HRP-319 | 03/01/2024

**WORKSHEET: Limited IRB Review**

The purpose of this worksheet is to provide support for IRB members performing limited IRB reviews[[1]](#footnote-1). It does not need to be completed or retained. (LAR = “subject’s Legally Authorized Representative (LAR)”)[[2]](#footnote-2)

**Method for limited IRB review**: (check one)

☐ Limited IRB review, for research as a condition of exemption, conducted via expedited review[[3]](#footnote-3)

☐ Limited IRB review, for research as a condition of exemption, performed by the convened IRB.

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

☐ 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 true[[4]](#footnote-4): (**Check if “Yes”**)

☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

☐ Category 3 (i)(C): Research involving benign behavioral Interventions[[5]](#footnote-5) 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 [[6]](#footnote-6) [[7]](#footnote-7):**(Check if “Yes”)**

☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

1. For VA Research,

   * If an exempt activity requires a limited IRB review, the limited IRB review must be completed prior to approval by the R&D Committee.
   * Research that has undergone limited IRB review and determined to be exempt requires approval by the R&D Committee and requires continuing review by the R&D Committee unless it is under the oversight of another subcommittee (e.g., Safety Review Subcommittee).

   [↑](#footnote-ref-1)
2. This document satisfies AAHRPP elements II.2.A, II.2.B, II.2.C, II.3.F, II.3.G [↑](#footnote-ref-2)
3. 45 CFR §46.110(b)(1) [↑](#footnote-ref-3)
4. 45 CFR §46.111(a)(7) [↑](#footnote-ref-4)
5. 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. [↑](#footnote-ref-5)
6. 45 CFR §46.111(a)(7) [↑](#footnote-ref-6)
7. 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. [↑](#footnote-ref-7)