JEFFERSON—Office of Human Research

# APPLICATION FOR EXEMPTION FROM IRB REVIEW

**Version Date – FOR OHR USE: 9/4/20**

**STUDY TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**TELEPHONE #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_E-MAIL: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Instructions: Check off the documents below that you have included with your OHR-18.**

OHR-1 – For all exempt studies

OHR-18 – For all exempt studies

Other relevant materials, if applicable (questionnaires, brochures, advertisements, etc.)

OHR-3 – If you are requesting a waiver of subject authorization to collect PHI

OHR-4 – If you are applying for category 4 exemption

OHR-5 – If de-identified health information will be collected

OHR-8/HIPAA Authorization – If subject authorization will be obtained to collect PHI

OHR-8H/OHR-8F –If you are requesting subject consent (verbal consent, survey, interview, focus group, etc.)

No identifiers or health information are being collected. HIPAA authorization/OHR-3/OHR-5 not required. Please see the [OHR-5](http://www.jefferson.edu/university/human_research/irb/forms.html) for a list of identifiers.

**SECTION 1:**

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review. (**Note**: Prisoners may be included in exempt research only when they are involved as a broader subject population that only incidentally includes prisoners. Child exceptions are noted as indicated below.)

**Please Check the Categories That Apply to the Research:**

1. Research conducted in established or commonly accepted educational settings, that specifically involves (i) normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or (ii) the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [**Note**: This category only applies to primary, secondary, collegiate, and medical education (including resident and fellowship) settings.]
2. Research that includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or audio recording) if at least one of the following criteria is met:
3. 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 **(When children involved, this category is limited to educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed);**
4. 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 **(Child exclusion same as above)**
5. 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. **(This may not be applied to research involving children).**
6. Research involving benign behavioral interventions in conjunction with the collection of information from adult subjects only (**children excluded**) 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:
7. 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;
8. 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
9. 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.

**Note 1:** For the purpose of this category, 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.

**Note 2:** 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 s/he will be unaware of or misled regarding the nature or purposes of the research.

1. 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:
2. The identifiable private information or identifiable biospecimens are publicly available;
3. 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;
4. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA; or
5. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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 applicable regulations.
6. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. This research is conducted pursuant to specific statutory authority of the US federal government. The research does not involve significant physical invasions or intrusions upon the privacy of participants. There is otherwise no statutory requirement that an IRB must review this study beyond designating it as exempt.

**SECTION 2:**

Please attach a brief summary (in lay language) of your research, and a justification for why it fits the exemption criteria you have chosen. Give definitions for all acronyms used. If research involves interaction with participants, please address the following items:

* 1. How, where, and according to what time-frame will participants be approached and consented? [Be sure to consult, adapt and include in your application the appropriate consent template (OHR-8, OHR-8H, OHR-8F, etc.)]
  2. How will privacy of participants be maintained?
  3. Explain criteria for participant selection. (Selection should be equitable, unless there is a justifiable scientific reason for exclusion of certain populations.)

**SECTION 3:**

Check all that apply.

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| --- | --- | --- |
| Does the research involve: | Yes | No |
| Pregnant women, Human fetuses and/or Neonates |  |  |
| Prisoners |  |  |
| Children |  |  |
| FDA-Regulated drug or device or biologic (i.e., Is the research FDA-Regulated?) |  |  |