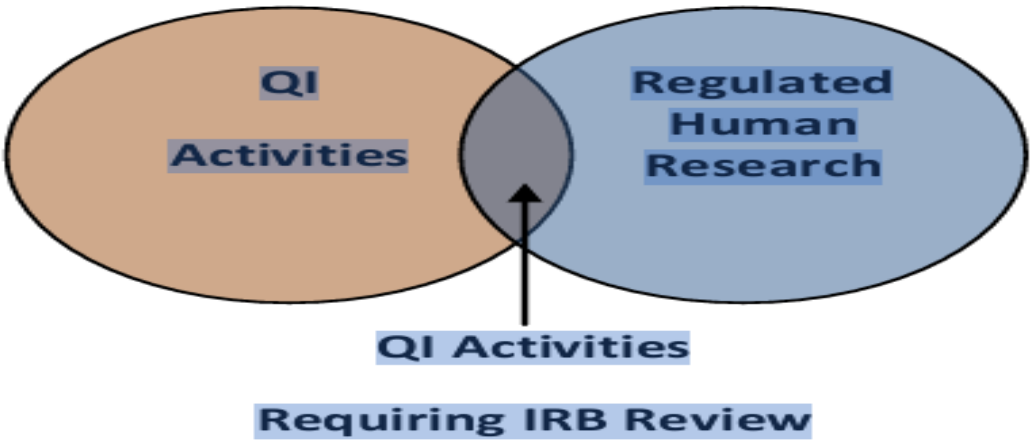
CHRISTUS Health

GUIDANCE FOR DETERMINING QI/QA ACTIVITY



Quality Improvement (QI) activities have been defined as systematic, data-guided initiatives designed to enhance health care delivery in a particular setting. QI is an integral part of good clinical practice whereby results are used to inform the provision of healthcare services for patients at the local institution. Patient populations are frequently the targets of QI study and the distinction between QI activities and regulated human research is not always clear. There can be understandable confusion about whether QI activities fall under the jurisdiction of the IRB. Prior IRB approval is required when any project, in whole or in part, meets the federal definition of human research. Attributes such as publication of findings, methodology, or the systematic collection of data, do not necessarily differentiate regulated human research from QI activities because these attributes can be shared by both research and non-research activities. Additionally, activities that start out as QI projects may lead to regulated human research when a decision is made to use previously collected QI data for a research purpose.

The range of traditional QI activities is broad, but they typically are projects:

- aimed at improving local systems of care, or improving the performance of institutional practice;
- designed to bring about immediate improvements in health care delivery;
- designed to verify that promising methods of care introduced into clinical practice result in improved outcomes
- intended to compare a program/process/system to an established set of standards such as standard of care, recommended practice guidelines, or other benchmarks.

Note: According to federal guidance, “the intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research.”

Quality Improvement Tool

This checklist is intended to provide a **tool to help determine which QI proposals are, in fact QI projects, and which constitute regulated human research**
Please answer both sets of questions below.

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Section A: Is this QI?

If you answer **Yes** to any question in Section A , then CHRISTUS Health IRB review is not needed. If you are uncertain, then please call the CHRISTUS Health IRB office for further guidance.

1. Are patients who receive the project intervention expected to benefit?
2. Will all groups in the project receive, at the minimum, the usual standard of care at this institution?
3. Is the purpose of the project to measure the performance of or to determine the effectiveness of a process change
   intended to improve health care delivery?
4. Will the results be used to inform and implement improvements in patient care at this
   Institution and no other institutions (other hospital systems)?

Section B: Is this regulated human research?

If you answer **Yes** to any question in Section B, then CHRISTUS Health IRB review and approval is required. You should log into iRIS and complete the appropriate application for your project. If you are uncertain, then please call the CHRISTUS Health IRB office for further guidance.

1. Is the intent of the project either to test a novel hypothesis or to replicate another researcher's original study?

2. Will patients or personnel be exposed to additional discernable risks or burdens beyond those of the usual standard of care at this institution?

3. Does the project involve withholding of any aspect of conventional care shown to be beneficial in prior well-conducted clinical trials?

4. Does the project seek to test interventions, practices or treatments that are not standard of care (neither consensus-based nor evidence-based)?

5. Does the project involve a drug or device used outside of usual medical practice, including non-FDA-approved agents, or off-label uses of FDA-approved drugs or devices?

6. Will the safety and/or effectiveness of a drug or regulated device be evaluated or be compared to that of another?

7. Will the project be described as research in grants, public presentations, academic dossier or other representations? (QI findings may be published but should not be represented as research. CHRISTUS Health IRB can provide, upon request, documentation to journals that the project was determined to be non-human subject research.)

8. Does the project have funding from an organization with a commercial interest in the use of the results?