

## What Does it Mean for an Institution to be “Engaged” in Research?

The question of engagement can be complicated depending on the specifics of the research and the various activities occurring at an institution."

"In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research."

Examples of different scenarios, and more details about the subject of engagement can be found in a [Guidance](#) by the federal Office of Human Research Protections (OHRP). They also have a [video](#). The Secretary's Advisory Committee On Human Research Protections (SACHRP) also has an [interpretation](#) of engagement.

**Engagement in Human Subjects Research = Need for CW HRPP and IRB of record oversight, as well as the activity occurring at the institution being subject to all applicable regulations, laws, policies, and requirements.**

If there are any activities part of a research project being conducted at a particular institution, the question of whether that institution is *engaged* in the research becomes key. Determining whether an *institution* involved in some aspect of the research is *engaged* in that human subjects research is necessary because if it is, certain regulatory requirements apply. An engagement determination obligates the institution and the investigator to adhere to regulatory and institutional requirements regarding the conduct of research activity. This includes IRB review and approval.

## What Will Happen if CW is Engaged in the Research?

Knowing whether an institution is "engaged" in research highlights the obligations of an institution to regulatory and institutional requirements regarding the conduct of research, including IRB review and oversight of the research activities occurring at that institution.

Any research activities occurring at CW that engages CW must be reviewed, approved and overseen by an IRB. If CW is engaged and the IRB of record is not the MCW pediatric

IRBs, a formal reliance agreement will need to be executed to defer IRB oversight of the research activities occurring at CW to that IRB. In the case of the Cooperative Groups we work with (Children's Oncology Group, National Marrow Donor Program) we have a standing master reliance agreement established with the IRB utilized by these groups (NCI CIRB and NMDP IRB).

When Children's Wisconsin is determined to be engaged in human subjects research it becomes necessary to identify the IRB of record. The MCW pediatric IRBs are CW's primary IRB of record in most cases per an [IRB services agreement](#). However, the investigator may request that CW rely on the services of another external IRB. If the IRB of record requested is not the MCW pediatric IRBs a formal reliance on the IRB of record if the IRB of record must be established. \_

## How Recruitment Activities at CW May Engage CW in the Research

The question of whether CW is engaged often comes up in the context of providers or CW clinics/departments assisting in recruitment for research happening at another institution. It is important to understand when "recruitment" activities cross over into engaging the institution.

"Recruitment of research participants involves presenting potential participants with information about a study, prior to their enrollment, to help establish their interest and willingness to serve as research subjects. Recruitment takes many forms and often includes the first information participants see about a study. Recruitment is considered by federal regulations and the IRB to be the beginning of the informed consent process." ([Chapman University – Recruitment of Research Participants](#))

"Study screening procedures are frequently confused with study recruitment. The two activities may overlap but are distinctly different. Recruitment includes all activities where information is provided to the prospective participant while screening includes obtaining information from prospective participants. Recruitment does not require the consent of the prospective subject whereas screening may." ([Children's Hospital of Philadelphia](#))

"Screening activities start the moment the investigator/provider obtains information about the prospective participant to determine if they are eligible for the research. Screening individuals to obtain and record information to **determine eligibility** involves obtaining identifiable private information and is considered human subjects research and is subject to 45 CFR 46." ([Children's Hospital of Philadelphia](#))

For example:

- Hanging flyers in a clinic, or handing flyers to ALL patients, to inform patients about research happening at another institution, with contact information for that institution if the patient is interested would likely not engage CW, and thus IRB oversight or reliance agreements would not be needed.
- Reviewing a patient's record to determine if a patient may be eligible for another institution's study to target which patients receive the information is a screening activity which may engage CW in that research.

Any activities for which CW may need to obtain consent from potential subjects, or starts the consenting process, will likely engage CW in the research. The recruitment activities may constitute the start of the consent process which would engage CW and require IRB review. ([FDA Information Sheet - Recruiting Study Subjects](#))

*Please consult with the CW HRPP office for assistance in determining whether plans to assist another site recruiting subjects for their research engages CW.*

#### **How recruitment for CW research at other institutions affect engagement.**

If an investigator conducting research at CW would like to enlist the help of another institution to recruit for the project, that institution must be consulted and make their own engagement determination.

## **Request an Engagement Determination**

Investigators cannot determine themselves whether an institution, including CW, is engaged in a research project. **Individual institutions make their own determinations regarding whether they consider themselves engaged in a research project.**

The CW HRPP makes engagement determinations. Other institutions involved in the research must make their own determination of engagement. This means that if an investigator has a project for which some services, collaboration, or activities for their project are being conducted at another institution, the investigator will need to reach out to that institution regarding this. If a determination is needed as to whether Children's Wisconsin is engaged in the research, this can be requested by completing the [Engagement Determination Form](#).

As always, please contact the Children's Wisconsin HRPP at [CWHRPP@childrenswi.org](mailto:CWHRPP@childrenswi.org) with any questions or to discuss whether CW is engaged in a research project and what additional steps may need to be taken.