Guidelines for

Quality Assurance Projects vs. Research

NOTE: If you are intending to publish the results of a project in a research journal, the project should be considered research and undergo the IRB review process. However, Quality Assurance (QA) projects are often published in journals that have been specially designed to report the results of QA projects. This type of project does not require IRB review.

The purpose of a Quality Assurance (QA) study is to ensure known quality. A QA study should present NO RISK to participants. These studies are mechanisms to ensure that Creighton University/Creighton University Medical Center functions optimally. Such projects are usually for internal auditing purposes only.

If you can answer “yes” to all of the following questions, IRB review is NOT REQUIRED:

1. Will you simply monitor an existing process for which there will be no manipulation of the existing process?
2. For biomedical QA studies, will physicians and caregivers be permitted to provide routine clinical care (without intervention), regardless of the conduct of the study?
3. Does the study involve collection of data to which the investigator routinely has access as part of his/her responsibilities within the institution to monitor data associated with, for example: treatment, cost containment, performance, or compliance?

QA studies must not:

1. infringe on a subject/patient’s privacy,
2. breach a subject/patient’s confidentiality, or
3. pose any risk to subject/patient, faculty, or staff.

45 CFR 46.102 (d) of the federal regulations defines research as a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.

Based on 45 CFR 46.102(d), IRB review IS REQUIRED when:

1. You anticipate in advance of conducting the project that you will analyze, interpret, and disseminate the findings of your investigation beyond the scope of your department or division, or
2. The knowledge you will gain from your project will be applied beyond quality assurance, service, or training to lead to a new procedure or process.
Examples to assist you:

Example #1 -
To provide better care, management decides to look at how many patients come through the Emergency Room each day and how long patients wait for care on a given day. With this information, additional staff might be needed to serve that population.

- This evaluation monitors an existing process (flow of patients through the ER).
- There is no intervention in the clinical care provided to hospital patients.
- Information about the number of patients seen in the ER is routinely available to designated managerial staff who are responsible for providing efficient care in the ER.

[Example #1 would be a QA project not requiring review.]

Example #2 -
Same project as above, with the exception that, from the onset, the management group intends to analyze the results for presentation to a national managerial conference in the fall.

- This evaluation monitors an existing process (flow of patients through the ER).
- There is no intervention in the clinical care provided to hospital patients.
- Information about the number of patients seen in the ER is routinely available to designated managerial staff who are responsible for providing efficient care in the ER.

[The QA project in Example #2 would need to be brought to the IRB for review since it is known in advance of conducting the project that the findings will be shared beyond the department or division involved.]

Examples of some of the numerous forms of data gathering from human beings that do not constitute research within the context of human subjects review regulations include the following:

- Example #3 - Data gathered for classroom training in research methods for which the only foreseeable purpose is teaching.

- Example #4 - Data gathered for administrative purposes alone within the context of the normal efforts of a department or an institution to find out what is happening or how to ensure quality services or operations.

[The types of data gathering in Examples #3 and #4 are not research because there is no foreseeable dissemination of the data. Any record of the data (or interpretation and analysis of the data) remains private, used only for purposes that are appropriate to the classroom or institutional facility in the normal conduct of its work.]