Exempt Review and Determination

Purpose and Scope

The SOP describes the criteria for determining exempt research to include categories that do not require IRB approval and continuing review.

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. The following categories of research are exempt from IRB review:

a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   1) 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;

b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, provided:
   1) Information obtained is not recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   2) Any disclosure of the human subjects’ responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation;

c. 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:
   1) The human subjects are elected or appointed public officials or candidates for public office; or
   2) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

1 45 C.F.R. §§ 46.101(b)(1)–(6).
2 Note: If research involves anyone below the age of 18, see Section Notes on the Categories and Section Research Involving Children of this document concerning research involving children.
d. **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.³

e. **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;
   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.

f. **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.

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**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 signed Determination Letter to the Investigator.

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³ Note: Such materials must already exist at the time the research is proposed. This category does not apply to activities involving prospective collection of such materials.
How to Apply for Exemption

An Investigator initiates the applications for exemption by submitting a completed **APP 03: New Research Protocol/ Proposal for Initial Approval – Exempt Research** and 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.⁴

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 non-exempt.
   b. The Investigator must notify the HSP of any proposed changes. The notification should be via email.
   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. Exempt status shall not be granted when:
   a. Research involves prisoners as participants, pursuant to subpart C (45 CFR 46.305 (a))
   b. Categories (1) through (5) apply and research is subject to FDA regulations
   c. Category (b)(2) applies and research involves children as participants, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed, pursuant to subpart D (45 CFR 46.401 (b))
   d. The project involves significant physical invasions or intrusions upon the privacy of participants.

⁴ The Belmont Report, supra note Error! Bookmark not defined.
2. **Emergency use of a test article** is exempt from prospective IRB review per 21 C.F.R. 56.104.

3. The exemptions at 45 CFR 46.101(b), **DO apply to pregnant women, but DO NOT apply to research involving prisoners.**

4. The exemption for research involving survey or interview procedures or observation of public behavior [45 CFR 46.101(b)], does not apply to research with children, Subpart D, except for research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), and observations of public behavior when the investigator(s) do not participate in the activities being observed.

5. **For Category 2,** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior two conditions must apply in order to allow for the collection of identifiable data:

   a. The investigator must provide reasonable assurance of data protection/confidentiality. **AND**
   
   b. The sensitivity of the data collected must not increase the overall risk to the research participants.

6. **For Category 4,** 'existing data' means data that exists at the time of IRB submission. Exempt category 4 does not allow for protocols designed to collect data that does not yet exist or has not yet been collected at the time the protocol is submitted to the IRB.

7. **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.

   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.

**NOTE:**
- Studies subject to FDA regulation cannot be granted exemptions unless the exemption category identified is Category 6.

- Note that although exempt review does not require a formal informed consent process, the investigator is expected to provide the following information to a prospective subject: A description of the project as research, an explanation of research procedures, and a statement that participation is voluntary, and name and contact information of the researcher.
8. Informed Consent
   
a. A claim of exemption in the application does not exempt Investigators from gaining informed consent from participants.
   
b. If the research involves interactions with participants, there should be a consent process to disclose information described in GUIDE 608: Informed Consent Requirement Checklist.
   
c. 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 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 in writing, 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

- WKSH 302 Requirements for Exempt Approval
- GUIDE 601 Review Category Flowchart
- GUIDE 608: Informed Consent Requirement (OHRP)

References

- 45 CFR 46.101(b)
- 45 CFR 46.201(b)
- 45 CFR 46.301(b)
• 45 CFR 46.401(b)
• 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 46.101(b), 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)