

Section 6. Exempt Studies

All research using human subjects must be approved by the medical school. However, certain categories of human subject research are exempt from the requirement for IRB approval. Exempt research is subject to review for determination of exemption status. At the medical school, exemptions are reviewed and granted by the IRB chair and vice chair.

Although exempt research is not covered by the Common Rule or FDA regulations, other regulations and requirements, such as HIPAA and disclosure of conflicts of interest and commitment, may apply. Furthermore, exempt research is not exempt from ethical considerations, such as the principles described in the Belmont Report. Determination of exemption must include determination of whether to require protections for subjects in keeping with ethical principles (eg, requiring consent).

6.1 Limitations on Exemptions

The following limitations on exemptions apply to research conducted or supported by DHHS.

- Research Involving 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.
- Research Involving Prisoners
 - Exemptions do NOT apply. IRB review is required.

6.2 Categories of Exempt Research

Within the limitations outlined in Section 6.1, research activities that are 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 qualify for exempt status:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - Research on regular and special education instructional strategies.
 - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless both of the following apply:
 - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects.

- 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.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the preceding, if either of the following apply:
 - The human subjects are elected or appointed public officials or candidates for public office.
 - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 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. In order to be eligible for this exemption, all of the materials have to exist at the time the research is proposed.
- Research and demonstration projects that are conducted by or subject to the approval of federal departments or agency heads, and which are designed to study, evaluate, or otherwise examine one or more of the following:
 - 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.

The program under study must deliver a public benefit (eg, financial or medical benefits as provided under the Social Security Act) or service (eg, 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.

- Taste and food quality evaluation 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.

6.3 FDA Exemptions

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

- Emergency use of a test article, provided that such emergency use is reported to the IRB within five (5) working days. Any subsequent use of the test article is subject to IRB review. [] See Section 13.2 for detailed discussion of this exemption and the procedures for reporting an emergency use.
- 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. []

6.4 Procedures for Exemption Determination

To request an exemption determination, investigators must submit all of the following:

- A completed *Exemption Request Form*.
- All recruitment materials (eg, letter of invitation, recruitment script, flyer).
- Consent form/disclosure/information sheet, if applicable.
- HIPAA authorization form, if applicable.
- All surveys, questionnaires, instruments, and other related information.
- Letter(s) of permission from each non-medical school site of performance.
- Verification of current human research protection training for all investigators and research staff.

The IRB chair or vice chair reviews requests for exemption determinations and determines whether the research qualifies for exempt status. In the event that the IRB chair and vice chair both have a conflict of interest or commitment, an experienced IRB member or consultant is identified by the HRPP director to make the determination.

The chair, vice chair, or designated reviewer uses the *Exemption Determination Checklist* to evaluate the submission and document their determination of whether the study qualifies for exempt status, and if it does, under which category/categories.

If applicable, the reviewer also evaluates and takes any actions necessary under other regulations, such as HIPAA. The reviewer determines whether to require additional protections for subjects in keeping with the guidelines of the Belmont Report.

The *exempt application*, review *form*, 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, HRPP/IRB staff send written notification of the results of the review to the investigator.

Investigators must submit any proposed modifications to the research for a determination of whether or not the modified activity still qualifies for exemption and must notify the HRPP/IRB staff by email or in writing when an exempt research project is complete so that the organization can maintain an accurate database of active research.