Ascension Wisconsin IRB Guidance

Determining if Your Project is Human Subject Research

The role of the Institutional Review Board (IRB) is to protect the rights, privacy and safety of individuals who volunteer to participate as *human subjects* in *research* studies. Projects that meet the definition of "research" that involves "human subjects" require review by the IRB. There are other kinds of projects, which do not meet this definition but may or may not require IRB review.

The information below is provided to help you to determine whether or not your project is human subject research and if you are required to submit the project to the IRB for review. The IRB is also available to assist researchers in this determination.

In general, your project will not require IRB review if your activity:

- Is not research; or
- Is research but does not involve human subjects

This document includes:

Is the project research?

Research is defined in the federal regulations that govern human subject research.

- FDA definition - Any experiment that involves an FDA-regulated test article and one or more human subjects and is already subject to FDA requirements (For complete definition see FDA regulations 21CFR50)

- DHHS definition - Any systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge (For complete definition see DHHS regulations 45CFR46)

  Systematic Investigation: typically a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. Examples: observational studies, interview or survey studies, group comparison studies, program evaluation, test development, interventional research.

  Develop or contribute to generalizable knowledge: typically requires that results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program. Examples: activities where there is an intent to publish the results in a peer-reviewed journal or to present at a regional or national meeting, thesis or dissertation projects conducted to meet the requirements of a graduate degree.
  - To help determine the intent or purpose of the activity ask yourself this question: Would this project be conducted as proposed if the project investigator knew that he or she 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 the project would remain exactly the same, the activity is likely not research.

- Quality Improvement (QI) is not considered research if the intent of the QI is to inform or improve a local process. If you intend to generalize the results outside of your local area, however, the activity is research.

Examples of projects that may not meet the definition of research (under 45CFR46 or 21CFR50)
Below are examples of projects that commonly occur at Ascension Wisconsin that may not qualify as research. This list does not include all possible examples.

Quality Improvement/Quality Assurance projects

Types of Quality Improvement/Quality Assurance activities would NOT require review by the IRB?

- Surveys whose primary Purpose is to gauge the opinions and perceptions of internal and external "customers" (trainees, staff, patients, referring physicians, and others) are an integral component of organizational quality assessment and may be considered a quality improvement activity that does not require IRB review. Results of such surveys may yield new knowledge deserving of dissemination external to the organization through presentations and publications. Therefore, surveys performed within an institution's QI/QA framework should not automatically require IRB consideration.
- QI/QA projects that are designed to improve clinical care to better conform to established/accepted standards are not considered research.

  Example: Clinical practice guidelines (CPGs) are intended to increase compliance with evidence-based or consensus-based practice. In general, CPGs and other QI projects that are designed to bring care in line with evidence or consensus-based standards will not require IRB approval.

  Example: Rapid cycle continuous quality improvement projects ("CQI") almost always are designed to bring care within accepted standards and may yield publishable data if conducted over a sufficient period of time for results to be statistically valid, or if the interventions are especially novel and successful. Such CQI studies almost never should require IRB review. CQI activities are often required to meet accreditation and regulatory standards.

  Example: Questionnaires that are distributed to patient and service populations for the Purpose of determining their satisfaction with a service, program or clinic and for gathering information on how to improve the service, program or clinic does not require IRB review.

However, there are Quality Improvement/Quality Assurance activities that would require review by the IRB because they include some research methods . The following types of studies, which may be performed under the general framework of QI/QA, should be submitted for IRB review:

- Studies in which subjects or groups of subjects will be randomized to different interventions or treatments. When these interventions or treatments involve minimal risk, and particularly when informed consent would be impractical, an IRB should consider waiver or alteration of informed consent.
- Studies involving care practices, interventions, or treatments that are not standard (neither consensus- nor evidence-based).
- Testing safety or efficacy of a medical device.
- Studies that involve more than minimal risk to participants.

Case Report/Series

A case report is a detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient. Case reports may contain a demographic profile of the patient, but usually describe an unusual or novel occurrence.

Case studies are prepared and disseminated for educational purposes are not a systematic investigation and therefore are not considered research when three or fewer cases are involved. However, if the case report

contains more than three cases, the IRB would consider that to constitute a pilot or descriptive research study involving human subject and IRB review would be required.

Although IRB review is not required for the case studies, as described above, there may be obligations under HIPAA privacy laws and state laws. If the case study report cannot be prepared without disclosing information that would make it possible to identify the patient, you must obtain permission from the patient before using their data or request a waiver of HIPAA authorization from the IRB (who is also the institutions HIPAA privacy Board).

Does the project include human subjects?

A **Human Subject** is defined in the federal regulations that govern human subject research as well.
Note, the DHHS definition of human subjects will generally apply to most human research conducted at Ascension Wisconsin unless the research involves a test article. Research involving a test article is subject to FDA definitions.

- FDA definition - an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. The FDA definition of human subject includes individuals on whose specimens an investigational device is used [see 21 CFR 812.3(p)].

- DHHS definition - a living individual about whom an investigator conducting research obtains either

  1) data through intervention or interaction with the individual; or
  Intervention: physical procedures done to the subject (e.g. venipuncture) or manipulations of living individuals or the living individuals' environment.

  Interaction: communication or interpersonal contact between the investigator and the living individual. Examples include: interviews, questionnaires, surveys, observations, manipulations of subject behavior, diet, or environment, physical measurements, specimen collection (e.g. blood tissue), and administration of experimental drugs or devices.

