Human Subject Research
vs.
Quality Improvement

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What is Human Subject Research?

"Research" as defined by the Department of Health and Human Services (DHHS) is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

A **human subject** is defined by DHHS as a living individual about whom a research investigator (whether a professional or a student) obtains data through intervention or interaction with the individual or from individually identifiable information.

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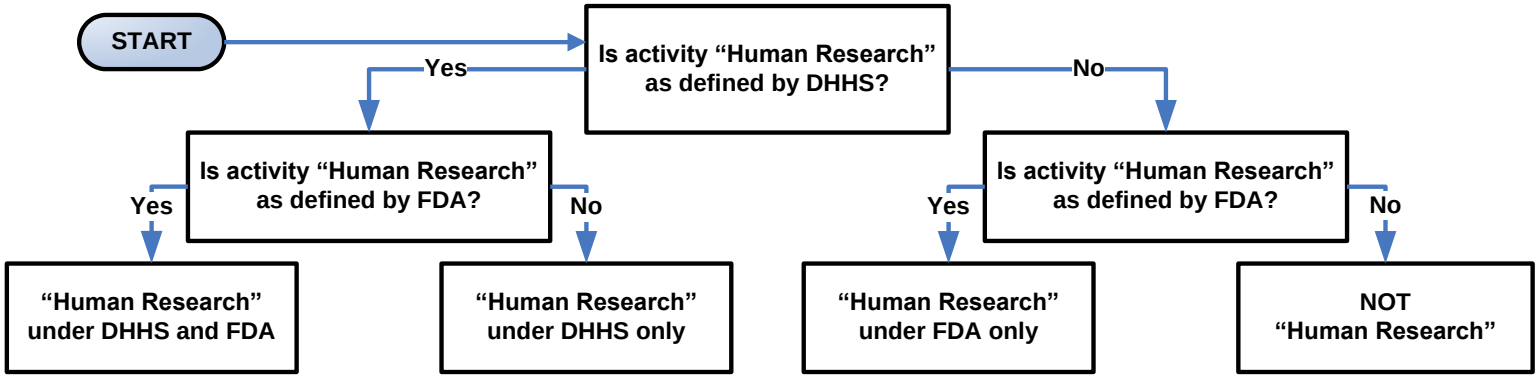
Determining Human Research



Research as Defined by DHHS Regulations

- Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination.)
- Is the investigation systematic? (Systematic: Having or involving a system, method, or plan.)
- Is the systematic investigation designed to develop or contribute to knowledge? (Designed: observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Knowledge: truths, facts, information.)
- Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: Universally or widely applicable.)

Human Subject as defined by DHHS Regulations

Is the investigator conducting the Research gathering data about *living* individuals?

- Will the investigator gather that data through either of the following mechanisms (specify which mechanism(s) apply):
  - Physical procedures or manipulations of those individuals or their environment for research purposes ("intervention").
  - Communication or interpersonal contact with the individuals. ("interaction"). Prospective collection of biological specimens for research purposes by noninvasive means
- Will the investigator gather data that is either? Specify which category(s) apply if yes:
  - The data are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. "Private information").
  - Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will **NOT** be made public, such as a medical record (i.e. "Private information").
- Can the individuals' identities be readily ascertained or associated with the information by the investigator (i.e. "Identifiable information")?

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Human Research Under FDA Regulations

- Does the activity involve any of the following?
  - The use of a drug in one or more persons other than use of an approved drug in the course of medical practice.
  - The use of a device in one of more persons that evaluates the safety or effectiveness of that device.
  - Data regarding the subjects or control subjects submitted to or held for inspection by FDA.
  - Data regarding the use of a device on human subjects (identified or unidentified) submitted to or held for inspection by FDA.

Quality Improvement

"A systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product" Source: The Institute of Medicine.

- QI involves implementing previously proven/tested, planned and systematic activities done to improve or satisfy quality requirements.

“Systematic, data-guided activities to bring about prompt positive changes in the delivery of health care and involve deliberate actions to improve care. Depending on the activity, QI can look like practical problem solving, an evidence-based management style or the application of a theory-driven science of how to bring about system change. Introducing QI methods often means encouraging people in the clinical care setting to use their daily experience to identify ways to improve care, implement changes on a small scale, collect data on the effects of those changes, and assess the results.” Source: A Hastings Center Special Report

Examples of QI activities that are likely NOT research include:

- Implementing a practice to improve the quality of patient care
- Collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes
- Measuring and reporting provider performance data for clinical, practical, or administrative uses
- A group of affiliated hospitals implements an application to reduce prescription amount errors, and collects patient prescription information from medical charts to assess whether the application helped reduce error rates as expected.

