

EXEMPTION DEFINITIONS

There are six specific categories of exemption. In order to receive an exempt review from the IRB you must fit into one of these categories.

XM 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.

Examples of research exempt through this criteria

- Study of normal educational practices conducted in commonly accepted settings such as elementary, secondary, or post-secondary schools.

Examples of research NOT EXEMPT via this criteria

- Research that involves evaluation of a radically new instructional strategy or use of random assignment of subjects to different instructional methodologies is not exempt because the methods employed deviate from normal educational practices.

- Educational research that involves deception or withholding of information from subjects is not exempt.

- Exemptions are not granted for research on physical education that involves exercise if the activity is altered in a significant way for the purposes of the research. Regardless of whether or not the exercise is considered a normal educational practice an element of risk may be introduced with physical exercise.

XM2 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.

Examples of research exempt through this criteria

- Research where no questions of a sensitive or private nature are asked AND where the data cannot be linked back to individual subjects.

Examples of research NOT EXEMPT through this criteria

- Surveys or questionnaires that ask invasive questions of a sensitive or private nature that might be deemed to cause the subject some discomfort or distress. This includes but is not limited to questions or inquiries about sexual preferences, sexual behaviors, substance use or abuse, or illegal conduct.

- Research where subjects can be identified as participating in the study. This can be found in the forms of collecting personal info such as name, SS#, or student ID number.

XM3 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 exemption 2, 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.

Examples of research exempt through this criteria

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior as long as that research is conducted on an elected or appointed public official. However, their participation in the research has to remain confidential.

Examples of research NOT EXEMPT through this criteria

- Research where the public official's participation is revealed or identifiable.

XM4 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.

Examples of research exempt through this criteria

- Information derived from the use of the data, records or biological specimens collected must be recorded in a manner whereas subjects cannot be identified. This means there must be no direct or indirect subject identifiers such as demographic information that can be linked to the subjects.

- Important to note that not having access to the subjects name does not automatically mean that the research is exempt. The existence of a one-way identifier, such as a code that can be used to identify a subject disqualifies the research.

- All research material must be existent (on-the-shelf) at the time the research begins. Any use of research material collected after the research is initiated constitutes a prospective study and disqualifies the study from exempt status. In order to be exempt under this rule, the research must be retrospective in nature.

Examples of research NOT EXEMPT through this criteria

- Research where materials will be collected after IRB approval

- Research where there are direct or indirect subject identifiers attached to the specimens that can be traced back to the respondent

XM5 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.

Examples of research exempt through this criteria

- Research that is conducted on public benefit or service programs such as welfare, Medicaid, unemployment, and Social Security.

XM6 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.

Examples of research exempt through this criteria

- Research that is limited to taste and food quality evaluation studies that do not involve consumption by the subject of any type of food that has any potential risks such as indigestion or vitamin deficiencies.
- Food consumed by the subject and the time frame in which this is accomplished should constitute reasonable eating behaviors.

Examples of research NOT EXEMPT through this criteria

- Studies that involve consumption of alcohol, vitamins, or supplements such as protein power, creatine, and glucosamine chondroitin sulfate should not qualify for exempt status.