Center for Research & Grants

VIDANT HEALTH™

Quality Assurance/Quality Improvement Project vs. Human Research Study (Requiring IRB approval) Determination Form

This worksheet is a guide to help the submitter to determine if a project or study is a quality assurance/quality improvement (QA/QI) project or research study and is involving human subjects or their individually identifiable information and requires IRB approval as defined by the Health and Human Services (HHS) or Food and Drug Administration (FDA). Once completed, please email the form to the Vidant Health Center for Research and Grants (VH CRG) CRG.Quality@vidanthealth.com. A CRG team member will contact you with the results of their review and may request additional information to assist with their determination. The determination will be made in conjunction with the UMCIRB office.

Please contact the VH CRG with any questions at 252-847-1177 or CRG.Quality@vidanthealth.com.

For more guidance about whether the activity meets the definition of Human Subjects Research see https://rede.ecu.edu/umcirb/irb-faqs/definitions/ or https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1

Project Title:		
Funding Source:		
Project Leader Name:	☐ Ed.D. ☐ J.D. ☐ M.D. ☐ Ph.D. ☐ Pharm.D. ☐ R.N. ☐ Other(specify):	
Job Title:	Phone:	Email:
	Primary Contact (If different from Project Leader):	
	Phone:	Email:

Key Personnel/ Project Team members:

Name and Degree:	Department: (Affiliation if other than Vidant)	Email:

QI/QA Assessment Checklist:

Consideration	Question	Yes	No
PURPOSE	Is the PRIMARY purpose of the project/study to: • IMPROVE care right now for the next patient? OR • IMPROVE operations outcomes, efficiency, cost, patient/staff satisfaction, etc.?	☐	☐
RATIONALE 1	The project/study falls under well-accepted care practices/guidelines or is there sufficient evidence for this mode or approach to support implementing this activity or to create practice change, based on: • literature • consensus statements, or consensus among clinician team	☐	☐
RATIONALE 2	The project/study would be carried out even if there was no possibility of publication in a journal or presentation at an academic meeting. (**Please note that answering "Yes" to this statement does not preclude publication of a quality activity.)	☐	☐
METHODS 1	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes?	☐	☐
METHODS 2	Are patients/subjects randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection? (Control group, Randomization, Fixed protocol Methods)	☐	☐
METHODS 3	Will there be delayed or ineffective feedback of data from monitoring the implementation of changes? (For example to avoid biasing the interpretation of data)	☐	☐
METHODS 4	Is the Protocol fixed with fixed goal, methodology, population, and time period?	☐	☐
RISK	The project/study involves no more than minimal risk procedures meaning the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.	☐	☐
PARTICIPANTS	Will the project/study only involve patients/subjects who are ordinarily seen, cared for, or work in the setting where the activity will take place?	☐	☐
FUNDING	Is the project/study funded by any of the following? • An outside organization with an interest in the results • A manufacturer with an interest in the outcome of the project relevant to its products • A non-profit foundation that typically funds research, or by internal research accounts	☐	☐

If all of the check marks are inside the shaded gray boxes, then the project/study is very likely QI and not human subject research. Projects that are not human subject research do not need review by the IRB.

In order to assess whether your project meets the definition of human subject research requiring IRB review or may qualify as a quality improvement/assurance activity, please provide the following information:

1. Project or Study Summary:
   As a separate attachment, please provide a summary of the purpose and procedures as well address all of the following:
   a) The project question/hypothesis.
   b) The project design.
   c) Any interaction or intervention with humans.
   d) A description of the methods that will be used and if they are standard or untested.
   e) Specify where the data will come from and your methods for obtaining this data -please specify who/where (i.e. CRG will provide you with the data, or someone from a specific department will provide you with the data, or you will pull it yourself).
   f) Specify what data will be used and any dates associated with when that data was originally collected (i.e Patient Name, Diagnosis, Age, Sex), *If applicable, please attach your data collection sheet.*
   g) Where will the data (paper and electronic) for your project be stored? Please specify how it will be secured to protect privacy and maintain confidentiality. For paper data, please provide physical location such as building name and room number and that it will be kept behind double lock and key. For electronic data, please provide the file path and folder name network drive where data will be stored and specify that it is secure/encrypted/password protected. If using other storage location, please provide specific details.
   h) Please specify how long data will be stored after the study is complete? (Keep in mind that data collected/generated during the course of the project that includes protected health information (PHI) should have identifiers removed at the earliest opportunity.)
   i) Please specify how the collected data will be used (internal/external reports, publishing, posters, etc.).

   Please attach a summary and/or any other additional documentation describing your project

2. If the Primary purpose of your project/study is for QA/QI, have you obtained approval from the operational leader within your department or health system:
   ☐ Yes [Please specify here whom and obtain their signature in the signature section below]:
   ☐ No [Contact the appropriate operational leader for approval.]

Please note:

- By submitting your proposed project/study for QA/QI determination you are certifying that if the project/study is established to qualify as QA/QI project, you and your Department would be comfortable with the following statement in any publications regarding this project: "This project was reviewed and determined to qualify as quality improvement by the Vidant Health Center for Research and Grants."
- If you are submitting a Poster to Media Services for printing, you will need to also submit this Quality Improvement Worksheet or proof of your IRB Application and IRB Approval.
- If the VH CRG determines the activity is not human subject research, then any presentation, publication, etc. should not refer to the activity as "human subject research," "exempt research," or "expedited research."
- If you would like the VH CRG to verify that a project/study is not human subject research, please provide this form completed with the summary of your activity and any additional information to the VH CRG at CRG.Quality@Vidanthealth.com and the following will be completed and returned to you for your records.

NHSR vs. HSR Determination:

☐ Not Human Subject Research: The VH CRG has determined that based on the description of the project/study, approval by the IRB is not necessary. Any changes or modifications to this project may be discussed with the VH CRG at that time to ensure those changes do not elevate the project to human research that would need IRB approval.

☐ Human Subject Research: This project/study requires review by the IRB prior to initiation. An application in the electronic IRB submission system should be submitted.

Approval Signatures:

Department (Site) Manager: _____ Date: _____

VH CRG Reviewer: _____ Date: _____

UMCIRB Office Staff Reviewer: _____ Date: _____