Exemptions with Limited IRB Review

There are four exempt categories that include a provision for limited IRB review in the Revised Common Rule (2018 requirements). These are:

1. Exempt Category 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:

    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 32 CFR 219.111(a)(7).

2. Exempt Category 3: 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 32 CFR 219.111(a)(7).

d. 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.

e. Note: 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.

3. Exempt Categories 7 & 8: For exempt categories 7 & 8, limited IRB review is always required. These categories are only available for use when broad consent will be (or has been) obtained. **Please note that the WRAIR IRB has opted-out of the broad consent option. Consequently, these categories are not applicable to exempt protocols reviewed by the WRAIR IRB Chair/Designee or Exemption Determination Official (EDO).**

Assessing when Limited IRB Review is required

For exempt categories 2 & 3, the requirement for limited IRB review is triggered when:

a. 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

b. Any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

Eligibility for Exempt Category 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:

Criteria	Yes	No
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		
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 32 CFR 219.111(a)(7).		

NOTE: A "yes" to a. or b. means that a limited IRB review is NOT required. A "yes" to "c", however, means that a limited IRB review IS required.

Reviewer Comments:

Eligibility for Exempt Category 3

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:

Criteria	Yes	No
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		
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 32 CFR 219.111(a)(7)		
d. The proposed 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		
e. Does the intervention involve deception?		
f. If there is no deception, write in "N/A". If "yes", is there a provision for the subject to authorize 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?		

NOTE: A "yes" to a., b., or d., means that a limited IRB review is NOT required. A "yes" to "c" and/or "e", however, means that a limited IRB review IS required.

Reviewer Comments:

Annual Progress and Closeout Reporting

Continuing reviews are not required for protocols reviewed under the limited IRB review procedures, however, annual progress reports and closeout reports are required.

Exempt Category Inserts for Approval Memorandums

Category 2/3:

SUBJECT: Project Qualifies as Category 2/3 Exempt Research, **WRAIR #XXXX**

1. I approve the protocol, **WRAIR #XXXX**, titled, "TITLE," (Version, date), submitted by PRINCIPAL INVESTIGATOR, DEPARTMENT, BRANCH, ADDRESS

2. This protocol requires Limited IRB review, under expedited review procedures in accordance with Category 2/3.