained at autopsy. The use of Battelle staff or their families as subjects is prohibited unless corporate waiver is obtained. Special instructions are provided for minors (ages 18 and under) and persons incompetent to provide informed consent. It is the prerogative of the Institutional Review Board to prohibit exemptions allowable under federal policy when risk to subjects is found to be greater than acceptable.

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.

- **10 CFR 745.101(b)(1) Educational 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.
 - *The above exemption is applicable to mentally handicapped individuals only if research involves no changes in the content, location, or procedures of instruction from those normally experienced by the subject.*
 - *This category may involve minors.*

- **10 CFR 745.101(b)(2) Survey/Interview/Observational Research (Video/Audio Taping)/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.

The above exemption applies to research with minors or mentally handicapped individuals as follows:

 - *Research involving survey or interview procedures is not exempt.*
 - *Research involving the use of educational tests is exempt, unless the subjects can be identified directly or through identifying links and disclosure may place them at risk.*
 - *Research involving observations of public behavior is exempt only when the investigator does not participate(interact) in the observed activities and the subjects cannot be identified directly or through identifying links and disclosure may place them at risk.*

- **10 CFR 745.101(b)(3) Survey/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.

- **10 CFR 745.101(b)(4) Use of Existing Data:** 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, such as codes, that are linked to the subjects.
 - *This category may include minors.*

- **10 CFR 745.101(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.
 - *This category may include minors.*

- **10 CFR 745.101(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.
 - *This category may include minors.*

* Harm to subjects means that any disclosure of the human subjects' responses or information outside the research could reasonably place the subjects at risk of criminal or civil liability or can be damaging to the subjects' financial standing, employability, or reputation.

** Existing data means the items exist before the research was proposed or was collected prior to the research for a purpose other than the proposed research (for purposes of HHS grants, this refers to data collected prior to the time the research was proposed).