Determining if an activity is **Research** or **Quality Improvement** can be challenging. Federal regulations require human subject research to be reviewed and approved by the IRB, while strictly QI activities do not require IRB oversight. However, some QI activities may also be research and therefore need IRB approval. Please review the following guidance and use the following RedCap decision tool to determine if your activity needs IRB approval PRIOR to beginning the activity.

**QI Decision RedCap Survey** - Please see page 3 of this guidance document for explanations about each question.

What is QI & how does QI differ from research?

**Quality Improvement**
There is no regulatory definition for QI, however it is often described 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" Source: The Institute of Medicine.

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

Some examples of QI activities that are 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

Please see **HHS guidelines and FAQs** for more information.

**Note:** A quality improvement activity may also qualify as human subject research if it meets the definition of research. For example, if 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, that quality improvement project may also constitute exempt or nonexempt human subjects research under the HHS regulations.

If an activity **DOES NOT** meet the definition of research under 45 CFR 46.102(d), then HHS regulations **DO NOT** apply, and IRB review is **NOT** required.
Research
A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research even if they are a component of a larger non-research activity (e.g., instruction, demonstration).

It involves human subjects: A living individual about whom an investigator conducting research obtains identifiable data through an intervention or interaction with the individual (or identifiable private information)

Systematic investigation involves a predetermined system, method or plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.

Generalizable Knowledge is information that is collected or gathered to draw general conclusions; inform policy; inform professional knowledge in a discipline; or generalize outcomes beyond the specific group, entity, or institution.

If an activity meets the definition of human subject research under 45 CFR 46.102(d), then HHS regulations apply, and IRB review is required.

Using Completed QI Activities for Research

Please note that if you begin QI activities with the intent to eventually use the activity or data for research, it is best to submit to the IRB prior to beginning the activity. However, if after a QI project is completed, you want to study it further and make it generalizable (research), then IRB submission is required (typically using secondary data).

For example:
- 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 to the IRB before beginning interviews.

It is important to note that the intent to publish is an insufficient criterion for determining whether a QI activity constitutes research.
RedCap Form Question Explanations

Q1. This is a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g., testing a hypothesis, randomization of subjects, comparison of case vs control, observational research, comparative effectiveness research, or comparable criteria in alternative research paradigms).
   - Please consider the primary intent and design of the project. Simply publishing or presenting the results of a QI project does not make it research. If the primary intent of the project is not generalizability (e.g., it is program evaluation/practice improvement related to a specific initiative) OR the project is not designed in a way that the findings would be generalizable (i.e., limitations to project design), then the answer to this question is "No". If the project is standardized using systematic research methodologies with strong external validity in order to obtain reproducible results, in areas that have not previously been proven, then it would be considered research. If the intended outcome is simply to report on what happened at the institution/program, this does not indicate research design or intent as it may or may not be generalizable outside of the institution.

Q2. The activity being implemented is untested or unproven in other settings.
   - If the activity will try to test or prove something that is untested or unproved in other settings, it is most likely research, and IRB review is required.

Q3. The project involves testing an experimental drug, device (including medical software or assays), or biologic.
   - The RedCap QI Decision Form is based on the definition of research pursuant to the Common Rule (45 CFR 46.102(d)). The purpose of this question is to determine whether federal regulations beyond the Common Rule, such as FDA regulations, need to be applied to a project. If the answer to this question is "Yes," IRB review is likely required.

Q4. This is a multi-site project (e.g. there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol).
   - This question is intended to determine whether the project is limited to local activities or whether multiple sites are conducting the same activities. If multiple sites are involved, it is an indication that the results may be generalizable (the outcomes are likely not being used for quality improvement or program evaluation at the local institution). However, it is possible to work with community partners on a QI project that may not be research. If the answer to this question is "Yes," IRB review may be required, but please contact the ORSP if you are unsure.

Q5. The project has received funding (e.g., federal, industry) to be conducted as a human subjects research study.
   - The purpose of this question is to determine whether the project has received funding to be conducted as a research study and not, for example, quality improvement or program evaluation. If you are unsure, consider contacting your program officer for the funding or funding entity to determine whether the funding source requires a specific level of IRB review and oversight. If the answer to this question is “Yes,” IRB review may be required.

Q6. Implementation of the activity requires rigid and strict adherence to process or protocol.
   - If the activity requires rigid and strict adherence to a process or protocol, it is indicative of a "systematic investigation" which would mean that the activity may be research, and IRB review may be required.

Q7. The findings will directly affect institutional or programmatic practice.
   - If the intention upon designing and conducting the project is to improve or evaluate a specific practice/program, then IRB review is not likely required.

Sources: Stanford, Bon Secour, HHS, Cambridge Health, University of Wisconsin-Madison