

6 Exempt Studies

All research using human subjects must be approved by the University of Virginia. However, certain categories of human subject research are exempt from IRB approval. Exempt research is subject to review for determination of exemption status. At the University of Virginia, exemptions are reviewed and granted by IRB Staff or Chair.

Individuals involved in making the determination of an IRB exempt status of a proposed research project cannot be involved in the proposed research. Reviewers must not have any apparent conflict of interest. Identification of individuals designated to conduct exempt determinations will be made in writing.

Exemptions are determined or granted, rather than approved. Exempt studies are exempt from the Common Rule [45 CFR 46] (i.e., FWA, IRB approval and full research consent are not required). The study team must receive a determination/confirmation of exemption status from the IRB. Although exempt research is not covered by the Common Rule, this research is not exempt from ethical considerations, such as honoring the principles described in the Belmont Report. Other federal regulations such as HIPAA or FERPA may still apply. The individual/s making the determination of exemption will determine whether to require additional protections for subjects in keeping with ethical principles (e.g., requiring disclosure/consent, etc.).

6.1 Limitations on Exemptions

The following limitations on exemptions apply to research conducted or supported by HHS:

Children: The exemption for research involving survey or interview procedures or observations of public behavior (#2) does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.

Prisoners: Exemptions do NOT apply. IRB review is required.

6.2 Categories of Exempt Research

With the above-referenced limitations, research activities not regulated by the FDA (see Section 6.3 for FDA Exemptions) in which the only involvement of human subjects are determined to be in one or more of the following categories are exempt from IRB approval:

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 subject's financial standing, employability, or reputation.
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 (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.
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.

NOTE: In order to be eligible for this exemption, all of the materials have to exist at the time the research is proposed.

5. Research and demonstration projects which are conducted by or subject to the approval of federal 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.

The program under study must deliver 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).

The research demonstration project must be conducted pursuant to specific federal statutory authority, there must be no statutory requirements of IRB review, the research must not involve significant physical invasions or intrusions upon the privacy of subjects, and the exemption must be invoked only with authorization or concurrence by the federal funding agency.

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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

6.3 FDA Exemptions

The following categories of clinical investigations are exempt from the requirements for prior IRB review and approval:

1. 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 is subject to IRB review. [21 CFR 56.104(c)]

Note: See Section 13.2 for detailed discussion of this exemption.

2. 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. [21 CFR 56.104(d)]

6.4 Procedures for Exemption Determination

In order to obtain an exemption determination, investigators must submit:

1. The required form depending on IRB of record;
2. All recruitment materials (e.g., letter of invitation, recruitment script, flyer);
3. Consent form/disclosure/information sheet (when appropriate);
4. All surveys, questionnaires, instruments, etc. (when appropriate);
5. Letter(s) of permission from each non-University of Virginia site of performance; and
6. Verification of current human research protection training for all members of the research team, including the faculty advisor.

The IRB staff, member or Chair reviews all requests for exemptions and determines whether the request meets the criteria for exempt research.

To document the reviewer's determination of the request for exempt research, the reviewer completes the required form depending on IRB of record. The reviewer verifies whether the submission meets the definition of human subject research (See Section 5). If the request meets the definition of human subject research, the reviewer then determines whether or not the research is eligible for exemption. Although exempt research is not covered by the federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report.

The individual making the determination of exemption will determine whether to require additional protections for subjects in keeping with the guidelines of the Belmont Report.

If there are interactions with participants, the reviewer should determine whether there should be a consent process that will disclose such information as:

- That the activity involves research.
- A description of the procedures.
- That participation is voluntary.
- Name and contact information for the researcher

The reviewer indicates whether the request for exemption was approved or denied, and if approved, the category/s under which it was permitted. The exempt application and determination letter are recorded and maintained in the same manner and for the same length of time as other IRB review documentation.

Once exemption review is completed, IRB staff will send written notification of the results of the review to the investigator.

Exempt determinations will include a termination date, with the maximum time allotted being 4 years. Investigators will be contacted every four years to determine if the study is to remain active. Investigators should report to any proposed modifications to the research during the course of the exempt study for a determination of whether or not the modified activity still qualifies for exemption. Finally, investigators must notify the IRB office when an exempt research project is complete so that the organization can maintain an accurate database of active research.