

Determinations of whether or not a proposed activity is research involving human subjects

Investigators who are uncertain if their proposed activities constitute human subjects research may submit a request to the Woman's Health Research Center for a determination. The IRB Chair and/or Human Protections Administrator will review the submission to determine if the proposed activity meets the regulatory definition of research and if it also meets the definition of human subjects and will provide the written determination to the investigator. The determination will be made using terms as defined in the Human Research Protection Program (HRPP) plan from 45CFR46 (DHHS) and 21CFR56 (FDA) for research, human subject, private information, experimental subject, and clinical investigation as well as guidance using the Office of Human Research Protections determination flow charts.

Any activities that meet both the regulatory definitions of research and research involving human subjects are subject to IRB review and approval before any research activities may commence. Proposed studies that do not meet the definition of research (e.g. case series, some quality improvement activities) do not require IRB review. Proposed studies that do not meet the definition of human subjects (e.g. use of data/specimens that are not readily identifiable) do not require IRB review.

If a research study submitted for IRB review does not meet the definition of human subjects research, the investigator will be notified via written correspondence stating that the project is deemed not to be human subjects research. Studies deemed not to be human subjects research may need to adhere to requirements as defined in The Privacy Rule / HIPAA and other institutional requirements, such as approval from hospital departments involved in the project.

Examples of studies not considered human subjects research may include:

1). Decedent research

Decedents are not considered human research subjects. The IRB, however, requires review of decedent research studies if information will be collected or used to contact living individuals. If this occurs, these living individuals would be considered human research subjects.

The researcher must also provide the IRB with a signed declaration that the following three conditions will be met:

- a. Representation that the use and disclosure sought is solely for research on the protected health information of decedents;
- b. Documentation will be provided, at the request of the hospital, of the death of such individuals; **AND**
- c. Representation that the protected health information for which use or disclosure is sought is necessary for research purposes.

Woman's Hospital requires authorization from the decedent's next of kin or a waiver or alteration of authorization from the IRB prior to the release of decedent information. Refer to the policy Decedents – Protected Health Information for further information.

2). Research on non-identifiable biospecimens that were originally collected for another purpose, such as other research or clinical care.

3). Certain journalistic, public health surveillance, and criminal justice or intelligence activities (45CFR46.102)

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 focus directly on the specific individuals about whom the information is collected

5). Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance, including:

- Collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority
- Trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products
- Those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural and man-made disasters).

6). Collection and analysis of information, biospecimens, or records for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes

7). Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland, security, defense, or other national security missions

8). Research with dried blood spots, including those from newborn screenings, is not considered research, and informed consent requirements can be waived.

9). Quality Assurance or Quality/Process Improvement projects are usually not considered human subject research. A Quality Assurance/Process Improvement project does not require IRB submission if it meets the following criteria:

a. There is an existing documented hazard (of patient injury, therapeutic failure, waste, etc.);

b. There is a plausible means of removing, reducing, or mitigating the hazard. (Such as evidence from the medical literature or pragmatic "obvious" improvements);

c. There is a measurable outcome.

In some cases, the result of a Quality Assurance/Process Improvement project is generalizable and some aspect of the methods used in the project is sufficiently novel so as to justify sharing with a larger audience. The best means of sharing such findings is to publish a description of the methods and results in a peer-reviewed publication. Almost always, preparation of a manuscript for such a publication requires that additional analysis be performed on existing identifiable patient data. Since this additional analysis is not necessary for purposes of the Quality Assurance/Process Improvement project, but instead is for the purpose of contributing to generalizable knowledge, this work is human subjects research and requires IRB submission.