Examples of QI:

- ensuring new evidence-based interventions are incorporated into practice
- improvement of over-all quality of life
- reduction of morbidity and mortality
- ensuring that patients receive evidence-based interventions for their particular illness
- improvement in patient and family comprehension
- reduction in in-patient admissions and length of stay
- reduction of ER visits
- reduction in costs of service
- evaluating procedures no greater than minimal risk to patients,
- •usual care practices, and
- interventions offered to all patients

Examples of Activities that Begin as QI and Become Research

- A QI project is implemented, and upon completion, the investigators realizes they want to do research about the project, and interview clinicians. The data they will collect from the interviews will be used for research, therefore, they would submit to the IRB before beginning interviews.
- A team uses biologic samples to compare two different types of tests to determine which one is better and therefore which one should be used at AHS [intent to improve care at AHS]. After they complete the comparison, they realize they want to share the success of these tests because they believe it will help other institutions [intent to contribute to generalizable knowledge]. They then submit to IRB and request to use the data collected for the QI project as secondary data for research.
- A surgeon believes that a certain technique will improve their own practice, so they implement it and record results as part of clinical practice. They then decide that this practice would help others, so they go back to their data to systematically analyze and generalize outcomes and results. They would need to submit to the IRB prior to the review of gathered data.

Research vs. Quality Improvement Comparison

	RESEARCH	QUALITY IMPROVEMENT
INTENT	Develop or contribute to generalizable knowledge (e.g., testing hypothesis)	Improve a practice or process within a particular institution or ensure it conforms with expected norms; not designed to contribute to generalizable knowledge
DESIGN	Systematic; follows a rigid protocol that remains unchanged throughout the research; may involve randomization	Adaptive, iterative design; may or may not be systematic; generally does not involve randomization
MANDATE	Activities not mandated by institution or program	Activity mandated by institution or clinic as part of its operations
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings are not expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional practice and identify corrective action(s) needed
POPULATION	Usually involves a subset of individuals; no obligation to participate; may involve statistical justification of sample size to achieve endpoints	Responsibility to participate as a component of the program or process; information on all or most involved in the practice or process is expected to be included; exclusion of some individuals significantly affects conclusions
BENEFITS	Participants may or may not benefit directly; often a delayed benefit to future knowledge or individuals	Directly benefits a process, program, or system; may or may not benefit participants
RISKS	May place participants at risk	Does not place participants at risk with the possible exception to risks to privacy or confidentiality of data
ANALYSIS	Statistically prove or disprove hypothesis	Compare program, process or system to established standards
DISSEMINATION OF RESULTS	Intent to disseminate results generally presumed at outset of project as part of professional expectations, obligations; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies	Intent to disseminate results generally not presumed at outset of project; dissemination often does not occur beyond the institution evaluated; when published or presented to a wider audience the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks rather than to develop or contribute to generalizable knowledge

Adapted in part from University of Wisconsin-Madison Health Sciences IRBs Comparison of the Characteristics of Research, Quality Improvement, and Program Evaluation Activities

Intent to Publish

The intent to publish is an ‘insufficient criterion’ for determining whether a quality improvement activity involves research, according to OHRP.

When QI is published or presented, the intent is usually to discuss potentially effective models, strategies, assessment tools or to provide benchmarks, rather than to develop or contribute to ‘generalizable’ knowledge.

PHI

HIPAA makes an exception for QQI activities, including outcomes evaluation and development of clinical guidelines or protocols. These activities fall under the category of ‘health care operations’ for which no HIPAA Authorization or Waiver of Authorization needs to be sought. The hospital’s Privacy Office can authorize the use of PHI for QI projects.

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Non Human Subjects Research Self-Certification (Form HRP-216)

- Use the form:
  - If you are unsure whether or not you need to submit your project to the IRB
  - If you are unsure if your project is research
  - If you are unsure if your research involves human subjects

The document is consistent with AHS IRB procedures and may be used as documentation that your research does not involve human subjects and does not require IRB review.

To request a written determination that an activity is not human research, please submit a complete application to the IRB.

For questions regarding IRB submission

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