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| **When to use this form** | | | |
| At times it is difficult to discern whether a proposed activity constitutes research or human subject 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 the CW Institutional Review Board (CW IRB), and if not, will serve as written documentation of the determination. The CW HRPP is the sole body designated to make formal IRB determinations at Children’s Wisconsin. | | | |
| **Instructions for submission** | | | |
| 1. Submit this form ELECTRONICALLY by attaching it in an email message sent to [hsr.determination@chw.org](mailto:hsr.determination@chw.org) with “Request for Research Determination” in the subject line. 2. Request a read receipt (under ‘tags’ in Microsoft Outlook) for documentation that the email was received. 3. You will receive a final email with the completed determination form attached for your records. 4. Allow a minimum of four weeks for review and determination.  * 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. * **^**A project being conducted by a 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 nursing students and nurse scientists, please review the [Children's Wisconsin Nursing Research web page](https://connect.chw.org/departments-services/clinical-departments/nursing-professional-practice/nursing-research/Nursing-Research-Review-Process)   + For Quality Projects please consult with Sarah Pouzar, Director Quality & Performance Improvements, and provide **written administrative acknowledgement** with this request for determination.   + For and Evidence Based Practice Projects, please consult with Karen Gralton, PhD, RN, Director Quality & Performance Improvements 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. * 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. | | | |
| **Requestor Information** | | |
| Activity Title: | | |
| Requestor Name (including earned degrees): | | |
| Contact Phone: | | Contact Email: |
| Organization: | | Department: |
| Affiliation Status:  Check all that apply | CW Staff /  MCW Faculty /  Other (explain):  Nursing Scientist/Nursing Student (**\*** **must include appropriate written administrative acknowledgmen**t and **^written CW departmental approval**)  Resident/Fellow/Student (**^** **must include written CW departmental approval**) | |

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| 1. Provide a brief summary of the activity, including objective(s). |
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| 1. 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. |
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| 1. 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.* |
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| 1. 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)? If yes, provide details: |
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| 1. 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. |
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| 1. To determine if the activity’s findings are **designed** to be used solely by and within Children’s Wisconsin, describe how the findings will be used. |
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| 1. 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. |
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| 1. 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. |
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| 1. Would the activity be conducted as proposed if the individuals conducting the activity knew that they would never receive any form of academic recognition for the project, including publication of results in a medical journal or presentation of the project at an academic meeting?  If prohibition from receiving any form of academic recognition for the project would affect the conduct of the project in any way, then research is a motive for the activity to a degree that the project should be classified as research from the regulatory standpoint. |
| 1. Do you intend to publish or present your results?   The intent to publish or present findings does not automatically make the activity designed to contribute to generalizable knowledge. Activities can be published or presented, but they should not be described as human subjects research. |

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.

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| **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 subject research | 🞏 | 🞏 |

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| * 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 | |

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| **Instructions to requestor following determination** |
| This review is to document whether the activity constitutes research or human subject research and should not be interpreted as “IRB approval.”  If this project is deemed not research or not human subject research, it must **NOT** be referred to as research in any publications.  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 Operations Activity* 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 subject 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 subject research but access or collect identifiable Protected Heath Information, contact either Tom Twinem, Director of CW Corporate Compliance, or Diane Bauer, CW Research Compliance Manager, at 414-266-6237 or [dbauer@chw.org](mailto:dbauer@chw.org) to ensure that HIPAA and privacy rules are followed.  For case reports of 3 or fewer patients that are deemed not Human Subject Research, contact Diane Bauer, CW Research Compliance Manager, at 414-266-6237 or [dbauer@chw.org](mailto:dbauer@chw.org) to determine whether obtaining consent would be feasible. |