



## Research Exemption Determination Worksheet

This worksheet is intended to provide support for individuals in determining whether an activity is *exempt research*. This worksheet is not meant to be completed or retained on record. Official determinations of exemption can only be made by the IRB office, and those determinations are documented in the eIRB system.

Is it exempt research under DHHS regulations?

Research not involving [prisoners](#) may be exempt under DHHS regulations if it falls into one or more of the following Categories. Note that ALL research procedures/components involving human subjects must fit under one or more categories below. Otherwise, the research cannot be deemed exempt.

- 1) Will research be conducted in established or commonly accepted educational settings? ([45 CFR 46.101b\(1\)](#)) Yes  No
- a. Will research involve only normal education practices? (Such as: research on regular and special education instructional strategies or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods)  
(Must answer "Yes" to both 1 and 1a to qualify for exemption under this category.) Yes  No
- 2) Does the research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? ([45 CFR 46.101b\(2\)](#)) Yes  No
- a. Does the research involve children who will be surveyed, interviewed, or observed in such a way that the investigator participates in the activities being observed? (If "Yes", does not qualify for exemption under this category) Yes  No
- b. Will the information obtained be recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects? (If "Yes", continue to 2c). Yes  No
- c. If information will be recorded such that human subjects could be identified, could disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?  
(Must answer "Yes" to 2, "No" to 2a, and "No" to 2b or 2c to qualify for exemption under this category.) Yes  No

NOTE: if the research involves an intervention/manipulation with pre- and post-activity measures, the research will not qualify for exempt category #2.

- 3) Does the research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item 2 above? Yes  No
- a. Are the human subjects elected or appointed public officials (i.e. senior officials, such as a mayor or school superintendent) or candidates for public office? ([45 CFR 46.101b\(3\)](#)) Yes  No
- b. Do federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter? ([45 CFR 46.101b\(3\)](#)) Yes  No
- (Must answer "Yes" to 3 and "Yes" to either 3a or 3b to qualify for an exemption under this category.)



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- 4) Research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? ([45 CFR 46.101b\(4\)](#)) Yes  No
- a. Are the sources publically available? Yes  No
- b. Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers? Yes  No
- (Must answer "Yes" to 4 and "Yes" to either 4a or 4b to qualify for an exemption under this category.)*

NOTE: Subject identifiers may not be recorded on the data collection sheet, but may be used to obtain research data.

- 5) Is research designed only to study any or all of the following ([45 CFR 46.101b\(5\)](#)): Yes  No
- Public benefit or service programs
  - procedures for obtaining benefits or services under those programs
  - possible changes in or alternatives to those programs or procedures
  - possible changes in methods or levels of payment for benefits or services under those programs
- a. Is the research conducted or approved by the Department or Agency Head? ([45 CFR 46.101b\(5\)](#)) Yes  No
- (Must answer "Yes" to both 5 and 5a to qualify for exemption under this category.)*

- 6) Is the research a taste and food quality evaluation or consumer acceptance study that involves only ([45 CFR 46.101b\(6\)](#)): Yes  No
- Wholesome foods without additives
  - Food that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration
  - Food that contains an 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
- (Must answer "Yes" to qualify for exemption under this category.)*

## Is it exempt research under FDA Regulations?

A research project that fits either of the following categories is exempt under FDA regulations.

- 1) Is the research a taste and food quality evaluation or consumer acceptance study that involves only ([21 CFR 56.104d](#)): Yes  No
- Wholesome foods without additives
  - Food that contains a food ingredient at or below the level and for a use found to be safe
  - Food that contains an agricultural, chemical, or environmental contaminant at or below the level found to be safe by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture
- (Must answer "Yes" to qualify for exemption under this category.)*
- 2) Was this action emergency use of a test article? Complete SLU IRB [Emergency Treatment Form](#). (Note: Further use of the test article is not exempt from research.) ([21 CFR 56.104c](#)) Yes  No