Stanford Medicine Center for Improvement

Guidelines for Oversight of Quality Improvement Projects

Helpful Definitions (From Stanford IRB):

- **Quality Improvement:** An activity conducted to assess, analyze, critique, and improve current processes in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements.

- **Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Check-List for Quality Improvement Projects

The check-list below consists of screening questions that can help you determine whether your proposed project is a Quality Improvement Project or more likely potentially human subjects research.

	Question	Yes	No
1	Is this project designed to increase general knowledge - as opposed to improving clinical care here at Stanford Medicine?		
2	Is the project funded by an outside organization (manufacturer, research foundation) with a commercial interest in the use of the results?		
3	Are patients randomized into different intervention groups (has a control group)?		
4	Is the protocol fixed with a fixed goal, methodology, population, and time period (as opposed to incorporating rapid evaluation, feedback, and incremental change)?		
5	Will the activity involve any participants (patients, parents, or staff) that are NOT ordinarily seen, cared for, or work in the setting where the activity will take place?		
6	Is there risk to the project greater than that which is normally encountered during usual care (or greater than the unavoidable minimal risk of implementing any changes in the process of care)?		
7	Does the project seek to test issues that are beyond current clinical practice standards, such as new treatments (as opposed to improving operations or efficiencies)?		
8	There will be a significant time delay (> 1year) between obtaining results and implementing changes.		

- If the answer to **all of the above questions is "no"**, the project is highly likely not to be human subjects research and does not need IRB review or approval to start the project.
- If the answer to **any of the above questions is "yes" or if there is any question in regards to any question**, the project is possibly human subjects research and a **SMCI Expert Consultation** should be called. To request a consultation, please email SMCI@stanfordhealthcare.org. A number of actions may be taken by the **SMCI Expert Consultation**:
    - Determination that the project is QI work and not human subjects research – the remainder of the flow chart is utilized
    - The project is or potentially is human subjects research - a "Determination of Human Subject Research Application" form should be completed and submitted to the IRB.
    - External Funding: If the answer to question #2 above is yes and there is external funding of the project, the project should be submitted to the IRB for review and approval. Externally funded projects will also be reviewed by SMCI Expert Consultation.
    - If there are potential compliance issues are identified – project submitted for review to ***Compliance and Privacy Office***.
- Note: The above questions are screening questions. Both quality improvement projects and human subjects research can have significant evaluation infrastructure, so answering "yes" to some of the above questions may not necessarily qualify the project as human subjects research. Answering "yes" indicates the need for further evaluation by the IRB.
- Note: As is for all activities in Stanford Health, all external regulatory requirements must be met – including: Privacy and security of patient data (HIPAA and COMIA); Antitrust laws; Anti-Kickback Statute; Stark Law; Not-for-profit and/or other tax-exempt laws; requirements set forth by the Centers for Medicare and Medicaid Services; False Claims Act; EMTALA; data use agreements; etc. If the leaders of the submitted project have questions or doubts about meeting any such oversight guidelines, the ***Compliance and Privacy Office*** should be consulted at ComplianceOfficer@stanfordhealthcare.org
- Note: All projects that need access to human subjects data that they do not have access to, must be evaluated through the Compliance and Privacy Office.

Publication: For leaders who desire to publish results of a completed QI project:

- There is not a need for IRB approval.
- There is not a need for review and approval by the Compliance & Privacy Office, SMCI, or other groups.
- Most journals do not require IRB evaluation of quality improvement projects. However, if a quality improvement project has been completed and is being submitted to a journal that requires confirmation that the project was not human subject research, the author may submit a "Determination of Human Subjects Research" Form to the IRB to have the project evaluated retrospectively.

Approval and Oversight of Quality Improvement Projects

At Stanford Medicine, we believe that all clinical providers have two aspects of their clinical work: 1. To provide care using our established clinical systems. 2. To continuously improve those clinical systems. In that sense, quality improvement is an innate part of practicing medicine and does not necessarily need system-wide oversight.

Guidelines for Oversight of Quality Improvement Projects:

- Local quality improvement project should be approved by the local leaders of the involved clinical unit or department.
- Quality improvement projects required for training (medical school, residency, fellowship) should be approved by the training program director in addition to the leaders of the involved clinical unit or department.
- Quality improvement projects that are part of an improvement training course such as CELT, RITE, or the Advanced Improvement Course should be approved by the course directors in addition to the leaders of the involved clinical unit or department.
- Quality improvement projects that have system-wide implications (changing approach to improve line infections, pressure injuries, other Key Performance Indicators, etc) or may have implications or impact on multiple clinical areas should be approved by the Chief Quality Officer of the associated healthcare system (Stanford Healthcare, Stanford Children's Health, Stanford Valley Care).

References & Links:

- Baily MA, Bottrell M, Lynn J, Jennings B, Hastings Center. The ethics of using QI methods to improve health care quality and safety. Hastings Cent Rep 2006;36:S1-40 https://www.thehastingscenter.org/uploadedFiles/Publications/Special_Reports/using_qi_methods_to_improve_health_care_quality_safety.pdf
- CHOP Quality Improvement vs Research. https://irb.research.chop.edu/quality-improvement-vs-research
- Lynn J, Baily MA, Bottrell M, Jennings B, et al. The ethics of using quality improvement methods in health care. Ann Intern Med 2007;146:666-673 https://annals.org/aim/fullarticle/734470/ethics-using-quality-improvement-methods-health-care
- Stanford University Quality Assessment and Quality Improvement (QA/QI) – file:///C:/Users/ladonnelly/Downloads/AID-H16_QA_QI_FAQs.pdf