Children's Wisconsin

Tracking #: _____ **/ Date received:** _____

Human Research Protection Program

Request for Determination of Human Subjects Research ('not HSR')

When to use this form

At times it is difficult to discern whether a proposed activity constitutes research or human subjects research. The Children's Wisconsin Human Research Protection Program (CW HRPP) has created this form to help with the assessment. The information provided will be reviewed to determine whether the proposed activity would require review and approval by an Institutional Review Board (IRB), and if not, will serve as written documentation of the determination. The CW HRPP is the sole body designated to make formal determinations that an activity is not research or human subjects research for Children's Wisconsin.

Instructions for submission

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

- **For faculty/staff conducting QI activities**, you must obtain approval from the appropriate CW administrator(s) of the department(s) where the activity will be conducted to ensure there is institutional support for the activity. Your initials document that you have obtained this departmental approval (this may be verified; failure to do so will result in delays processing your request): **Enter Initials**
- **^**A project being conducted by any **resident/fellow/student** (including nursing students) or an individual who is not faculty/staff at CW/MCW must also include with this request **written departmental approval from an appropriate CW administrator** to indicate project support.
- ***For projects being conducted by any nursing students or being led by any nursing personnel, please review the Children's Wisconsin Nursing Research web page found on Children's Connect.
  - For Quality Improvement projects please consult with Holly O'Brien, Director Quality & Patient Safety, and provide **written administrative acknowledgement** with this request for determination.
  - For and Evidence Based Practice projects, please consult with Karen Gralton, PhD, RN, Evidence-Based Practice Specialist and provide **written administrative acknowledgement** with this request for determination.
- For requests that involve obtaining de-identified or coded data or biologic specimens that are stored in a bank or registry, provide reference to the IRB-approved banking or registry protocol or include the banking/registry protocol with sufficient operational details for evaluation. Additional materials may be requested to help with the determination.
- For multi-center projects, submit lead site documents (project manual or manual of operations, collection tools, etc.) as well as lead site's determination of the type of project. Additional materials may be requested to help with the determination.

Requestor Information

Activity Title: Click here to enter text.	
Requestor Name (including earned degrees): Click here to enter text.	
Contact Phone: Click here to enter text.	Contact Email: Click here to enter text.
Organization: Click here to enter text.	Department: Click here to enter text.
Affiliation Status: Check all that apply	☐ CW Staff / ☐ MCW Faculty ☐ Other (explain): Click here to enter text. ☐ Nursing Personnel/Nursing Student (*** must include appropriate written administrative acknowledgment** and **^written CW departmental approval**) ☐ Resident/Fellow/Student (**^ must include written CW departmental approval**)

Children's Wisconsin

Human Research Protection Program
Request for Determination of Human Subjects Research (HSR)

1. Provide a brief summary of the activity, including objective(s).
Click here to enter text.
2. To determine whether the activity is **designed** (and/or will be implemented) solely for internal CW purposes in support of the organization's mission, describe the purpose of the proposed activity as it relates to Children's Wisconsin.
Click here to enter text.
3. Describe in sufficient detail the proposed methods and procedures. Include details about whether/how any data/specimens involved will be de-identified or coded. *Definitions: Private information collected for research that is **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) is considered human subjects research.* ***Coded** means that: **(1)** identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and **(2)** a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.*
Click here to enter text.
4. Will individually identifiable data or records obtained from CW (such as patient medical records) be shared with individuals/entities outside Children's Wisconsin/Medical College of Wisconsin as part of this activity (this does not include publications or presentations of aggregated or deidentified data)? Choose an item.
If yes, provide details: Click here to enter text.
5. To determine if the activity meets the FDA definition of "clinical investigation," or if the activity involves design elements generally associated with "research" activities (e.g., use of FDA-approved agents, double-blind intervention, placebo controls, inclusion of subjects who would not normally receive the intervention) briefly describe the **design** of the activity.
Click here to enter text.
6. To determine if the activity's findings are primarily intended to be used solely by and within Children's Wisconsin, describe how the findings will be used.
Click here to enter text.
7. To help determine whether the activity is **designed** for the purpose of contributing to generalizable knowledge that expands the knowledge base of a scientific discipline or other scholarly field of study, describe the professional group(s) that would find the results of the activity to be of value. This is one consideration and does not automatically make the activity designed for the purpose of contributing to generalizable knowledge.
Click here to enter text.
8. To determine if the activity has been **funded** as research, list all sources of funding and indicate whether any funding group or agency has funded the project as research. You may need to inquire specifically to determine if the activity is funded as research.
Click here to enter text.

9. Does the requestor plan to use eligibility criteria based on clinical factors? Select One

   If yes, does the investigator plan to analyze interventions based on clinical factors to inform the care of future individual patients? Select One

10. Do you intend to publish or present your results? Select One

    The intent to publish or present findings does not automatically make the activity designed to contribute to generalizable knowledge. Activities deemed not research or human subjects research can be published or presented, but should not be represented as such.

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. **Enter Initials**

Children's Wisconsin

Human Research Protection Program
Request for Determination of Human Subjects Research (HSR)

CW HRPP Determinations **For HRPP Office Use Only**		
	Yes	No
The activity is designed for internal CW purposes in support of the organization's mission	☐	☐
The findings of the activity will be used by and within CW	☐	☐
The activity is **not** designed for the purpose of contributing to generalizable knowledge that expands the knowledge base of a scientific discipline or other scholarly field of study	☐	☐
The activity is **not** funded as research	☐	☐
The activity does **not** meet the FDA definition of clinical research	☐	☐
The activity does **not** involve elements generally associated with research activities	☐	☐
The activity is designed as research but does not meet the definition of human subjects research	☐	☐

☐ The proposed activity, as described, **DOES NOT** constitute research or human subjects research. Submission of an IRB application is not required.

☐ The proposed activity, as described, **DOES** constitute human subjects research. Submission of an IRB application IS REQUIRED. Appropriate IRB approval must be obtained before the investigator begins their research.

IRB Chair/Research Integrity Manager/Designee Signature Title Date

Instructions to requestor following determination

This review is to document whether the activity constitutes research or human subjects research and should not be interpreted as "IRB approval."

If this project is deemed not research, it must **NOT** be referred to as *research* in any publications. If the project is deemed research that is not human subjects research it must **NOT** be referred to as *human subjects research* in any publication.

If any significant changes are made to the activity after the request is submitted, the determination that IRB oversight is not required no longer applies and a revised *Request for Determination of Human Subjects Research* form must be submitted.

For research projects that exclusively evaluate de-identified or coded data or biologic specimens derived from humans, the determination that the activity is not human subjects research is recognized by the Office for Human Research Protections of the Department of Health and Human Service, but is not recognized by the FDA.

For activities that are deemed not research or human subjects research but access or collect identifiable Protected Heath Information, contact Maria Vallejo in CW Research Compliance mvallejo@childrenswi.org to ensure that HIPAA and privacy rules are followed.

For case reports of 3 or fewer patients that are deemed not Human Subjects Research, contact Maria Vallejo in CW Research Compliance mvallejo@childrenswi.org to determine whether obtaining consent would be feasible.