

**OFFICE OF HUMAN RESEARCH AFFAIRS (OHRA)**

**GUIDANCE: DISTINGUISHING OPERATIONAL vs. RESEARCH PROJECTS**

Overview and Definitions

Federal regulations require human participant research to have appropriate regulatory review, while projects classified as operational do not require regulatory oversight. Determining if an activity is Research or Operations can be challenging. The following guidance is provided to assist in distinguishing operational projects from research projects. This guidance is meant to support project planning and development only. This guidance should not be used to determine whether your project requires OHRA submission or IRB review. Please contact the Office of Human Research Affairs for any further assistance needed regarding project specific determinations and following the correct pathways based on goals of the project.

**Research Projects**

Research is defined in US regulations as *“A systematic investigation, including research development, testing and evaluation,* ***designed******to develop or******contribute to generalizable knowledge”***

Research involves the study of materials and sources in order to establish facts and reach new conclusions.

**Operational Projects**

As noted above, operational projects do not require regulatory oversight; so there is no regulatory definition for operational projects. Operational projects are often referred to as Quality Improvement or Quality Assurance initiatives. The Institute of Medicine describes Quality Improvement as;

“***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***"

Operational projects involve implementing previously proven/tested, planned and systematic activities to improve or satisfy quality requirements.

It is important to note that the intent to publish is an insufficient benchmark for determining whether an operational project (or quality improvement activity) constitutes research.

*\*A note about the term “Quality Improvement” - At UHG, Quality improvement is embedded into so much of what everyone does at every level that referring to any special projects in research and development as “Quality Improvement” is likely to lead to some confusion about the need for OHRA involvement. When you engage the OHRA, we will determine whether your project qualifies as “research”, “operations” or other type of project.*

What is Research vs. Operations Rubric

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|  | **Human Participant Research** | **Operational Project** |
| **Purpose** | To develop or contribute to generalizable knowledge | To implement knowledge, assess a process or program as judged by established or accepted standards |
| **Design** | Follows a rigid protocol that remains unchanged throughout the research | adaptive, iterative design |
| **Products utilized** | Experimental, unproven, investigational products  (assessing safety and/or effectiveness of the product) | Using products as currently approved or available in a structured setting to assess impact of the product |
| **Benefits** | may or may not benefit current participants; intended to benefit future patients | directly benefits a process, system or program; might or might not benefit patients |
| **Risks** | may put participants at risk | does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data |
| **Participant Obligation** | no obligation of individuals to participate | responsibility to participate as component of care |
| **Endpoint** | answer a research question | improve a program, process or system and make appropriate data impact argument to internal policy review |
| **Analysis** | statistically evaluate product safety and/or effectiveness | compare program, process or system to established standards |
| **Adoption of Results** | little urgency to disseminate results quickly (product development) | results rapidly adopted into local care delivery (medical policy review) |
| **Publication/ Presentation** | investigator obliged to share results | practitioners encouraged to share systematic reporting of insights |

Why is this distinction important to anyone besides the OHRA or IRB?

Now that we understand generally how the goals and components of a research project differ from the goals and components of an operational project, let’s think about why this is important for investigators to consider. Here are a few main points;

* The development, execution and outcomes of a research project are different from those of an operational project. Understanding the differences will streamline the approach to each of these milestones and improve the utility of your findings.
* It is important to consider that many operational projects may include research components in their design. Therefore those aspects need regulatory approval before beginning. Being prepared for that will eliminate roadblocks.
* Similar to the previous point, many operational projects may lead to a research project which will require regulatory approval. If you begin an operational project with the intent to eventually use the activity or data for research, it is best to engage regulatory review early to determine if/when regulatory review will be required. Being prepared for that will eliminate roadblocks.
* An underlying goal of the OHRA in making these determinations as early as possible is to maximize potential use of data being analyzed in operational projects. Applying regulatory criteria considerations early in project development will reduce roadblocks in the event a true “human subject’s research protocol” is an end result of an operational project. If you execute an operational project without any regulatory considerations and then decide to transition to research after that project has concluded, you may find that the process for approval is more arduous than if you had started out with a foundation that aligns with research regulations.

Specific Examples

**Examples of Operational Projects 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 Activities that are likely a hybrid of Operations and Research:**

* A project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results.
* Collaborative (multi-site) – All the sites are trying to improve some aspect of clinical care (ex. implementing an application to help improve making clinical decisions). The whole department decides this app will improve care, and implement the app. They collect data as the app is implemented, and in addition, analyze this data for generalizable knowledge.
* A teacher implements a practice to have all students reflect on their learning by keeping a journal, with the intention of improving teaching practice. However, the teacher also wants to prove that this method works, so they analyze student journals with grades to generalize the success of this method.

**Examples of Activities that Begin as Operational and Become Research:**

* A QI project is implemented, and upon completion, the investigator 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 for regulatory review 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 UHG. 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 for regulatory review 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 for regulatory review prior to the review of gathered data.

How would the process for the 3 example scenarios look?