The project is clearly research or has research components

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

QI Project idea/planning stage- Consult with Operational Leader*

Submit IRB application in HS ERA system

Submit QI application to qiirb@upenn.edu

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***

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 assurance/improvement project.

**To avoid confusion, QI 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.”