Governors State University

Institutional Review Board
Room G353
1 University Parkway
University Park, IL 60484
www.govst.edu/irb

SOP: Quality Assurance and Quality Improvement Projects in Applied Health Sciences

1. PURPOSE

Quality Assurance and Quality Improvement Projects (QA/QI) are important building blocks of the health care system. Engagement with Quality Assurance and Quality Improvement Projects (QA/QI) may offer useful learning experiences for students in applied health sciences. This could take the form of a thesis, major paper or directed study. The purpose of this guidance is to clarify the Governors State University (GSU or the University) Institutional Review Board (IRB) approach to reviewing QA/QI projects conducted as learning experiences within the GSU health science programs, such as nursing.

2. GUIDANCE

2.1. QA/QI projects are undertaken for ensuring quality, upholding standards and/or for monitoring outcomes of organizational activities. Such projects are conducted for internal clinical or administrative purposes rather than for creating generalizable knowledge through public presentation or publication. Furthermore, because QA/QI projects typically fall under the jurisdiction or mandate of the organization, participation in such projects may not be voluntary and individual's consent to participate, or consent for access to information may not be required.

2.2. Although QA/QI project may necessitate gaining information that identifies individuals or employ research type methodologies (e.g., surveys, analyses of administrative data, chart reviews, etc.), such projects, by their nature, do not meet the definition of human subjects research stated in the Federal Regulations for the Protection of Human Subjects (45 CFR 46), and, therefore, do not require IRB oversight.

2.3. ***Because of the potential for conflict of interest, investigators are not given the authority to make an independent determination about whether or not their projects require IRB oversight. The IRB has the sole authority to make such a determination. The project should not begin until the investigator has received the IRB determination. When a determination is made that the project requires IRB oversight, IRB approval must be requested and granted before the project begins.***

2.4. The Office for Human Research Protections (OHRP) provides the following **examples** of projects for non-research clinical or administrative purposes:

2.4.1. A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.

2.4.2. A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected.

2.4.3. A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

2.5. **Exceptions** include projects that have a clear intent to contribute to generalizable knowledge. Also, if the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

2.6. **QI/QA projects as learning experiences within academic nursing programs do not require IRB oversight when they meet <u>all</u> of the following conditions:**

2.6.1. Implementing the practice outlined in the project will not incur patient harm, i.e., will be of minimal risk to patients;

2.6.2. The practice outlined in the project is not new or novel and has been published elsewhere;

2.6.3. The project is not testing issues that go beyond current knowledge or attempting to fill a gap in knowledge regarding a specific patient population, disease, or treatment;

2.6.4. The project will not involve randomization of patients or staff into different intervention groups;

2.6.5. The project will not involve comparison of an intervention (i.e., treatment, training, drug, or device) to a control group or a different intervention;

2.6.6. The project is not providing an intervention that is less than standard of care, or imposes risks or burdens that go beyond standard of care;

2.6.7. The practice outlined in the project will be implemented in a specific project location (e.g., a hospital or clinic);

2.6.8. The project has no funding support from an outside organization with a commercial interest in the use of the results;

2.6.9. There is an identified faculty member who supervises the project and ensures that the student is aware of ethical and/or legal issues associated with the proposed project and seeks to ensure that the student upholds legal and ethical standards when engaged with the project; and

2.6.10. The sponsoring organization agrees to the student's participation in the QA/QI project, and provides a letter of support to the student and the supervising faculty member.

3. PROCEDURES

3.1. **Student investigators involved in QI/QA projects must request an IRB determination prior to implementing the project.**

3.2. The GSU IRB has developed a short questionnaire in Cayuse that should assist with determining if the project meets the criteria for QA/QI and can be implemented without IRB oversight or if it requires IRB oversight. After completing the questionnaire, the investigator will receive a letter of determination that states:

3.2.1. The project does not require IRB oversight, or

3.2.2. The project is determined to require IRB oversight and the investigator will receive instructions for submitting the project to the IRB are included.

3.2.3. Additional information is required in order to make a determination.

REGULATIONS

45 CFR 46.102
OHRP Quality Improvement Activities FAQs

AUTHOR REFERENCE

The University of British Columbia, School of Nursing, "Student Involvement in Quality Assurance or Quality Improvement Projects and "Research""
Governors State University Policy 53

CONTACT INFORMATION

Office of Sponsored Programs and Research
Governors State University
1 University Parkway
University Park, IL 60484
708.235.2846

DISCLAIMER

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this guidance, but not to the guidance statement, must be presented in writing to the Responsible Officer.