



IRB Review Procedures: Exempt Certification Review

1 Purpose

Investigators who conduct, or intend to conduct, human subject research under the auspices of the University are responsible for ensuring that their human subject research activities are reviewed and approved (or certified as exempt) by the IRB prior to engaging in such research. Certain activities that meet the criteria for "human subject research" are considered exempt from on-going oversight by the IRB. This document sets forth the categories and conditions under which human subject research activities are regarded as "*exempt*" under federal regulations and university policy; it also describes the procedures through which such activities are to be certified as exempt. The IRB (or designated staff members of the Office of Research Assurances [ORA]), not the investigator, shall make the formal determination as to whether a particular research activity involving human participants is exempt under federal human subject regulations and University policy.

2 Exempt Research

Research activities in which the only involvement of human subjects will be in one or more of the categories established at 45 CFR 46.101(b)(1-6) or 21 CFR 56.104(a-d) may be determined to be exempt from the initial and continuing review required by federal human subject research regulations. Even when research is certified by the IRB to be exempt, the ethical principles of *The Belmont Report* shall be applied by the investigator in carrying out the research activities.

2.1 HHS Exempt Research Categories [45 CFR 46.101(b)(1-6)]

Category 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. [46.101(b)(1)]

Category 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 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. [46.101(b)(2)]

Category 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. [46.101(b)(3)]

Category 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. [46.101(b)(4)]

Category 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. [46.101(b)(5)]

Category 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. [46.101(b)(6)]

2.2 FDA Exempt Research Categories [21 CFR 56.104(a-d)]

Category 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. [21 CFR 56.104(a)]

Category 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. [21 CFR 56.104(b)]

Category 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. [21 CFR 56.104(c)]

Category 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. [21 CFR 56.104(d)]

3 Exempt Research Review and Certification Procedures

3.1 [Exempt Determination Request] Submission

The exempt review process begins when the investigator completes and submits an [Exempt Determination Request form] to the IRB [by e-mail at irb@uidaho.edu].

3.1.1 Exempt Determination Request forms shall be made available to investigators through the IRB website.

3.2.1 A submission is considered "complete" only if all information required in the Exempt Determination Request form has been provided and all supporting materials necessary for the review have been included with the form.

3.2 [Exempt Determination Request] Intake

ORA staff assigned to support the IRB are responsible for receiving Exempt Determination Request forms and for reviewing the submission for completeness.

3.2.1 ORA staff will make a new entry for the submitted Exempt Determination Request in the Protocol Database, indicating the status of the Request.

3.2.2 If the submission is **complete**, ORA staff will provide the application materials to an individual designated to review and certify Exempt Determination Requests and will enter the Designated Reviewer for this submission into the Protocol Database.

3.2.2.1 Individuals designated to review and certify Exempt Determination Requests may include: ORA staff who, in the view of the IRB Chair and ORA Manager, have sufficient experience in and knowledge of the conditions under which research activities may be considered to fit within the exempt research categories (See 2.1 and 2.2, above); the ORA Manager; the IRB Chair.

3.2.2.2 Designated Reviewers eligible to review and certify Exempt Determination Requests shall be listed in the IRB Designated Reviewer database.

3.2.3 If the submission is **incomplete**, ORA staff will contact the investigator and request that the omitted information or materials be provided to the IRB; the date of the request and the information requested will be recorded in the Protocol Database.

3.2.3.1 If the investigator does not provide the requested materials within two weeks, ORA staff will notify the investigator that the IRB regards the Exempt Determination Request as withdrawn; ORA staff will note in the Protocol Database that the request is "Withdrawn."

3.2.3.2 If the investigator provides the requested information, processing of the request will continue following 3.2.2, above.

3.3 [Exempt Determination Request] Review

After receiving an Exempt Determination Request submission from ORA staff, the Designated Reviewer:

3.3.1 reviews all materials

3.3.2 determines that the proposed activity qualifies for classification as exempt under one or more of the Exempt Research Categories at 2.1 or 2.2.

3.3.3 if consultation is necessary in order to appropriately evaluate the proposed activity, consults with the ORA Manager, the IRB Chair, or, following "IRB SOP: Consultation," identifies and consults with an individual designated to advise the IRB.

3.3.4 completes the [IRB Exempt Determination Review] checklist

3.3.5 *returns the completed [IRB Exempt Determination Review] checklist within five (5) business days to ORA staff.*

3.4 Post-Review Documentation and Notification

Upon receiving the completed IRB Exempt Determination Review checklist from the Designation Reviewer, ORA staff:

3.4.1 records the outcome of the review in the Protocol Database

3.4.2 if the activity is determined by the Designated Reviewer to be **exempt**, completes the Exemption Certification form, indicating the applicable exempt categories; one copy of the Exemption Certification for the activity is provided to the investigator (as formal notification of exemption) and one copy is retained for IRB files.

3.4.3 if the activity is determined by the Designated Reviewer to be **ineligible for exemption**, notifies the investigator that the proposed activity is non-exempt research and requests completion of [IRB (Non-Exempt) New Study Application.]

3.4.4 if the study is determined not to be human subject research, completes a non-Human Subject Research Certification form letter and provides this to the investigator as notification that IRB oversight is not required.

3.4.5 include the outcome of the review as part of the agenda of the next scheduled IRB meeting, as notification to the IRB of completed non-committee reviews.

4. Applicable Regulations and Guidelines

45 CFR 46.101

21 CFR 56.104