OTHER THAN RESEARCH PROJECT TYPES

- **Case Report or Case Series**

In general, such projects will highlight one or a few particular cases for purposes of demonstration rather than for purposes of drawing generalized conclusions. By nature, such projects will not have potential impact on an established body of knowledge. The number of patients to be included is not a defining factor in determining when the 'research' threshold has been met, rather, the use of statistical methodology and systematic investigation. Even so, the Piedmont Healthcare Institutional Review Board (PHCIRB) has identified five as the upper limit for a case report or case series for consideration for IRB review. Consider the following non-exhaustive comparison of research and case reports/series:

Research	Case Report / Series
Report on more than 5 subjects.	Report on 5 or fewer subjects.
Draws conclusions about a broader population based on the reported cases (even if not statistically significant; e.g. pilot studies can be "research").	Not meant to be a representative sample (not drawing conclusions).
Reported/Published in a way that suggests broad findings or recommendations.	Reported/Published without attempting to draw broader conclusions.

* Many journals now require a letter, or other acknowledgement, from an IRB prior to publication of a case report. Specifically, they wish to know whether IRB approval was obtained or was not required for the described case. See more.

- **Program Evaluation**

Program evaluation is the inquiry into past, present and potential human service programs to understand or clarify their need, working process or impact. Consider the following non-exhaustive comparison of research and evaluation:

Research	Evaluation
Produces generalizable knowledge. Generalizes.	Judges merit or worth. Particularizes.
Scientific inquiry based on intellectual curiosity. Provides basis for drawing conclusions.	Policy and program interests of stakeholders is paramount. Provides basis for decision-making.
Advances broad knowledge and theory. Designed to prove something or potentially alter standard procedures or normal activities.	Provides information for decision-making on specific program. Designed to improve something.
Controlled setting.	Conducted within setting of changing 'actors', priorities, resources, and timelines.
Involves experimental or non-standard interventions.	Do not involve experimental or non-standard interventions.

NOTE: Program evaluations intending to publish results in scholarly journals will require IRB approval with the assumption being that publishing the findings generalizes the data.

- **Public Health Practice**

Public health practice focuses on improving the health of communities through continual quality improvement of public health decision making and the provision of public health services. The major difference between research and nonresearch lies in the purpose of the activity. The purpose of research is to generate or contribute to generalizable knowledge. The purpose of nonresearch in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service. Consider the following non-exhaustive comparison of research and public health practice:

Research	Public Health Practice
Often conducted by academic centers and institutions that have experience conducting research.	Involves direct performance or oversight by a governmental public health authority (or its authorized partner) and has public accountability.
Main aims are to research and draw conclusions about a hypothesis in order to contribute to the field at large.	Primary intent is to prevent or control a disease or injury.
Focused on generating knowledge that can be disseminated and applied broadly.	Focused on improving the health of a specific population or group.
Benefits are intended to apply beyond the participating community who bear the risks.	Benefits and risks are primarily designed to accrue to the participating community.
Involves research subjects who voluntarily consent to participate (or else a specific waiver of such).	May legitimately involve persons who did not specifically volunteer to participate (i.e. no informed consent).

- **Quality Assurance**

Quality Assurance is a systematic approach to review of practices and procedures in order to identify possible improvements and to provide a mechanism for bring them about. Research is a systematic investigation which aims to increase the sum of knowledge. It usually involves the testing of a hypothesis or theory.

