**University of Idaho Institutional Review Board**

**Standard Operating Procedures Manual**

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**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; or (iii)The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducted a limited IRB review to make the determination required by 45.111(a)(7). [46.101(b)(2)]

**Category 3**: (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(B) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

[46.101(b)(3)]

**Category 4**: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

[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 Exempt 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