Research vs. Quality Improvement: Resolving Institutional Review Board Concerns
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Problem
The conduct and reporting of best practice is hampered by defining all clinical care activities as research. Quality improvement (QI) efforts and research are different forms of scholarship and articulating the differences continues to be challenging, particularly in light of the proliferation of Doctor of Nursing Practice (DNP) programs. This divergence creates confusion and delay related to language, the application process, and publication considerations.

Evidence
Most QI efforts do not satisfy the definition of “research” under 45 CFR 46.102(d) and therefore are not subject to the Health and Human Services (HHS) protection of human subjects regulations. However, in instances where QI activities also accomplish a research purpose, regulations for the protection of subjects in research apply. Additionally, uniform scientific manuscript requirements necessitate that informed consent be indicated in the published article. This requirement has significant implications for reporting the application of best practice. Casarett, Karlawish, and Sugarman, (2000) propose two criteria to determine whether a QI initiative should be considered research: (1) if the majority of patients involved are not expected to benefit directly from the knowledge to be gained or (2) if additional risks or burdens are imposed to make the results generalizable.

Strategy
Two universities with Doctor of Nursing Practice (DNP) programs have facilitated the resolution of QI issues through continuous dialogue, education, and collaboration with their students and IRBs.

Practice Change
Retooling existing documents and processes to ask the right questions to clearly articulate project outcomes and issues affecting human subject protection aids IRB functioning.

Evaluation and Results
DNP programs focus on translating evidence into practice to innovate systems and improve healthcare outcomes. Amended IRB forms and new processes have clarified QI and research outcome differences, reduced approval delay while insure human subject protection. Early indicators indicate success.

Recommendations and Lessons Learned
Establish clear QI project expectations, utilize appropriate terminology in the project description, and dialogue with the IRB. Attempting to describe QI activities in the traditional research format.
Bibliography