

GUIDANCE FOR APPLYING THE SIX EXEMPTION CATEGORIES

For a study to be eligible for exemption all of the research activities must fit in one or more of the six categories below. If one or more of the research activities does not fit into an exemption category, the study cannot be exempted.

Guidance for Applying the Six Exemption Categories

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular or special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

The IRB reviewer has to consider whether the proposed activities constitute “normal educational practice” and if the setting is a “commonly accepted educational setting”. For example, a study to develop a “quiz first” method for teaching *Introduction to the Psychology of Leadership* would be eligible under this exemption provided the curriculum development methods reflected normal educational practices. Typically the educational setting would be a classroom. However, if this class met in the squadron, the squadron may be considered a “normal educational setting.”

(2) 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.

The category defines two conditions, that when both exist, exclude the activities from consideration for exemption. The study can be exempt if the activities only meet one of the conditions below:

- the information gathered during these activities can be linked to the subject, either directly or by some coding system if the researchers can access the codes
- should a third party gain access to that information, the subject would be placed at risk. The risk can be for criminal or civil liability or can be the risk of damaging a subject’s financial standing, reputation, employability, or insurability.

An example of a study that meets both of the above conditions and would NOT be exempt is as follows: A survey is randomly sent to the Class of 2019. The survey asks cadets if they engage in underage drinking. The investigator does not ask the subject’s name or social security number, she codes the questionnaires so she can tell who responds. After a certain period of time, she sends a second questionnaire to those randomly selected individuals who did not respond to the first request. Also, she plans to keep the code so that

she has the option to follow up with subjects if she needs clarification regarding their responses.

Since there is a code that links data with names, breach of confidentiality is possible even though it might be unlikely to occur. There is a possibility that a cadet could suffer a negative consequence if it is learned that s/he engaged in underage drinking. Consequently, this study would not be eligible for exemption. If, however, there is no risk associated with a subject's responses, having identifiers will not disqualify a study from exemption. There are many studies that ask for information that, if disclosed, would not put a subject at any type of risk. A study could have identifying information on the survey or questionnaire and still be eligible for exempt review provided disclosure of subject responses would not put subjects at risk.

(3) Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (b) of this section, 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.

This category differs from the previous one in the situations to which it applies. If the population targeted for the research activities are elected or appointed officials or candidates running for public office, the research qualifies for exempt review. Public officials or candidates running for office give up their right to confidentiality in certain situations in lieu of the public's "right to know."

(4) 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.

Clarification on Existing Data

According to the Office for Human Research Protections (OHRP), to qualify for this exemption criterion the data, documents, records, or specimens must be in existence at the time of IRB review. OHRP interprets the term "existing" to mean that all of the data, documents, records, or specimens to be used in the research are in existence prior to IRB review and were collected for purposes other than the proposed research. The IRB reviewer must assure that the investigator has shown that all of the data to be collected under this category are currently in existence at the time of IRB review.

Based on the federal definition of "existing data," research conducted using data obtained **prospectively** and taken strictly *for research purposes* **does not** qualify for exempt review. A study involving Spring DSAT survey administration for the purpose of research and data analysis in October CANNOT be exempted under this category.

Publicly Available or Subject Identifiers

What is meant by “publicly available resources”? This language in the regulation was intended to apply to public sources of data, such as local telephone directory information. For example, student records which are covered under the Privacy Act are not public records.

What is meant by “identifiers linked to the subjects”? Identifiers can include names, social security numbers, medical record numbers, or other codes that permit specimens or data to be linked to living individuals.

Recording identifiers

It is important for the person making the exempt determination to understand the investigator’s plans for recording the data. Temporarily recording a name or other identifier that allows individual subjects to be identified will exclude this type of research activity from meeting the exempt 4 criteria

(5) 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 payments for benefits or services under those programs.

This category of research is narrowly defined and only applies to Social Security Act programs and other public benefit programs that are specifically designated by the Department of Health and Human Services or the Secretary of one of the 19 other Federal Departments which have adopted the Common Rule.

(6) Taste and food quality evaluation and consumer studies, (i) if wholesome food 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

This category addresses two different types of research activity.

1. First, if the taste test involves wholesome food without any additives it is then eligible for exemption. The IRB reviewer must make sure that the food product to be researched is “wholesome” (no additives).

An example of such a research project would be a taste-test conducted on different types of grapefruit to determine consumer preference. The grapefruits are those normally grown in different sections of the country, using normal agricultural practices, and do not involve the addition of food additives or chemicals. The subjects merely indicate which of the grapefruit tasted they prefer.

2. The second item (ii) involves food with ingredients (including additives) at or below a level found to be safe by the FDA or EPA and USDA. All foods purchased at a local grocery store would be exempt under this category.