What is Human Subjects Research?
The Office of Human Research Protections (OHRP) defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)). A systematic investigation is an activity that is planned in advance and that uses data collection and analysis to answer a question. A human subject is a living individual about whom an investigator conducting research: obtains information biospecimens through intervention or interaction with the individual, and uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. If a project is designed to test a novel hypothesis, replicate another researcher’s original study, or withhold any aspect of conventional care shown to be beneficial in prior studies, OHRP’s definition of human subject research would apply. Although research must include systematic investigation, many non-research activities also include systematic investigation. Systematic investigation does not, in and of itself, define research.

The FDA does not use the term research, but considers it to be synonymous with clinical investigations, meaning any experiment that involves a test article and one or more persons (21 CFR 56.102(23)(c)). For example, if you are comparing the safety and/or effectiveness of a drug, or comparing a regulated device to another, you are engaged in a clinical investigation and must follow FDA regulations.

The following activities are generally considered to be research in accordance with the regulatory definitions:

- Thesis or dissertation projects conducted to meet the requirements of a degree
- Projects conducted in response to an RFP (Request for Proposal) issued by a federal agency
- Clinical trials
- Behavioral studies
- Projects initiated by Sponsor-investigators and involving FDA test articles

When is IRB approval needed for human subjects research activities?
If your project is research and involves human subjects, IRB review prior to the conduct of your study is required.

What is Quality Improvement/Program Evaluation?
While there is no regulatory definition of Quality Improvement (QI) or Program Evaluation (PE), these projects can be described as, “systematic, data-guided activities designed to bring about immediate improvement or changes in a particular setting.” QI is designed to implement knowledge or assess a process or program as judged by established/accepted standards. Much like human subjects research, QI/PE can result in generalizable knowledge, have human participants, and utilize protected health information. For this reason, IRB approval may be needed for QI/PE activities.
Is My Project Research?  
*Quality Improvement, Program Evaluation, and Class/Student Projects*

<table>
<thead>
<tr>
<th>Points to consider</th>
<th>Research</th>
<th>QI/PE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>To test a hypothesis OR establish clinical practice standards where none are accepted</td>
<td>To assess or promptly improve a process, program, or system; OR improve performance as judged by accepted/established standards</td>
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<tr>
<td><strong>Starting Point</strong></td>
<td>To answer a question or test a hypothesis</td>
<td>To improve performance</td>
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<tr>
<td><strong>Benefits</strong></td>
<td>Designed to contribute to generalizable knowledge and may or may not benefit subjects</td>
<td>Designed to promptly benefit a process, program or system and may or may not benefit patients</td>
</tr>
<tr>
<td><strong>Risks/Benefits</strong></td>
<td>May place subjects at risk and states such</td>
<td>By design, does not increase patient risk, with exception of possible privacy/confidentiality concerns</td>
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<tr>
<td><strong>Data Collection</strong></td>
<td>Systematic data collection</td>
<td>Systematic data collection</td>
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<tr>
<td><strong>End point</strong></td>
<td>Answers a research question</td>
<td>Promptly improves a program/process/system</td>
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<tr>
<td><strong>Testing/Analysis</strong></td>
<td>Statistically proves or disproves a hypothesis</td>
<td>Compares a program/process/system to an established set of standards</td>
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**When is IRB approval needed for QI/PE activities?**

IRB approval may be required when the activity involves some of the following characteristics:

- Seeks to develop new knowledge or validate new treatments rather than to assess the implementation of existing knowledge or existing practices;
- When the protocol is fixed with a rigid goal, methodology, population, time period, etc.;
- When the funding for the activity comes from the outside organizations such as the NIH or those with a commercial interest in the results;
- When there will be a delay in the implementation of results;
- When the risks from the intervention to participants are greater than minimal.

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 nonexempt human subjects research under the Health and Human Services regulations.

**What if I need to access Protected Health Information?**

HIPAA makes an exception for QA/QI 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 for research is needed. However, local HIPAA policies of the entity from which the data is taken still apply, and should be followed.
What are Class/Student Projects?
A class or student project usually does not have to receive IRB approval. These projects are intended to provide an educational experience about the research process or methods. These projects usually occur as part of assigned course/classwork or a requirement of an educational program in order to learn a new technique or pass a course. They do not meet the definition of human subjects research in that they are not designed to develop or contribute to generalizable knowledge. Class or student projects may include individuals as research participants. However, the intent of the subject recruitment is learning how to select and consent subjects.

Is it research if I intend to publish?
The intent to publish is an ‘insufficient criterion’ for determining whether a quality improvement activity involves research, according to OHRP.

When quality improvement, program evaluation, or student/class projects are 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.

What if I am getting funding for my project?
Outside external funding may make a difference in distinguishing between a non-research and research project. If the project is funded by an outside organization with an interest in the results or the manufacturer has an interest in the outcome of the project relevant to its products, then the project could be considered human subjects research. An NIH research grant to support a project would often be considered research. Internal funding to improve a program may not.

What if I still don’t know if I need IRB review?
In the IRB system, iRIS, please submit the Non-Human Subjects Research (NHSR) application. This allows the IRB to make the determination rather than the investigator.