

Exempt Determination & Limited IRB Review

SOP 111

Revised: January 21, 2019

Purpose and Scope

The SOP describes the criteria for determining exempt research. Exempt research are categories of research that do not require IRB approval and continuing review. The revised Common Rule requires a new type of review called “Limited IRB review” for certain exempt protocols.

This SOP applies to all HSP staff, IRB members, and Investigators and their staff who are involved in research determined to be exempt.

Definitions

Categories of Exempt Research

As defined per the Common Rule, Subpart A of 45 C.F.R. part 46, exempt research encompasses categories of research that do not require IRB approval and continuing review.

Changes due to the revised Common Rule are highlighted in yellow.

The following categories of research are exempt from IRB review¹:

- 1 **Research conducted in established or commonly accepted educational settings**, involving normal educational practices **that are not likely to adversely impact students' opportunity to learn required educational content, or the assessment of educators who provide instruction**. This includes:
 - 1) Most research on regular and special education instructional strategies, or
 - 2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods;
- 2 **Research that ONLY includes interaction involving the use of educational tests** (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior **(including visual or auditory recording), if at least one of the following criteria is met:**
 - 1) Information obtained is recorded **by the investigator** in such a manner that **the identity of human subjects can not** be readily ascertained, directly or through identifiers linked to the subjects;

¹ 45 C.F.R. §§ 46.104(d)(1)–(8).

- 2) 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, or reputation; or
- 3) The information obtained is recorded by the investigator in such a manner that the identity of the participants 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 section 45 CFR 46.111(a)(7).

Children may only be included in research under this exemption when involving educational tests or observation of public behavior if the investigator(s) do not participate in the activities being observed and the information obtained is recorded by the investigator in such a manner that the identity of the participants cannot be readily ascertained, directly or through identifiers linked to the participants.

3 Research involving benign behavioral interventions² 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 intervention³ and information collection and at least one of the following criteria is met:

- 1) 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;
- 2) Any disclosure of the human subjects' responses outside of 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
- 3) 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 section 45 CFR 46.111(a)(7).

Children may not be included in research under this exemption.

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:

- 1) The identifiable private information or identifiable biospecimens are publicly available; or
- 2) 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; or

² For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing (e.g., playing an online game, solving puzzles, etc).

³ If the research involves deception, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

- 3) 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
 - 4) 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
- 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:
- 1) Public benefit or service programs; (this exemption is for Federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency)
 - 2) Procedures for obtaining benefits or services under those programs;
 - 3) Possible changes in or alternatives to those programs or procedures; or
 - 4) Possible changes in methods or levels of payment for benefits or services under those programs.
- 6) **Taste and food quality evaluation and consumer acceptance studies**, if:
- 1) Wholesome foods without additives are consumed; or
 - 2) A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or
 - 3) 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.

IMPORTANT NOTE: Exempt criteria 7 and 8 below require the use of a new requirement in the revised Common Rule called "broad consent" as well as Limited IRB review. UH is not formally implementing use of "broad consent", so exempt criteria 7 and 8 should not be used.

- 7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by section 45 CFR 46.117;
- 8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - 1) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with section 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);
 - 2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with section 45 CFR 46.117;
 - 3) An IRB conducts a limited IRB review and makes the determination required by section 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is

- within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section;
and;
- 4) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Limited IRB Review

Limited IRB Review is a new provision under the revised Common Rule that allows certain research to be considered Exempt from IRB review even when the identifiable information might be sensitive or potentially harmful if disclosed. In order to qualify for the exemption, the study must meet the standards of Limited IRB review.

For Exempt categories 2 and 3, the requirement for Limited IRB Review is triggered when:

- 1) The information obtained is recorded by the investigator in such a manner that the identify of the participants **can** be readily ascertained, directly or through identifiers linked to the subjects, AND
- 2) Any disclosure of the participants' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation.

Continuing Review is not required for research approved under Limited IRB Review. When changes to research are proposed that fall within the scope of the Limited IRB Review requirement (e.g., storage or maintenance, privacy and confidentiality), the changes must undergo Limited IRB Review and be approved before implementation (except when necessary to eliminate apparent immediate hazard to participants).

Limited IRB Review under Exempt categories 2 and 3 requires that the IRB determines that the criteria for IRB approval under the revised Common Rule at 45 CFR 46.111(a)(7) is satisfied:

45 CFR 46.111(a)(7): When appropriate, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

Note the statement above that guidance will be issued to assist IRBs in evaluation whether research satisfies this criterion. The preamble to the revised Common Rule provides a framework for the anticipated guidance. The factors below should be considered when conducting Limited IRB Review:

- The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- The use of the information;
- The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;

- The likely retention period or life of the information;
- The security controls that are in place to protect the confidentiality and integrity of the information; and
- The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under exemption.

Procedures

Persons Authorized to Determine Exemption

An Investigator who intends to involve human subjects in research may not make the final determination of exemption. Nor may the Investigator initiate research believed to be exempt until the HSP approves the exemption.

The HSP has the authority to review Investigators' preliminary determinations of exemption and make the final determination. The HSP Staff will review applications for exemption and, afterwards, recommend approval to the Director.

Once the Director approves of exempt recommendation, HSP provides a Determination Letter to the Investigator.

