An activity will require IRB review if it is determined to be both research and involves human subjects. Except for some special types of projects (e.g., Expanded Access Humanitarian Use Devices), activities that do not meet the federal definitions of research and human subject do not require (as a matter of regulation) IRB review and oversight. *IRB Management and Function Chapter 5.*

The responsibility for initial determination of whether an activity constitutes "research" rests with the individual who has primary responsibility for the activity. This individual should make this determination based on the definitions of "research" and "clinical investigation" as provided by the Common Rule and U.S. Food and Drug Administration (FDA) regulations, respectively (see definitions). Consultation with the CW HRPP Office is encouraged.

Activities that are not human subject research under the Common Rule:

There are select activities that have been deemed not to be research under the revised Common Rule. As long as all conditions are met, these four activities are deemed to not be research. (45 CFR 46.102(1)(1-4)

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focuses directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigation purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Quality Improvement v. Research:

- At times it may be difficult to discern whether a proposed activity constitutes research or human subject research, quality improvement or an operational activity. This distinction is important in that only human subject research requires IRB review and oversight. The Children's Wisconsin HRPP has developed guidance to help with this assessment. Additional information can be found on HHS's Office for Human Research Protections (OHRP) web page.

- The responsibility for initial determination of whether an activity constitutes "research" rests with the individual who has primary responsibility for the activity. This individual should make this determination based on the definitions of "research" and "clinical investigation" as provided by the Common Rule and U.S. Food and Drug Administration (FDA) regulations, respectively (see section 5.1).
- Consultation with the Children's Wisconsin HRPP Office is encouraged.

Requesting a formal determination of whether an activity is human subject research:

While a formal written determination of whether an activity is human subject research is not required, many investigators want this documentation to provide to publishers if requested. The Children's HRPP is the sole body designated to make formal written determinations at Children's Wisconsin.

- If ALL activity for the proposed project will occur at CW, this request can be made via Children's Wisconsin Human Subject Research Determination Requests Form. The CW HRPP staff reviews and makes the determination and the investigator will receive the form signed by HRPP staff indicating the determination.
- If some activity will occur at CW and some at Froedtert/MCW, this request should be made through the eBridge submission system. The reason for this is that in these cases both institutions need to make a determination about whether the activity occurring in their space is or is not human subject research. Both institutions use and have access to eBridge and can view the request.
- Any request for a formal written determination that an activity is research not involving human subjects must include materials in sufficient detail to make the determination.
    - Protocol or detailed description of the activity.
    - 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 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 projects being conducted by any nursing students or being led by nurse personnel/investigators/scientists, please review the Children's Wisconsin Nursing Research web page

- 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.