

Guidance for Determining Engagement in Human Research at Northwestern University and Affiliated Institutions

According to Northwestern University's policy on [Human Research Protection Program Compliance](#), the Northwestern University Institutional Review Board (IRB) has the authority to determine whether a project engages Northwestern University in human participant research. The Northwestern University IRB also determines whether projects engage affiliated institutions (e.g., Northwestern Memorial HealthCare and the Shirley Ryan Ability Lab) and any other institution for which Northwestern University has an agreement to provide IRB services, pursuant to the terms of the agreement(s). Northwestern University, its affiliated institutions, and those institutions for which Northwestern University provides IRB services are henceforth referred to as the "Institution(s)." The Northwestern University IRB reviews non-exempt human participants research only when the Institution(s) is engaged in the research, where "engagement" is defined as outlined in federal guidance and in accordance with Institutional policy.

The Institution(s) are considered to be "engaged" in human research when its employees or agents:

- a) Obtain data about the participants of the research through intervention or interaction with them;
- b) Obtain identifiable private information about or identifiable biospecimens from the participants of the research;
- c) Obtain the informed consent of human research participants.

Please note that for FDA regulated research, the institution may be considered engaged even when working solely with de-identified samples or data if they are being used to develop an investigational medical device, such as Software as Medical Device or a diagnostic assay or test.

The information below should be noted when considering whether an activity engages the Institution(s) in research that is conducted at either an institution's facility or at a non-affiliated site. For the purposes of this guidance, non-affiliated sites include institutions, pharmaceutical and medical device companies, private medical offices and clinics, and other organizations that are not affiliated with the Institution(s). The HHS guidance on [Engagement of Institutions in Human Subjects Research](#) may be referenced for additional details.

1. The Institution(s) are engaged if its employees or agents are conducting the human research procedures (obtaining consent, performing research procedures, administering test articles, obtaining or analyzing identifiable information or specimens, etc.)
2. If the Institution(s) receives money through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human participants research (i.e. awardee institutions), even where all activities involving human participants are carried out by employees or agents of another institution.
3. If the Institution(s) provides research intervention to participants who were previously enrolled or treated at another research site, *unless* the research intervention being tested or evaluated is limited to a one-time or short-term basis (see specific criteria in the HHS guidance referenced above, see Section III.B.3).

4. The Institution(s) are considered engaged if they are a statistical center for a multi-center trial and receive identifiable private information. There must be mechanisms in place to ensure that the privacy of participants and confidentiality of data are adequately maintained.
5. Activities that **do not involve “engagement”** in research include the following examples:
 - a. Informing potential participants about the research or “facilitating recruitment” (e.g., providing recruitment materials).
 - b. Allowing another institution (under a formal agreement) to use the Institution(s) facilities for the research intervention (i.e., to conduct a specific research procedure only).
 - c. Obtaining private coded information (data or specimens) of which the Investigator is unable to readily ascertain the identity and for which the Investigator was not involved in the original collection (e.g., Investigator has no link). Note: that the release or receipt of such information may be subject to additional institutional requirements prior to release.
 - d. When individuals who would normally be considered employees or agents conduct research at non-affiliated sites acting as an agent of another entity (e.g., privately-owned health practice, consulting business, other academic institution through joint faculty appointment.)