GUIDELINE FOR DETERMINING ENGAGEMENT IN RESEARCH

According to OHSP Policy 301 Scope and Authority of the RSRB, at the request of an employee or agent of the UR, 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 (includes all types of institutions, such as educational/non-profit organizations, commercial repositories, and pharmaceutical and medical device companies) and the requirements based on that determination, use the decision tree on the next page. 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 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 research intervention is a limited 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 & 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 research intervention.
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 DETERMINATION OF ENGAGEMENT INVOLVING COLLABORATING NON-UR SITES

Is the non-UR facility engaged in research?

Yes

Is the non-UR facility federally funded?

Yes

Is the non-UR facility engaged in research?

Yes

Letter of support from non-UR facility required (e.g., only facilitating recruitment)

1) The REB reviews the activities of the non-UR facility as part of the Investigator's research plan;
2) Plan outlining Investigator oversight of the research activities and
3) Letter of support from non-UR facility.

No

1) Copy of non-UR facility IRB approval letter;

Yes

No

Let the non-UR facility have an FWA?

Yes

Letter of support from non-UR facility required (e.g., only facilitating recruitment)

No

Yes

No

One of the following is required:
1) Non-UR facility obtains an FWA and lists UR as IRB of Record;
2) Individual Investigator Agreement