

Exempt Activities

Investigators may not determine their own research to be exempt from HSRC review. Exemption decisions are made through the expedited review process.

Activities that are not research are exempt from HSRC review. Research is defined as: “A systematic investigation designed to develop or contribute to generalizable knowledge.”

Research that does not involve human subjects is also exempt from HSRC review. A human subject is defined as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

Research activities in which the only involvement of human subjects will be in one or more of the following categories may be determined to be exempt from UHSRC review. Requests for exemption must cite the statutory basis for the requested exemption from the categories listed below:

I. Research

- A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, 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 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.

NOTE: This exemption does not apply to research involving children, unless the investigator is a non-participant observer of behavior.

- C. 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 Criterion 2, above, if:
 - 1. The human subjects are elected or appointed public officials or candidates for public office; OR

2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- D. 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.
- E. 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:
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; or
 4. Possible changes in methods or levels of payment for benefits or services under those programs.
- F. Taste and food quality evaluation and consumer acceptance studies, if:
1. Wholesome foods without additives are consumed, or
 2. 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.

II. Program Review

- A. **Federal Regulations Exemptions.** Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that 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; or 4) possible changes in methods or levels of payment for benefits or services under those programs.
- B. **EMU Program Review Data.** Data collected for the purpose of the evaluation, review, and improvement of EMU academic and extra-curricular programs is exempt from review under the Federal Regulations exemptions listed above *unless* these data are collected: 1) for use beyond program review, and/or 2) for publication beyond the review process for EMU programs administered by EMU, by its associated accrediting agencies, and by other related educational bodies. Program Review proposals that meet the criteria for exemption from review do not need to be sent to the EMU HSRC.

Note: The above exemptions do not apply to research involving prisoners as subjects.