CHRISTUS Research Institute
QI/QA vs Research Decision Tree

Will the project involve testing an experimental drug, device (including medical software or assays) or biologic?

- YES: IRB approval is likely required to address FDA requirements. Access the CHRISTUS Health IRB website for guidance.
- NO: IRB approval is likely required. Access the CHRISTUS Health IRB website for guidance.

Has the project received funding (e.g., federal, industry) to be conducted as a human subjects research study?

- YES: IRB approval is likely required. Access the CHRISTUS Health IRB website for guidance.
- NO: IRB approval is likely required. Access the CHRISTUS Health IRB website for guidance.

Is this a multi-site project (e.g., there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?

- YES: IRB approval is likely required. Access the CHRISTUS Health IRB website for guidance.
- NO: IRB approval is likely required. Access the CHRISTUS Health IRB website for guidance.

Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g., testing a hypothesis; randomization of subjects; comparison case vs. control, etc.)?

- YES: IRB approval is likely required. Access the CHRISTUS Health IRB website for guidance.
- NO: IRB approval is likely required. Access the CHRISTUS Health IRB website for guidance.

Will the results of the project be published, presented or disseminated outside of the institution conducting it?

- NO: The project doesn’t appear to fit the definition of QI/QA. Contact the CHRISTUS Health IRB for guidance.
- YES: This project appears to constitute QI/QA and doesn’t fit the federal definition of research. Further IRB review is not required. Ensure that all those associated with the project are aware that it is ongoing.

Will the project occur regardless of whether individuals conducting it may benefit professionally from it?

- NO: The project doesn’t appear to fit the definition of QI/QA. Contact the CHRISTUS Health IRB for guidance.
- YES: This project appears to constitute QI/QA and doesn’t fit the federal definition of research. Further IRB review is not required. Ensure that all those associated with the project are aware that it is ongoing.

Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?

- NO: The project doesn’t appear to fit the definition of QI/QA. Contact the CHRISTUS Health IRB for guidance.
- YES: This project appears to constitute QI/QA and doesn’t fit the federal definition of research. Further IRB review is not required. Ensure that all those associated with the project are aware that it is ongoing.

In future publications/presentations, it is recommended you refer to this as a QI/QA project and not as research.