

QA/QI Checklist

CONDITIONS FOR DETERMINATION OF QA/QI STATUS	Yes	No
The primary intent of the project is not peer reviewed publication and if publication of the results was prohibited, the project would still have merit as a QA/QI effort.		
The purpose is to improve the quality of the program under investigation by assessing and encouraging standard medical care or educational goals.		
The PI has both clinical supervisory responsibility and the authority to impose a corrective plan based on the outcomes of the project.		
The project does not involve prospective assignment of patients to different procedures or therapies based on a predetermined plan such as randomization.		
The project does not involve a “control group” in whom therapeutic or study intervention is intentionally withheld to allow an assessment of its efficacy.		
The project does not involve the prospective evaluation of a drug, procedure or device that is not currently approved by the FDA for general use (including “off-label” indications).		
Participants won't be exposed to additional physical, psychological, social or economical risks or burdens (beyond patient satisfaction surveys) in order to make the results of the project generalizable.		
Adequate protections are in place to maintain confidentiality of the data to be collected and there is a plan for who can access any data containing participant identifiers.		