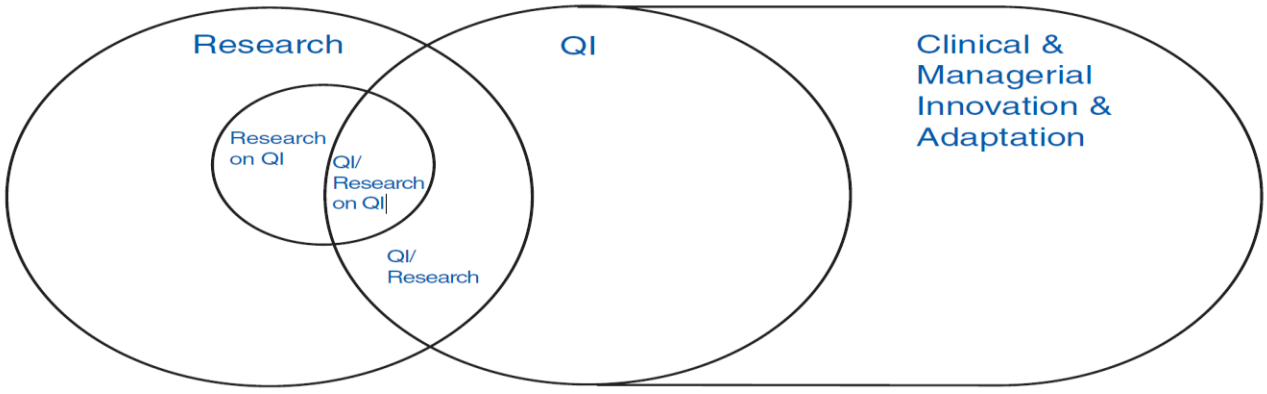
Research	Quality Assurance
A systematic investigation that aims to increase the sum of knowledge. It usually involves the testing of a hypothesis or theory.	A systematic approach to review of practices and procedures in order to identify possible improvements and to provide a mechanism to bring them about.
Generates knowledge that may be tested in quality assurance.	Raises questions that might be answered by further research.
Is the act of finding the correct thing / may help determine what is or might be the best practice.	Is a test of whether things are being done as well as they could/should be. It compares current practice with current standards/best practices.

Results can be generalized across a wide population.	Results are local to the participant population or location.
Results are generally for external information.	Results are generally for internal information.
Requires the participation of patients and others outside the specific site so a presentative sample can be obtained and the results generalized.	Requires the participation of site specific people and departments. The data relates only to the specific site or area.
Will often have a defined endpoint when an adequate sample sized has been obtained.	Is a continuous and on-going process that includes follow up.
Results ae published universally to share the knowledge with a wide user base.	Results are disseminated at the local/internal level to educate on how to achieve best practices.

- **Quality Improvement**

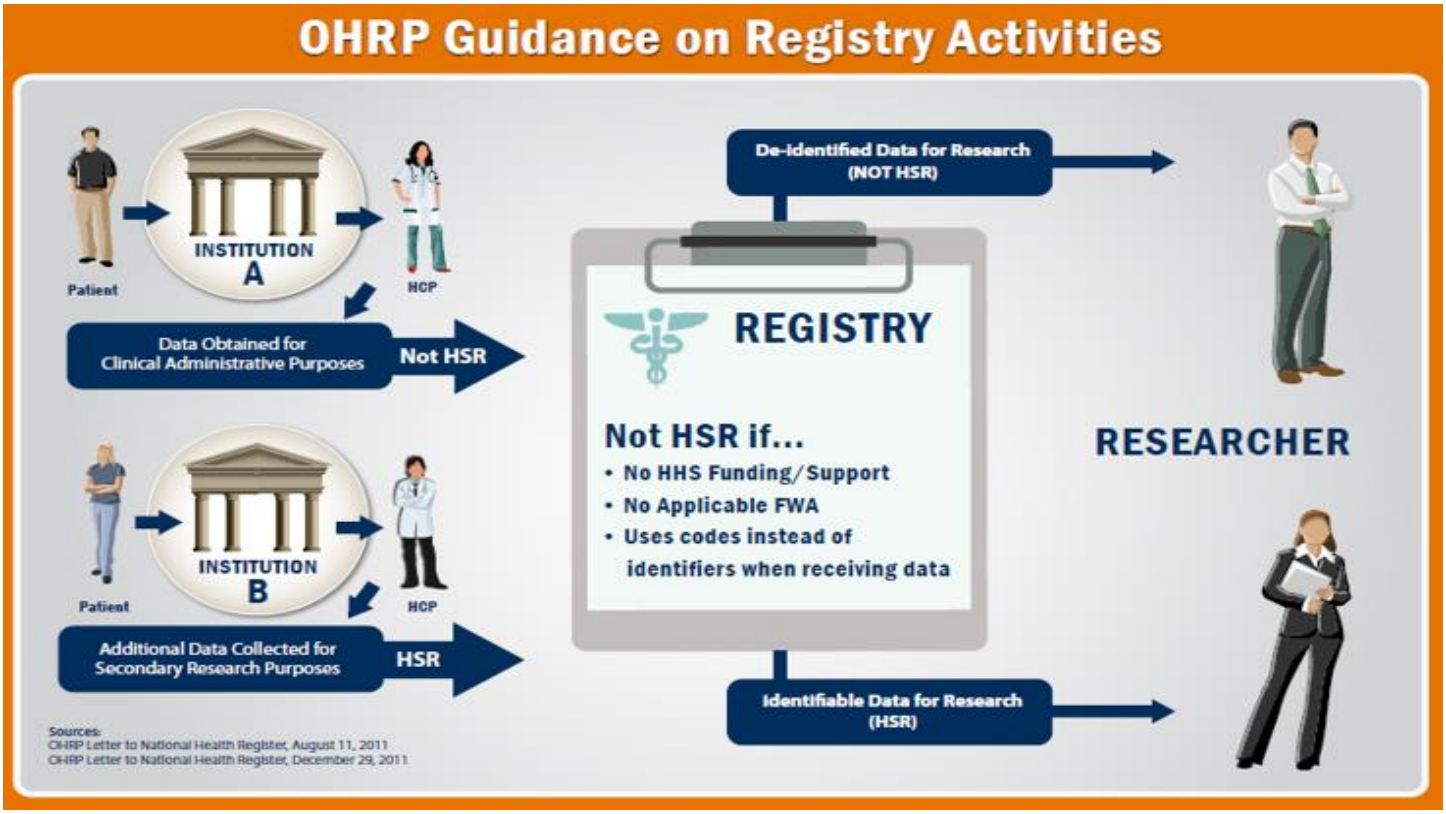
Quality improvement is the scenario where an activity is specifically initiated with the goal of improving and established standard. IRB review is needed when 1) project seeks to develop new knowledge or validate new treatments rather than assess the implementation of existing knowledge, 2) the methodology employs a standard research design, such as randomization, 3) the funding for the activity comes from an outside organization such as the NIH or a body with a commercial interest in the results, or 4) the risks from the intervention are greater than minimal. Consider the following non-exhaustive comparison of research and quality improvement:

