



**Worksheet: Limited IRB Review or Exempt Research Review
When HIPAA Applies**

NUMBER	DATE	PAGE
3.213 (HRP-319)	05/01/2024	1 of 1

The purpose of this worksheet is to provide support for IRB Board Members performing Limited IRB Review or Exempt Research Review when HIPAA applies. It does not need to be completed or retained.

Confirm the Limited IRB Review Mechanism For Research As A Condition Of Exemption: (check one)

- Conducted via Expedited Review ⁱ
- Performed by the Convened IRB

1 Limited IRB Review Exempt Categories

The research falls into one the following exempt categories: (One or more categories must be checked)

- Exempt Category 2 (iii):** 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) where 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. The following must be trueⁱⁱ: **(Check if “Yes”)**
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Exempt Category 3 (i)(C):** Research involving benign behavioral interventionsⁱⁱⁱ 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 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. The following must be true ^{iv}: **(Check if “Yes”)**
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2 Exempt Review When HIPAA Applies

Select an applicable category below which applies because the exempt study is governed by HIPAA regulations.

- Exempt Category 4(iii):** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens if 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), subparts A and E, for 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). The following must be true. **(Check if “Yes”)**
- There are adequate provisions to protect the privacy of personal health information, and sets limits and conditions on the research uses and disclosures that may be made of such information without subjects’ HIPAA authorization, and protects the confidentiality of electronic health information.

ⁱ 45 CFR §46.110(b)(1)

ⁱⁱ 45 CFR §46.111(a)(7)

ⁱⁱⁱ 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.

^{iv} 45 CFR §46.111(a)(7)

^v 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.