



WORKSHEET: Limited IRB Review and Broad Consent

The purpose of this worksheet is to provide support for IRB members performing limited IRB reviews and/or reviewing broad consent. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative (LAR)")ⁱ

Method for limited IRB review: (check one)

- Limited IRB review, for research as a condition of exemption, conducted via expedited reviewⁱⁱ
- 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 trueⁱⁱⁱ: **(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^{iv} 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^v: **(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 research for which broad consent is required: Storage or maintenance of Identifiable Private Information or Identifiable Biospecimens for potential secondary research. The following must all be true^{vii}: **(Check if "Yes")**
 - Broad consent for storage, maintenance, and secondary research use of Identifiable Private Information or Identifiable Biospecimens is obtained. (See Section 2: Criteria for Broad Consent)
 - Broad consent is appropriately documented or waiver of documentation is appropriate. **(One must be checked below)**

Section 3: Broad Consent (Long Form)

HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent

HRP-317 - WORKSHEET - Short Form of Consent Documentation

- 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 for which broad consent is required: Research involving the use of Identifiable Private Information or Identifiable Biospecimens for secondary research use. The following must all be true: **(Check if “Yes”)**
- Broad consent for the storage, maintenance, and secondary research use of the Identifiable Private Information or Identifiable Biospecimens was obtained.
 - Documentation of informed consent or waiver of documentation of consent was obtained for the broad consent.
 - There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 - The research to be conducted is within the scope of the broad consent that was obtained.
 - The investigator does not include returning individual research results to subjects as part of the study plan^{viii}.

2. Criteria for Broad Consent (Check if “Yes” or “NA”, all must be checked)

Broad Consent Process

- The investigator will obtain the legally effective informed consent of the subject or LAR.
- The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence
- Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
- The subject or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability from negligence.

Elements of Broad Consent Disclosure

- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others that may reasonably be expected from the research.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit **(NA if not using biospecimens)**
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) **(NA if not using biospecimens)**
- A general description of the types of research that may be conducted with the Identifiable Private Information or Identifiable Biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted
- A description of the Identifiable Private Information or Identifiable Biospecimens that might be used in research, whether sharing of Identifiable Private Information or Identifiable Biospecimens might occur, and the types of institutions or researchers that might conduct research with the Identifiable Private Information or Identifiable Biospecimens
- A description of the period of time that the Identifiable Private Information or Identifiable Biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the Identifiable Private Information or Identifiable Biospecimens may be used for research purposes (which period of time could be indefinite)
- Unless the subject or LAR will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's Identifiable Private Information or Identifiable Biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies **(NA if subjects will be provided details about specific research studies)**
- Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject **(NA if research results will be disclosed to subjects in all circumstances)**
- An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's Identifiable Private Information or Identifiable Biospecimens, and whom to contact in the event of a research-related harm

3. Broad Consent Long Form of Consent Documentation (Check if "Yes" or "NA". All must be checked)

- The written consent document is accurate, complete, and consistent with the protocol.
- The written consent document embodies the elements in **Section 2-Elements of Broad Consent Disclosure**
- The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.

- The subject or LAR will sign and date the consent document.
- The person obtaining consent will sign and date the consent document.
- A copy of the signed and dated consent document will be given to the person signing the document.
- If there is a LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **(NA if no signature line)**
- When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. **(NA if all subjects are able to read)**

ⁱ This document satisfies AAHRPP elements II.2.A, II.2.B, II.2.C, II.3.F, II.3.G

ⁱⁱ 45 CFR §46.110(b)(1)

ⁱⁱⁱ 45 CFR §46.111(a)(7)

^{iv} 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.

^v 45 CFR §46.111(a)(7)

^{vi} 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.

^{vii} 45 CFR §46.111(a)(8)

^{viii} This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.