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| The purpose of this worksheet is to provide support for IRB members performing limited IRB reviews. This worksheet does not need to be retained. (LAR = “subject’s Legally Authorized Representative”) |
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| **Method for limited IRB review:** (Check one.) |
| ☐ | Limited IRB review, for research as a condition of HRPP review +/- limited review (exemption), conducted via single member (expedited) review[[1]](#footnote-1) |
| ☐ | Limited IRB review, for research as a condition of HRPP review +/- limited review (exemption), performed by the full (convened) IRB. |
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| **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. |
| ☐ | 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. |
| ☐ | Category 7: Storage or maintenance for secondary of identifiable private information or identifiable biospecimens for potential secondary research. The following must all be true[[6]](#footnote-6): **(Check if “Yes”.)**☐ If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. |
| ☐ | Category 8: Secondary research involving the use of identifiable private information or identifiable biospecimens for secondary research use. The following must all be true: **(Check if “Yes”.)**☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.☐ The investigator does not include returning individual research results to subjects as part of the study plan[[7]](#footnote-7).  |
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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)
6. 45 CFR §46.111(a)(8) [↑](#footnote-ref-6)
7. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results. [↑](#footnote-ref-7)