Feb 2026

IRB Engagement Determination Checklist

Instructions: Check all that apply for each institution conducting the research. If an institution has at least ONE category checked, the institution is considered to be engaged in human subjects research (HSR). If an institution has NO categories checked, the institution is most likely not considered engaged. If more than one institution is engaged and the research is federally funded, submit a Reliance Intake Form to request a reliance review.

***Please Note:** This form is simply a tool. The final decision on engagement will be made by the IRB.*

An Institution is considered engaged in HSR if it's employees or agents:	MUSC	Collaborating Institution
1. Receive an award through a grant, contract or cooperative agreement directly from HHS for human subjects research **even if all activities involving human subjects are carried out by another institution**	☐	☐
2. Intervene for research purposes with any subjects by performing research procedures. **Examples:** • draw blood • collect buccal mucosa cells using a cotton swab • administer individual or group counseling or psychotherapy • administer drugs or other treatments • surgically implant medical devices • utilize physical sensors • utilize other measurement procedures	☐	☐
3. Intervene for research purposes, with any subjects by manipulating the environment	☐	☐
4. Interact for research purposes with any human subject of the research **Examples:** • engage in protocol dictated communication or interpersonal contact • ask someone to provide a specimen by voiding or spitting into a specimen container • conduct research interviews or administering questionnaires	☐	☐
5. Obtain informed consent of subjects for the research.	☐	☐
6. Obtain for research purposes identifiable private information or identifiable biological specimens from **any source** for the research **Examples:** • observe or record private behavior • use, study, or analyze for research purposes identifiable private information or identifiable specimens provided by another institution • use, study, or analyze for research purposes identifiable private information or identifiable specimens already in the possession of the investigators	☐	☐

Institutions would be considered **not engaged** in human subjects research if the involvement of their employees or agents in the research is limited to one or more of the following:

1. Perform commercial or other services for investigators provided that **all** of the following conditions also are met:
   - the services performed do not merit professional recognition or publication privileges;
   - the services performed are typically performed by those institutions for non-research purposes; and
   - the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.
2. Provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators provided that all of the following conditions are also met:
   - Do not administer study interventions being tested or evaluated under the protocol;
   - The clinical trial-related medical services are typically provided by the institution for clinical purposes;
   - The institution does not enroll subjects or obtain informed consent;
   - Investigators from an institution engaged in the research retain responsibility for overseeing the protocol-related activities and reporting data and reportable events.
3. Administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis provided that all of the following conditions are met:
   - Engaged investigator determines it is in the subject's best interest;
   - The institution does not enroll subjects or obtain informed consent;
   - Investigators from an institution engaged in the research retain responsibility for overseeing the protocol-related activities and reporting data and reportable events.
   - an IRB designated on the engaged institution's FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site
4. Inform prospective subjects about a research study, provide them with information, a consent form or contact information of study team or seek the prospective subject's permission for investigators to contact them
5. Institutions (e.g., schools, nursing homes, businesses) that permit use of their facilities for intervention or interaction with subjects by investigators from another institution.

6. Obtain de-identified PHI/biological specimens (none of the 18 HIPAA Identifiers are included)
7. Release identifiable private information or specimens to investigators at another institution but do not collaborate with them in any other manner including publication.
8. Obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information and are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain.
9. Institutions whose employees or agents access or utilize individually identifiable private information only while visiting an institution that is engaged in the research, provided their research activities are overseen by the IRB of the institution that is engaged in the research.
10. Institutions whose employees or agents access or review identifiable private information for purposes of study auditing.
11. Institutions whose employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.
12. Institutions whose employees or agents author a paper, journal article, or presentation describing a human subjects research study.