

IOWA STATE UNIVERSITY Institutional Review Board

Information about Exempt Research

Background

Federal regulations designate certain types of research involving humans as being exempt from Institutional Review Board (IRB) oversight (see Exempt Criteria listed below). At Iowa State University, all research involving humans must be submitted for review by the IRB staff for determination of exemption.

Principal investigators (PIs) may request exemption by submitting the Exempt Study Review Form, which includes several questions to aid IRB staff in determining whether exempt review is appropriate.

If the IRB staff determines that the project does not qualify for exempt status, the application is returned to the PI and the PI will be asked to apply for consideration under either expedited or full board review by submitting an Application for Approval of Research Involving Humans.

Submission Requirements for Exempt Research

Generally, copies of data collection and consent materials are not required for exempt review. Submission of the completed form is sufficient.

Informed Consent for Exempt Studies

PIs conducting exempt research are not required to obtain a volunteer's consent to participate using an informed consent document containing all of the elements of consent. However, the Iowa State University IRB recommends that, in general, the following items be included in an informed consent document or letter of introduction:

- A statement that the project involves research
- A statement that participation is voluntary
- A statement that the participant may skip any questions they do not feel comfortable answering in a survey
- The measures that will be used to ensure confidentiality of data collected in the research

As noted above, the informed consent document or letter of introduction does not need to be submitted for IRB review.

Exempt Criteria—DHHS

Under Department of Health and Human Services (DHHS) regulations, exemptions are limited to research activities in which the only involvement of human subjects will be in one or more of the following categories:

1. Research conducted in established or commonly accepted education settings involving normal educational 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.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless
 - information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects; and
 - 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 their financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, and achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 above if
 - the human subjects are elected or appointed public officials or candidates for public office; or
 - federal statute(s) requires 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
 - public benefit or services programs;
 - procedures for obtaining benefits or services under those programs;
 - possible changes in, or alternatives to, those programs or procedures; or
 - possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation consumer acceptance studies if
 - wholesome foods without additives are consumed; or
 - 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 (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA).

The exemption criteria above do not apply to research involving prisoners. (Subpart C of 45 CFR 46).

Research involving children (Subpart D of 45 CFR 46) may be exempt under exemptions (1) through (6). However, in Exemption 2, research involving survey or interview procedures is not exempt, and observation of public behavior is only exempt when the investigator(s) does not participate in the activities being observed.

Exempt Criteria—FDA

Research subject to FDA oversight is exempt only under very specific conditions as follows:

1. 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.
2. Any investigation commenced before July 27, 1981, and was not otherwise subject to requirements for IRB review under FDA regulations before that date.
3. Emergency use of a test article, provided that such emergency use is reported to the IRB within five working days. Any subsequent use of the test article at the institution is subject to IRB review.

4. 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 found to be safe by the FDA or approved by the EPA or the FSIS/USDA.

For FDA-regulated studies, research involving children may not be deemed exempt.

When both DHHS and FDA regulations apply to research involving human subjects, the IRB applies the most restrictive regulations from each to the research being conducted to ensure the protection of the rights and welfare of the human participants.