Project idea/planning stage - Consult with Operational Leader*

The project is clearly research or has research components

Submit IRB application in HS-ERA system

Project leader and the Operational Leader discuss the project and are unsure if IRB approval is required OR they desire a formal determination by the IRB

Submit QI/PI application to: PROVOST-IRB-QUALITY@pobox.upenn.edu

Project leader and the Operational Leader discuss the project and believe that the project is QI/PI and no formal determination by IRB is needed**

Proceed with Project***

IRB reviews and determines the project is research

Submit IRB application in HS ERA system

IRB reviews and determines the project is QI/PI****

Proceed with Project

*Operational Leader = the leader of the unit/clinic/area where the QI work will be implemented. Examples of operational leaders include a medical director of a unit or clinical area, division/department chief, nurse manager, Dean, other health system or institutional leader that can approve the implementation of a quality/performance improvement project.

**To avoid confusion, QI/PI projects should not be referred as research in publications/presentations.

***When results from a QI project that was not submitted to the IRB for a formal determination is published, the Operational Leader and the project team should be comfortable with including a statement along the following lines in the publication: “This project was undertaken as a Quality Improvement Initiative and as such was not formally reviewed by the University of Pennsylvania’s Institutional Review Board.”

****If a project is established as quality improvement by the IRB the following statement may be included in the resulting publication: “This project was reviewed and determined to qualify as Quality Improvement by the University of Pennsylvania’s Institutional Review Board.”