



## GUIDELINE FOR DETERMINING ENGAGEMENT IN RESEARCH

According to OHSP Policy 301 Scope and Authority of the RSRB, the RSRB has the authority to determine whether a project engages the UR in human subject research. The UR is considered as conducting human subjects research when, for the purposes of the research project, its employees or agents:

- 1) Obtain data about human research subjects through intervention or interaction with them;
- 2) Obtain identifiable private information about human research subjects, through direct or indirect interaction;
- 3) Obtain informed consent of human subjects for research; or
- 4) Conduct a clinical trial as defined in FDA regulations.

The information below should be noted when considering whether an activity engages the UR in research (either at a UR facility or at a non-UR facility). When considering whether a collaborating non-UR site/facility is engaged in research and the requirements based on that determination, use the decision tree on the next page. Non-UR sites include all types of institutions, such as, educational/non-profit organizations, commercial repositories, and pharmaceutical and medical device companies. The HHS guidance on [\*Engagement of Institutions in Human Subjects Research\*](#) may be referenced for additional details.

1. The UR is engaged if its employees or agents are conducting the research (obtaining consent, performing research procedures, administering test article, obtaining identifiable information or specimens, etc.).
2. If the UR receives money through a grant, contract or other agreement as the primary awardee, it is engaged even if the research is conducted by employees or agents of another institution.
3. The UR is engaged if the institution provides research intervention of subjects previously enrolled/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 Section III.B.3).
4. The UR is engaged if it is a statistical center for a multi-center trial and receives identifiable private information. There must be mechanisms in place to ensure that privacy of subjects and confidentiality of data are adequately maintained.
5. Activities that **do not involve “engagement”** in research include the following examples:
  - a. Informing potential subjects about the research or “facilitating recruitment” (e.g., providing them with a consent form, providing the potential subject contact information of the study team to obtain more information, asking permission from the potential subjects for the study team to contact them).
  - b. Allowing another institution to use UR 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 (e.g., Investigator receives no link). Note that the release or receipt of such information may be subject to additional institutional requirements prior to release).

## DECISION TREE FOR DETERMINING ENGAGEMENT OF NON-UR SITES

