GUIDELINE FOR DETERMINING ENGAGEMENT IN RESEARCH

According to the Office for Human Subject Protection (OHSP) Policy 301 Research Subject Review Board (RSRB) Scope and Authority, the RSRB has the authority to determine whether a project engages the University of Rochester (UR) in human subject research and therefore requires Institutional Review Board (IRB) review and approval.

The UR is considered to be conducting human subject 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.

Below are examples of activities that engage an Institution in research. 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.

Activities that **do not involve "engagement"** in research include the following examples:

1. Informing potential subjects about the research or facilitating recruitment without engaging in the informed consent process (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).

2. Allowing another institution to use UR facilities for the research intervention (i.e., to conduct a specific research procedure only).

3. 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 require a data use or material transfer agreement prior to release).

Engagement of Non-UR Sites

When collaborating with non-UR sites, UR Investigators need to consider whether the non-UR site is engaged in the research. Non-UR sites include all types of institutions, such as, educational/non-profit organizations, commercial repositories, and pharmaceutical and medical device companies. Based on the nature of the non-UR site's involvement, use the decision tree below to identify additional requirements necessary for facilitating Institutional Review Board review. See **OHSP Policy 504 IRB Reliance and Collaborative Research.**

Decision Tree for Determining Engagement of Non-UR Sites