

Quality Improvement Standard Operating Procedures

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1 Quality Improvement

1.1 Policy

Quality Improvement promotes accountability for the quality of health care delivery and service. This is accomplished through a systematic approach of assessing, defining interventions, implementing, and evaluating effectiveness of interventions with the goal of continuous improvement of clinical care and service. Quality Improvement is supported by a structure that establishes accountability to Stony Brook University and allows for information flow to and from Stony Brook University and personnel.

1.2 Quality Assurance/Quality Improvement (QA/QI) Initiatives

QA/QI initiatives are a mandated function of Stony Brook Medicine. Some of these initiatives are implemented after thorough evidenced-based best practices are identified; in response to an identified safety issue; or to improve the delivery of care and avoid potential safety issues. **The overarching intent of these initiatives is continuous monitoring of hospital operations and improved care of patients at Stony Brook Medicine.**

Please note that the “Application for Designation of Activity as Quality Assurance/Quality Improvement” is available [here](#) to assist the Project Lead in providing information needed for review and approval of the project.

The following activities are not considered research activities at the University. The responsible conduct of the activities listed below falls under the jurisdiction of Stony Brook Medicine’s Division of Medical and Regulatory Affairs and/or a hospital-recognized departmental quality assurance committee (collectively referred to from this point on as ‘Hospital QA’):

- Any hospital QA initiatives, and presentation/publication of results thereof, that are conducted within Stony Brook Medicine only, and that serve to:
 - Measure or improve SBU’s ability to meet or exceed an existing national standard of care or benchmark (Joint Commission, etc.), or
 - **Develop** a standard of care or benchmark **for applicability within Stony Brook Medicine**
 - **Submission of data to a national or state registry/database:**
 - That is mandated at the state or federal level, **OR**
 - That directly impacts reimbursement and funding available from the state, Department of Health, or federal Centers for Medicare & Medicaid Services (CMS) based on performance and/or clinical or quality outcomes, **OR**
 - That is maintained by an organization/consortium, formally recognized by Stony Brook Medicine’s benchmarking and/or performance improvement, the use of which is for internal activities.

- Hospital QA use of data from a registry/database, meeting any of the criteria above, for the purpose of:
 - **Measuring or improving SBU's** ability to meet or exceed an existing national standard of care or benchmark (JCAHO, etc.). OR
 - **Developing** a standard of care or benchmark **for applicability within Stony Brook Medicine.**

QI is a part of the normal operations of the organization. Someone seeking care from a health care organization cannot insist on the freedom to opt out completely from efforts to improve the quality of care in that organization. Therefore, informed consent is not normally sought from patients who are part of a quality improvement project.

1.3 Research Activities

The following activities are considered research activities. The responsible conduct of the activities below fall under the jurisdiction of ORC and/or Institutional Review Board (IRB):

- Any hospital QA initiative, conducted within Stony Brook Medicine only, designed to **develop** a standard of care or benchmark **for general applicability** (i.e. not only for operations within Stony Brook Medicine but to outside entities as well).
- Submission of data to a registry/database that is not covered by those described above.
- Use of data from any registry/database for the purpose of measuring, improving or developing a standard or benchmark, under any condition not covered in the section above, including the use of registry data for the purpose of research.
- Any activity that proposes comparisons of one or more prospective interventions that are deliberately administered or made available (through a randomization or other process) to some patients (if within the University) or some hospitals (if part of a consortium or organizational effort) and not to others. This does not include, e.g. initiating a QI process in a small percentage of patients at SBUMC first to ensure feasibility, before introducing it to the entire patient population.

1.4 Activities that have a mix of both QA/QI and Research Components

When your activity involves a mix of activities from Sections A and B, you will need to ensure compliance with the applicable entity, i.e. Stony Brook Medicine's Division of Medical and Regulatory Affairs for the QA/QI aspects and Office of Research Compliance (ORC) IRB for the research aspects of the activity (including securing approval prior to conducting the research aspect). Additionally, a project may start off as a quality improvement project and evolve to have a research component.

1.5 Publication of Quality Improvement Projects

The federal agency overseeing research (Office for Human Research Protections – OHRP) has stated that the act of presenting or publishing a quality improvement project does not change

its classification to be research. Guidelines developed by SQUIRE (Standards for Quality Improvement Reporting Excellence) provide a framework for reporting the findings of QI initiatives. (See <http://www.squire-statement.org/>). As a reminder, when discussing QI projects in publications and presentations, do not refer to Quality Improvement as research. Please see [OHRP FAQs on Quality Improvement](#) for more information.

If the project was not submitted to the IRB for a determination, the following statement may be included in the publication/presentation:

“This project was undertaken as a Quality Improvement project and as such does not constitute human subject research.”

If the project was reviewed by the IRB and was determined not to be human subject research, the following statement can be included in the manuscript/presentation:

“This Quality Improvement project was reviewed by the Stony Brook University Institutional Review Board and determined not to meet the criteria for human subject research.”

For any ‘questionable’ (QA vs. Research) activity not described above, please consult with the ORC and/or the Division of Medical and Regulatory Affairs for assistance.

