Penn
University of Pennsylvania
Human Research Protections Program

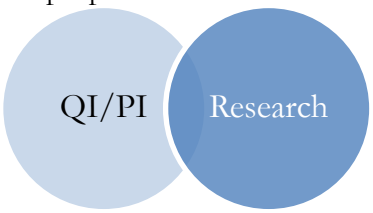
Quality or Performance Improvement Versus Research Guidance

Applicability: This guidance applies to the following activities, which are defined below:

1. **Quality Improvement (QI):** efforts to improve practice performance with the goal of improvement in healthcare services and the health status of targeted patient groups.
2. **Performance Improvement (PI):** efforts to improve effectiveness and efficiency to enhance the ability of an organization or program to deliver goods and or services. Program is defined as "any set of organized activities supported by a set of resources to achieve a specific and intended result."

Quality or performance improvement activities may be systematic and formal, or they may be non-systematic and informal. Likewise, these activities may be targeted at different organizational levels: an individual performer, a team, an organizational unit, or the organization as a whole.

Background: There is often confusion as to whether a QI/PI project may meet the criteria for human subjects' research. Most QI/PI efforts do not require IRB review. However, in some cases these activities are designed to accomplish a research purpose as well.



In these cases the regulations for the protection of human subjects in research (45 CFR part 46) may apply. Additionally, institutional policy does not allow research to be conducted with human subjects without IRB approval. Hence, it is important to make the distinction regarding which QI/PI activities may qualify as research. This determination can be a challenging task.

There is no clear definition for quality improvement in the federal regulations. However, **research** is defined in the regulations:

- "*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.*"
- FDA regulations define a clinical investigation to be *any study that administers a drug products* OR *any study that is investigating a drug or device product.*

The regulations also define a **human subject**:

- DHHS regulations (Revised Common Rule): "*a living individual, about whom an investigator*
  - *obtains information / biospecimens through intervention or interaction with the individual, AND uses, studies, or analyzes the information / biospecimens; or*
  - *obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.*"
- FDA regulations: "*an individual (healthy volunteer or patient) who is a recipient of an FDA regulated product (e.g., drug, biologic, device, dietary supplement, etc.) or a control.*"

These definitions can be used to guide our thinking. The QI/PI review process is designed to identify activities that may qualify as research needing IRB review, or confirm such activities are quality improvement not subject to further review.

For QI/PI projects where the project leaders are certain that the project is quality improvement and there is no requirement for a formal IRB determination, submission to the IRB is not required. However, in some circumstances, journals or professional organizations may require documentation that IRB review was not required before accepting a publication or presentation. QI/PI projects that may qualify as human subjects' research, should be submitted directly to the IRB for review.

General attributes of QI/PI projects that may be research needing IRB approval:

- Projects that involve research design elements such as blinding, random selection, or randomization to interventions.
- Projects that involve the validation of new instruments, scales, algorithms, prediction models, artificial intelligence, etc. that may be used to make decisions about individuals
- Projects that may involve experimental procedures or non-standard interventions
- The majority of the individuals/patients involved (including those from whom data are collected) are not expected to benefit directly from the knowledge to be gained
- Multi-center projects which involve collecting data from other national/international sites to create guidelines or other types of generalizable (universally applicable) knowledge
- Projects designed to advance the scientific literature
- Projects designed to advance the clinical care of patients generally, as opposed to being designed to solve a problem unique or local to Penn or the program / organization involved.
- Projects designed to develop new national practice benchmarks
- Typically would NOT be performed if the project team knew no professional recognition would result.

Other Considerations: Even when a project is determined to qualify as QI/PI other regulations or institutional policies may apply. For example, if a QI project involves accessing patient records, confidentiality measures must be adhered to because the HIPAA Privacy Rule applies to the individually identifiable health information of a decedent for 50 years following the date of death of the individual. For more information and guidance on these aspects, please contact your operational leader. For HIPAA related questions, please contact your HIPAA Entity Privacy Officer or the IRB.

Additionally, while there are no regulatory requirements for obtaining consent for activities that do not meet the definition of human subjects' research, **informing project participants and ensuring autonomy is best practice**, whenever feasible.

References

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