Exempt Review

OHRP Exempt Categories 45 CFR 46.101(B) - (HRP-312)

Federal regulations specifically defines eight categories of human subject research that are **exempt** from the other provisions of the regulations. Exempt does not mean that the activity is not research, and review may still be requires based on the requirements of the exemption categories.

Many organizations grant the authority to make determinations of exempt status to the IRB. Check with your IRB office to find out who has been granted the authority to make the exemption determination. This determination must be made prior to initiation of research or activity; it cannot be made retroactively.

The regulations at 45CFR 46 (Protection of Human Subjects 2018) have determined that the following eight categories of research are eligible for exemption status.

Category 1

Education .104(d)(1)

Research, conducted in established or commonly accepted educational settings, which specifically involves 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 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.

a) In educational settings with normal educational practices?

b) Research on Regular/Special educational instructional strategies?

Category 2

Tests, Surveys, Interviews, Observation .104(d)(2)

Research that only includes interactions involving 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:

(i) 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;

(ii) 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

(iii) 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 §__.111(a)(7).

Involves educational tests(s), surveys, interviews or observation of public behavior?

Data recorded to prevent identification of subjects?

Prevention for risk of disclosure of subjects' responses outside the research (placing subjects at risk of criminal, civil liability, or damage financial standing, employability, or reputation)?

*__NO EXEMPTION AVAILABLE IF:__ children are involved in survey or interview procedures; children are involved in observation of public behavior and the observers participate in the activities observed.

Category 3

Benign Behavioral Interventions – New

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 .111(a)(7).

3(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.

3(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.

Category 4

Secondary research .104(d)(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…. [HIPAA]

(iv) 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 [various federal privacy laws.]

Important note here: The information or biospecimens do not have to be existing at the time of the exemption determination; they can be collected into the future. The data can be collected prospectively and still be used for exempt research under Category 4 in the Final Rule.

Involves collection/study of existing archival data, specimens, or diagnostic specimens (publicly available or recorded to protect identity of subjects).

Category 5

Federal Research and Demonstration Project.104(d)(5)

Research and demonstration projects that are conducted or supported by a Federal department or agency, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs.

New requirement: Each agency must maintain a public list of these projects, to be published prior to conducting the research. Research and/or demonstration project, subject to approval of department/agency head, designed to study, evaluate:

public benefit or service programs

procedures to obtain benefits/services

changes/alternatives to programs/procedures

changes in methods/levels of payment for benefits/services

See OHRP's guidance regarding this category

Category 6

Unchanged Taste and food quality evaluation and consumer acceptance studies. .104(d)(6)

Involves taste and food quality evaluation; consumer acceptance studies

a) wholesome foods without additives are consumed

b) food consumed is at or below safe level; agricultural chemical, environmental contaminant at or below safe levels (established by FDA, EPA or USDA)

*** CCC-UPR IRB does not typically review these types of studies. Please contact the CCC-UPR IRB to discuss *before completing this application*.**

Category 7

New: Storage and maintenance for secondary research .104(d)(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 § 46.111(a)(8). This category is for the storage of identifiable biospecimens and identifiable private information, prior to secondary analysis.

Note: The storage and maintenance may be exempt if the IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and if **broad consent is obtained**.

***CCC-UPR IRB does not plan to implement this Exemption at this time. Limited exceptions may be considered.**

Category 8

Use of information or biospecimens in secondary research .104(d)(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: – **Broad consent was obtained**, – Consent documented or has waiver of documentation, – IRB conducts a limited review under 46.111(a)(7), and – The investigator does not include returning individual research results to subjects as part of the study plan.

* **CCC-UPR IRB does not plan to implement this Exemption at this time. Limited exceptions may be considered.**

Comments:

1. Final Rule allows research with children to be exempt for categories 1, 4, 5, 6, 7, and 8.
2. For exempt categories, 7 & 8, **limited IRB review** is always required.
3. It is also important to remember that exempt categories 7 & 8 are only available for use when **broad consent** will be (or has been) obtained.