HRP-403 | 08/07/2025

**CHECKLIST: Limited IRB Review**

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer when research involves limited IRB review as a contingency for exemption. This checklist must be used for initial review or when a modification impacts previously considered limited IRB review criteria.

* For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to “Submit Non-Committee Review” activity. The IRB Office retains this checklist in the protocol file.
* For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:

1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the protocol file.

**Submission Information**

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| **Basic Information** | **Submission Details** |
| IRB Number: | Click or tap here to enter text. |
| Study Title: | Click or tap here to enter text. |
| Short Title: | Click or tap here to enter text. |
| Investigator: | Click or tap here to enter text. |
| Person Completing Checklist (Name): | Click or tap here to enter text. |
| Date Checklist Completed: | Click or tap here to enter text. |

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

☐ Limited IRB review, for research as a condition of exemption, conducted via expedited review[[1]](#footnote-1)

☐ 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[[2]](#footnote-2): (**Check if “Yes”**)

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

*Provide protocol specific findings justifying this determination:* *Click or tap here to enter text.*

☐ Category 3 (i)(C): Research involving benign behavioral Interventions[[3]](#footnote-3) 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 [[4]](#footnote-4) [[5]](#footnote-5):**(Check if “Yes”)**

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

*Provide protocol specific findings justifying this determination:* *Click or tap here to enter text.*

1. 45 CFR §46.110(b)(1) [↑](#footnote-ref-1)
2. 45 CFR §46.111(a)(7) [↑](#footnote-ref-2)
3. 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-3)
4. 45 CFR §46.111(a)(7) [↑](#footnote-ref-4)
5. 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-5)