Research	Quality Improvement
Designed to contribute to generalizable knowledge. Seeks new knowledge.	Designed to implement knowledge on a particular local issue.
The endpoint is to answer a research question.	Intended to improve a program, process or system.
May include risk exposure.	</= minimal risk.
Not necessary for the entity.	Necessary/ integral to entity.
May prove or disprove a hypothesis.	Compare to established standard.
May or may not benefit.	Directly benefit process/ program.



- **Registries / Repositories**

  The question of IRB involvement with registries/repositories pivots on the discussions of intent, storage, use, and sharing of data and/or biospecimens. When the primary intent for the creation of a registry/repository is clinical use, the creation itself is not a research activity and therefore does not come under the jurisdiction of the IRB. When, however, the registry/repository will be used for research (such as a recruitment tool) it is then under the oversight of the IRB and will require review. Additionally, consenting to the registry will be required when there is planned collection of tissue/specimens beyond what is needed for a clinical procedure. Consider OHRP guidance below.



- The application of the regulations to an activity depend in part on whether the activity meets the regulatory definition of "research," which depends on the specific facts of the activity, and not whether it is labeled "quality improvement" or something else.
- A research registry could be designed so that the regulations would not apply to the creation and operations of the registry through various mechanisms, including the use of codes instead of identifiers in the original release of data to a registry, or the use of computer programming to merge identifiable data-sets without any person being able to view the data in identifiable form.
- Institutions holding information originally obtained for clinical or administrative purposes whose agents simply release identifiable private information to a registry are not engaged in any research conducted by the registry, and do not have to meet any regulatory requirements of the 45 CFR 46 in this regard.
- Outside researchers who request the release of non-identifiable private information from the registry for secondary research analyses are not conducting "human subjects" research, and therefore the regulations do not apply to this activity, and there is no requirement for either IRB review or informed consent.
- If healthcare providers enhance or extend their standard of care in follow-up interviews with their patients and those changes would have been implemented regardless of any secondary research purpose, then the data collected through those interviews would not be considered research; in contrast, if part of the reason for the change in interview data collected is for research, then the data collection would be considered part of a research activity.