When required, **Limited IRB Review** must be performed by the IRB chairperson or by an experienced IRB member. The review can occur on an expedited basis and does not require consideration by a convened board. The reviewer may require modifications to the proposal prior to approval. Disapprovals must be made by the convened board. If the Limited IRB Review does not result in an approval under the exempt categories, then the IRB can evaluate whether or not approval is appropriate under the expedited categories.

How to Apply for Exemption

An Investigator initiates the applications for exemption by submitting a new project application on the UH eProtocol online application system, including all required documents.

The required documents may include consent forms, completion report of CITI training, interview guides, survey questionnaires, flyers, or other instruments to be used in the gathering of information.

I. Criteria in Approving Exemption

- a. In reviewing research, the HSP will use the criteria for exemption under applicable laws and guidance, and consider the following:
 - i. the risks to the subjects,
 - ii. the protection of the subjects' privacy interests,
 - iii. the confidentiality of private identifiable information,
 - iv. the anticipated benefits to the subjects and others,
 - v. the importance of the knowledge reasonably expected to result,
 - vi. the process to recruit and select subjects, and
 - vii. the process of informed consent

- b. The above considerations are to ensure that the research complies with ethical principles delineated in the Belmont Report.

II. Continuing Review and Review on Modifications

- a. Approval of exempt status is valid for the duration of the study. The study is not subject to continuing review by an IRB as long as no modifications to the study change it to nonexempt.
- b. The Investigator must notify the HSP of any proposed changes. The notification should be via the UH eProtocol application system⁴.
- c. If changes to an exempt study renders the study non-exempt, the study would be subject to regular and continuing review by the IRB, and reporting requirements. In this case, the Investigator must submit an application for approval of a new study and obtained the approval of the IRB before the Investigator may implement the changes.

Special Considerations

1. There are additional considerations for research subject to the requirements of subparts B, C, and D:
 - a. Subpart B. Each of the exemptions may be applied to research subject to subpart B, provided the conditions of the exemption are met.
 - b. Subpart C. The exemptions do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
 - c. Subpart D. Exemptions 1, 4, 5, and 6 may be applied to research subject to subpart D, provided conditions of the exemption are met.
 - d. Exemption 2 may apply only to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Research subject to subpart D, requiring limited IRB review will not meet exempt category 2 criteria.
2. Categories (1) through (5) may not apply to research subject to FDA regulations
3. **Emergency use of a test article** is exempt from prospective IRB review per 21 C.F.R. 56.104.
4. **For Category 5**, Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, the following additional criteria apply:
 - a. 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).
 - b. The research or demonstration project must be conducted pursuant to specific federal statutory authority.

⁴ Revisions to exempt approved projects started prior to implementation of the eProtocol system (June 2016) should be conducted by email (to the uhirb@hawaii.edu account) rather than through the eProtocol system.

- c. There must be no statutory requirement that an IRB review the project.
- d. The project must not involve significant physical invasions or intrusions upon the privacy of participants.
- e. OHRP (or the applicable federal agency) has authorized or concurred with this exemption determination.

Informed Consent:

A claim of exemption in the application does not exempt Investigators from gaining informed consent from participants.

If the research involves interactions with participants, there should be a consent process to disclose information to participants including a description of the project as research, an explanation of the research procedures, and a statement that participation is voluntary, and name and contact information of the researcher and the HSP program. It is highly recommended that investigators use the templates provided on the HSP website. Further information is also provided in **GUIDE 608: Informed Consent Requirement Checklist**.

If collected data is anonymous, an information sheet, a cover letter, or a statement may substitute a written and signed consent form.

Document Distribution and Board Actions:

1. Applications for exemption are:
 - a. Completed by the principal investigator,
 - b. Submitted to the Human Studies Program,
 - c. Screened for completeness, and
 - d. Assigned/distributed to a single member of the UH HSP staff, or a member of the IRB, on an ongoing basis.
2. If there is any protocol-related information requiring clarification, the exempt reviewer will contact the principal investigator directly.
3. Final documentation of approval will be generated by HSP staff and communicated to investigators via the online application system (eProtocol), and
4. Final documentation will include the exempt category as well as any other specified approval or comments regarding documents and information to be provided to research participants.
5. Reporting to the IRB: Reviewed and approved protocols, which are determined to be exempt, are reported on a monthly basis to the relevant IRB Panel (as part of the meeting agenda) and are attached to the IRB Meeting Minutes for the appropriate month.

Questions

Investigators may consult the HSP website or email the HSP with questions regarding whether a study is exempt from an IRB review and how to apply for exemption.

Materials

- GUIDE 601 Review Category Flowchart
- GUIDE 608: Informed Consent Requirement (OHRP)

References

- 45 CFR 46.104
- 45 CFR 46.201
- 45 CFR 46.301
- 45 CFR 46.401
- 21 CFR 56.104(c)-(d)
- Federal Register, Vol.48, pp.9266-9270, March 4, 1983
- OHRP Decision Charts for Exempt Review
- Categories of exempt research are stipulated in the Common Rule, Subpart A of 45 CFR 46. See [45 CFR 46.104](#), and [21 CFR 56.104](#) (FDA).
- The IRB has and follows written policies and procedures for determining when activities are exempt from applicable laws and regulations, when permitted by law or regulation and exercised by the IRB. Such policies and procedures indicate that exemption determinations are not to be made by Researchers or others who might have a conflict of interest regarding the studies. (**AAHRPP Element II.2.A**)