

## Tip Sheet 8: Exemptions: Criteria for Making Determinations

### Related Accreditation Elements: II.2.A. and II.2.B.

Some laws, regulations, codes, and guidance exempt certain types of research. In the United States, the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) regulations describe criteria under which certain types of research is exempt. This Tip Sheet provides a guide for combining the exemption criteria from these two sets of U.S. federal regulations. It also includes the criteria for exemption under the Department of Veterans Affairs regulations.

### Criteria Allowing Exemption from Federal Regulations

1. Category 1
  - a. The research is conducted in established or commonly accepted educational settings.
  - b. The research involves normal educational practices, such as:
    - i. Research on regular and special education instructional strategies.
    - ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
  - c. The research does not involve prisoners as participants.
  - d. The research is not FDA-regulated.
2. Category 2
  - a. The research involved the use of one or more of the following:
    - i. Educational tests (cognitive, diagnostic, aptitude, achievement).
    - ii. Survey procedures.
    - iii. Interview procedures.
    - iv. Observation of public behavior.
  - b. If any disclosure of the participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
    - i. Information obtained is not recorded in such a manner that participants can be identified, directly or indirectly through identifiers linked to the participants.
  - c. If the research is regulated by the Department of Veterans Affairs:
    - i. If any disclosure of the participants' responses outside the research could reasonably place the participants at risk of loss of insurability.
      - A. Information obtained is not recorded in such a manner that human.
      - B. Participants can be identified, directly or through identifiers linked to the participants.

- d. If the research involves children as participants:
  - i. The procedures do not involve any of the following:
    - A. Survey procedures.
    - B. Interview procedures.
    - C. Observation of public behavior where the Researchers participate in the activities being observed.
  - e. The research does not involve prisoners as participants.
  - f. The research is not FDA-regulated.
- 3. Category 3
  - a. The research is not exempt under Category 2.
  - b. Research involving the use of one or more of the following:
    - i. Educational tests (cognitive, diagnostic, aptitude, achievement).
    - ii. Survey procedures.
    - iii. Interview procedures.
    - iv. Observation of public behavior.
  - c. Either of the following is true:
    - i. The participants are elected or appointed public officials or candidates for public office.
    - ii. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
  - d. The research does not involve prisoners as participants.
  - e. The research is not FDA-regulated.
- 4. Category 4
  - a. The research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.
  - b. Either of the following is true:
    - i. The sources are publicly available.
    - ii. The Researcher records information in such a manner that participants cannot be identified, directly or indirectly through identifiers linked to the participants.
  - c. The research does not involve prisoners as participants.
  - d. The research is not FDA-regulated.
- 5. Category 5
  - a. The project is a research or demonstration project.
  - b. The research is conducted by or subject to the approval of a federal Department or Agency head.
  - c. The research is designed to study, evaluate, or otherwise examine one or more of the following:
    - 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.
  - iv. Possible changes in methods or levels of payment for benefits or services under those programs.
  - d. The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
  - e. The research is conducted pursuant to specific federal statutory authority.
  - f. There is no statutory requirement that an IRB or EC review the research.
  - g. The research does not involve significant physical invasions or intrusions upon the privacy of participants.
  - h. The research does not involve prisoners as participants.
  - i. The research is not FDA-regulated.
6. Category 6
- a. The research involves taste and food quality evaluation or is a consumer acceptance study.
  - b. Either of the following is true:
    - i. Wholesome foods without additives are consumed.
    - ii. If a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant, the food ingredient or agricultural chemical or environmental contaminant is at or below the level and for a use found to be safe by one of the following:
      - A. The Food and Drug Administration.
      - B. The Environmental Protection Agency.
      - C. The Food Safety and Inspection Service of the U.S. Department of Agriculture.
  - c. The research does not involve prisoners as participants.