

**See Common Rule 45 CFR 46.101 for full text;**

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- (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.

**(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.\*  
\*or risk of loss of insurability

**(3)** 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 paragraph (b)(2) 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.

**(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.

**(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 payment for benefits or services under those programs.

**(6)** 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.

***Exempt status shall not be granted when:***

- Research involves prisoners as participants, pursuant to subpart C (45 CFR 46.305 (a))
- Categories (1) through (5) apply and research is subject to FDA regulations
- Category (b)(2) applies and research involves children as participants, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed, pursuant to subpart D (45 CFR 46.401 (b)).
- The project involves significant physical invasions or intrusions upon the privacy of participants.

***All protocols must meet*** MD Anderson HRPP ethical standards governing the conduct of research (e.g., acceptable risk-benefit relationship, equitable selection, informed consent, protections of privacy, main

***FDA 21 CFR 56.104***

The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

- (a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.
- (b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.
- (c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.
- (d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or 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

**Note:** For clinical investigations meeting FDA categories (a) and (b), IRB review is not required. For category (c), see IRB procedures and forms found [here](#). For studies meeting FDA category (d), IRB PDOL review and certification are required.