

Quality Assurance/Quality Improvement Project Worksheet

Quality assurance or quality improvement (QA/QI) projects can often seem like the type of human subjects research that the IRB needs to review. By their nature, QA/QI projects often include activities such as conducting surveys, reviewing identifiable data, drawing conclusions about problems, and suggesting methods for improvement.

Typically, QA/QI projects are particularly focused on improving the performance of an institutional practice in comparison with an established standard or goal. They are focused on a local practice and consequently limit their scope to the specific institution. The results of the project are not *intended* to apply to anyone beyond the scope of the project, and conclusions are drawn only in relation to the particular practice at the institution. In other words, if the results of the project are shared outside the institution (i.e. published or presented), then it would only be for the purposes of sharing a successful improvement in practice; other institutions could then interpret the results and draw their own conclusions, but the key is that the institution conducting the QA/QI project is not drawing broad conclusions and is not using their participants as a representative sample.

Name:

Project Title:

Instructions: Please answer the following questions to determine if you need to submit an IRB.	
The focus is local and specific, aiming to improve a particular institutional practice. Yes No	Aims to explore a hypothesis or theory in order to draw general conclusions beyond the scope of the institution. Yes No
Does not use participants as a representative sample of a broader population. Yes No	Results or data from participants may be generalized as being representative of the population at large. Yes No
Conclusions are intended to only be directly applicable to the particular institution; no claim that the results apply outside the institution. Yes No	Conclusions are meant to be disseminated and applicable to people and institutions beyond the site where the project took place. Yes No
Any publication or presentation on the project would still focus on the specific practice and improvement at the particular institution; it is only relevant to external institutions to the extent that they can draw their own conclusions about applicability at their institution. Yes No	Publications and presentations aim to be applicable to the field more broadly. For example, if a particular intervention in the research study led to better outcomes, a publication would generalize those findings and suggest that they are applicable to other institutions as well. Yes No

Sign

Date

Please sign and submit this with any other project-related documents to untirb@unt.edu. We will review the document and make a determination. Thank you.