1.6 Project Submission

Projects that meet the criteria as Quality Improvement need to be submitted using the **Application for Designation of Activity as Quality Assurance/Quality Improvement** - which is uploaded into the Quality Improvement Survey. This document includes the following:

- Project description
 - Who will be involved in conducting this activity
 - Who will be responsible for implementing the practice change
 - Definition of the problem you are looking to improve
 - Description of how baseline data will be collected and how Protected Health Information will be kept confidential
 - How the data will be analyzed and the tool used to display it
- Description of two potential PDSA cycles (Plan/Do/Study/Act)
- Description of how you plan on maintaining the solution long term
- Aims statement describing **how much** improvement is expected and **by when** (Project interventions should be directly linked to project aims)
 - Population that will be included in the quality improvement project; why they are part of the project and whether the population are patients ordinarily seen at the institution where the activity will take place
 - Risks to the population that is ordinarily expected when practice changes are implemented with a health care environment

- Benefits to the population or a future group of patients

1.7 Project Review

Determinations about QI versus research are made on a case-by-case basis. Faculty members and other researchers are required to seek a formal determination about their project to ensure that compliance requirements are met. These determinations are made by the Chief Quality Officer and are submitted through a Quality Improvement Survey format. The process includes the following:

- Quality Improvement initiatives must be reviewed and approved by their department chair/division heads or designee in collaboration with the quality director for that department (project must occur within the hospital or a clinic setting).
- Quality Improvement initiatives must be reviewed and approved by the Chief Quality Officer.
- If the project is complex or involves other factors that need special consideration, the Chief Quality Officer and a team of individuals knowledgeable in the area of Quality Improvement and compliance will be consulted as to the outcome of the initiative.

1.8 Process

In order to submit a project you will first need to complete an attestation document signed by the Department Chair or designee. This attestation information can be found at the end of the “Application for Designation of Activity as Quality Assurance/Quality Improvement”. This document will need to be uploaded into the electronic Quality Improvement Survey application. The project needs to be completed in one year. If the project is not completed in a year the project will need to be reviewed again.

Quality improvement projects must be submitted into the Quality Improvement Survey electronic system and include the following documents:

- Application Form for Quality Improvement Activities
- Data Collection Tool(s)

Once the project has been reviewed and approved by the Chief Quality Officer you will receive a letter acknowledging that the project can be conducted. If the project does not meet the criteria for approval, you will be contacted for additional information.

1.9 Criteria for Quality Improvement Applications

Projects must include **at least two linked cycles of improvement** (e.g., Plan-Do-Study-Act). Following baseline data, an improvement cycle should address the identified problem, general goals/aims within a measurable timeframe for achievement, the main underlying root causes of

the problem, interventions or countermeasures to address causes and operational plans to implement the interventions.

- Projects must address the care health care providers can influence in **one or more dimensions of quality patient care**: safety, effectiveness, efficiency, equity, timeliness or patient-centeredness. The project must also address **one or more of the ACGME/ABMS Competencies (if applicable)**: communication/interpersonal skills, medical knowledge, patient care & procedural skills, professionalism, practice-based learning, and improvement or systems-based practice.
- Improvement changes **must include a process change** in addition to any educational interventions. **Education-only interventions will not meet approval criteria.**
- Projects should include plans for appropriate and repetitive data collection and reporting of data to support the assessment of the impact of interventions. There must be:
 - Consider the sample size to minimize the impact of random variability and permit reasonable decision-making regarding subsequent project steps.
- Use of appropriate charting or reporting tools to document performance over time (e.g., annotated run charts, control charts, etc.). Projects must use **one or more** of the following quality measures where applicable:
 - **Outcome Measures** - Evaluation of the results of an activity, plan, process or program and their comparison with the intended or projected results (e.g., % of diabetics with hemoglobin A1c less than 7mg/dl).
 - **Process Measures** – Evaluation of the performance of a process. Measuring the results of process changes will indicate if care is improving (e.g., % of diabetics who have hemoglobin A1c measured).
 - **Balancing Measures** – Evaluation of new problems that may occur as a result of the intervention (e.g., % of patients with hypoglycemia complications).
- The team should possess sufficient and appropriate resources to support the successful planning, implementation, and sustainable conclusion of the project without the need for external funding. To the extent that resources are needed, they should be identified within the department or hospital division's budgets.

1.10 Minimal risk

Projects identified as quality improvement will be reviewed according to risk. Accordingly, quality improvement projects should not expose patients to more than minimal risk or what would be considered routine care. Exposure to risk in a quality improvement project typically is limited to privacy and confidentiality. Measures must be implemented to reduce the patient exposure to risks associated with privacy and confidentiality.

1.11 Data security

Projects identified as quality improvement should include a component for protecting information obtained. These practices can include but are not limited to:

- All paper records must be kept secure, and located in a closed and locked area when unattended. If information is kept electronically, the electronic files must be stored securely.
 - Information that is identifiable must have all identifiers removed prior to storage
 - Destruction of any identifiable information must occur once the quality improvement project has been completed