

Human Research Protection Program
Request for Engagement Determination**When to use this form**

Submit this form when a written determination is required to document that Children's Wisconsin is not engaged in human subjects research. Please review this OHRP guidance document for additional information:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

This guidance document describes:

1. scenarios that, in general, would result in an institution being considered engaged in a human subjects research project;
2. scenarios that would result in an institution being considered not engaged in a human subjects research project; and
3. IRB review considerations for cooperative research in which multiple institutions are engaged in the same non-exempt human subjects research project.

Instructions for submission

Submit this form ELECTRONICALLY by attaching it in an email message sent to hsr.determination@childrenswi.org with **"Request for Engagement Determination"** in the subject line.

Consult with appropriate CW administrator(s) of the department(s) where the activity will be conducted to ensure there is institutional support for the activity.

Include the following as attachments to the email:

- Lead site protocol that describes what proposed activities will take place at an external organization;
- Documentation of IRB approval of the protocol;
- Any patient facing materials to be provided to Children's Wisconsin patients (e.g, recruitment flyers, brochures, etc.);
- Written administrative signoff from an appropriate Children's Wisconsin leader that the proposed activity can take place in the Children's Wisconsin clinic/department;
- Any other information that is relevant to consider this determination request.

Requestor Information

Activity Title:

Requestor Name (including earned degrees):

Contact Email:

Organization and department:

Lead site overseeing research activities:

1. Using the above-referenced OHRP guidance, indicate what scenario (referenced by section and number) best represents the proposed activity at Children's Wisconsin:

2. Describe in detail what activities will take place in Children's Wisconsin space and who will be responsible for the activities:

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3. In what departments/clinics will the activities take place:

4. Provide any other information relevant to this request (or enter N/A):

By entering your initials in this box and submitting this document electronically via email attachment, you are attesting that the information provided is representative of the proposed activities and that you will notify the CW HRPP of any significant changes that may affect the determinations made by the CW HRPP. The CW HRPP acknowledges this, and accepts in lieu of your written signature.

- ☐ The proposed activity, as described, **DOES NOT** engage Children's Wisconsin in human subjects research. Submission of an IRB application is not required.
- ☐ The proposed activity, as described, **DOES** engaged Children's Wisconsin in human subjects research. Submission of an IRB application IS REQUIRED. Appropriate IRB approval must be obtained before the activities can be conducted in Children's Wisconsin space.

IRB Chair/Research Integrity Manager/Designee Signature

Title

Date