  2) identifiable private information (includes obtaining information from a medical record)
  Identifiable: if 1) the identity of the individual from whom the information was obtained is ascertained or may be readily ascertained by the investigator; or 2) the identity of the individual from whom the information was obtained is associated or may be readily associated with the information

  Private Information: information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place or information that has been provided for specific purposes that the individual can reasonably expect will not be made public (e.g. medical record, employee or student records).

  Examples of individual identifiers include the subject's name, address, phone number, social security number, medical record number, student or employee identification number, or in some cases, the combination of data such that they can identify a single individual through deductive reasoning. For example, data about employer, job title, age and gender may not individually identify a subject, but when combined, could in certain cases, identify a specific individual.

Examples of research that may not involve human subjects (under 45CFR46 or 21CFR50)

Below are examples of projects that commonly occur at Ascension Wisconsin sites that may not include human subjects. This list does not include all possible examples.

De-identified or coded private information or biological specimens

If you are using specimens and/or data and neither you nor your collaborators can identify the subjects from whom the specimens and/or data were obtained either directly or indirectly through coding systems, the activity is not DHHS research involving human subjects and does not require review by the IRB.

However, use of specimens in FDA-regulated research requires IRB review even if the specimens do not contain identifiers or codes. In addition, any research involving the use of newborn dried blood spots is considered human subject research whether or not it contains identifiers, based on federal law.

Research using publicly available data

Use of a publicly available data set that does not contain identifiers or codes linked to individuals does not involve human subjects research (such as from Data.gov).

If the information or is considered public or is given with the expectation that it will be made public and that it will be linked to the individual (e.g. biography or news story), then it would not be considered private identifiable information.

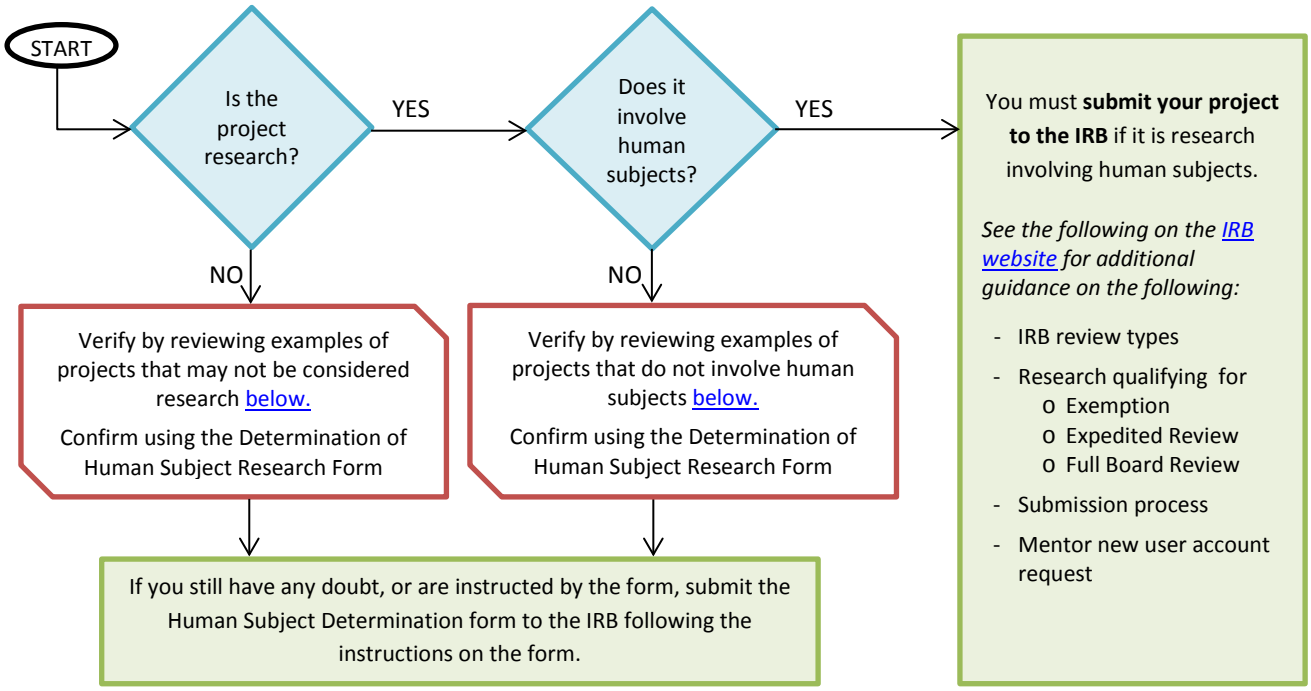
Decedent Research

Decedent research projects involve research that is limited to records and/or samples from deceased persons. This research may not involve any records and/or from living individuals. Because of this, decedent research does not involve human subjects, and therefore does not require IRB review.

However, if protected health information (PHI) is included in the records and/or data the HIPAA privacy laws apply for 50 years after death. In those cases, you must request a waiver of HIPAA authorization from the IRB (who is also the institutions HIPAA privacy Board).

Deciding if your project needs IRB review

Use this chart and examples below to help to determine if you need to submit your project to the IRB.



Note about publishing

Publishing alone does not qualify a project as human subject research. You may share or publish projects that are not considered human subject research and do not require IRB review, such as QI project results or research using only de-identified data.

However, it is not uncommon for journal editors to require a determination letter from the IRB confirming the decision that the project does not constitute human subject research. Therefore, if you have any intention of publishing the result of your project, we recommend that you obtain a determination from the IRB before you start your project. You can do this using the Determination of Human Subject Research Form.

For additional information to about the determining if a project is human subject research, see:

- IRB policy: Definitions
- IRB policy: QA - QI vs. Research
- IRB policy: Use of PHI for Research
- OHRP: Human Subject Regulations Decision Charts

You may also contact IRB staff with questions.