The Wright Center for Graduate Medical Education
Institutional Review Board
WCGME – IRB

Request for Human Subjects Research Determination

Project Title:	**Date:**

I. Applicant Information

Name:	
☐ Faculty ☐ Student ☐ Other:	Dept./Unit:
Address:	
Email:	Phone:

Faculty/Resident Advisor *(if appropriate)* ☐ NA

NOTE*: A Faculty Advisor is required if the applicant is a student, resident or fellow.*

Name:	Department/Unit:
Address:	
Email:	Phone Number:

II. PROJECT DESCRIPTION

Summary. Provide a summary of the proposed project. The summary should summarize the subjects involved, the objectives of this project and the procedures to be used. Alternatively, a narrative or protocol may be attached and submitted.

III. QUALITY IMPROVEMENT, PROGRAM EVALUATION ASSESSMENT

QI and research, and Program Evaluation and research, are not mutually exclusive terms, sometimes an activity can be both. The questions in this section help differentiate whether an activity is purely QI or Program Evaluation, or if the activity includes a research component. Complete this section if you believe your activity is Quality Improvement or Program Evaluation; otherwise, skip the questions in this section and move forward to **Section IV**.

Quality Improvement (QI) - involves systematic activities that are designed and implemented by an organization to monitor, assess, and improve the quality of its services, processes, or programs.

Program Evaluation – individual systematic activities conducted to assess how well a program is working and why.

1. The methods used in an activity can help distinguish whether a project is QI, program evaluation, or research. Please answer the following:

a. Does the project involve randomization, blinding, or assignment into two or more subject groups or arms?

☐ **Yes.** These methods are more consistent with research than quality or program evaluation

☐ **No**

b. Does the activity use Quality Improvement methods such as FADE, PDSA, Six Sigma, CQI, or TQM?

☐ **Yes.** These methods are more consistent with quality improvement than research

☐ **No**

2. Similarly, the intent of the activity is informative to the determination.

a. Evaluate or improve clinical care or a process, practice, or program at TWC?

☐ **Yes** ☐ **No**

b. Only be applied to populations, or inform practice within the target population or TWC?

☐ **Yes** ☐ **No**

c. Implement an evidence-based practice, process, or program and evaluate whether it functions as intended within TWC or with the local target population?

☐ **Yes** ☐ **No**

d. Evaluate an existing practice, process, or program to determine if it is functioning as intended?

☐ **Yes** ☐ **No**

e. Establish scientific evidence, or build upon early existing evidence, in support of a new or modified practice, process, or program?

☐ **Yes** ☐ **No**

3. Based upon the scientific literature, is it expected that all participants will benefit from the practice, process, or program or is this unknown?

☐ **Yes** ☐ **No** ☐ **Unknown** ☐ **NA to this proposal**

4. Are there any risks to participants anticipated as a result of inclusion in the program or initiative?

☐ **Yes** ☐ **No**

If Yes:

a. Does this represent an overall increase or decrease in risk exposure?

b. What steps are being taken to minimize those risks?

5. Please use this space to explain if you were unable to answer any of the above questions or provide additional information that may be relevant to the determination:

Once you've completed the questions in this section, move forward to Section IV.

IV. COMMON RULE DETERMINATION

1. Is the activity **"research"**?
As defined by Department of Health and Human Services (DHHS) regulations: *"Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."* 45 CFR 46.103(d)

a. Does the activity involve a **systematic investigation** *(i.e., an activity that involves a prospective plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a question)*?

☐ **Yes** ☐ **No**

b. Is the activity is designed to develop or contribute to **generalizable knowledge** *(i.e., the evidence base for the process, practice, or program is not yet firmly established or accepted; and, the activity is not dependent on the unique characteristics of the target population or system in which it will be implemented)*?

☐ **Yes** ☐ **No**

2. Does the activity involve **"human subjects"**?

a. Will you obtain data through **intervention** with living individuals? *This includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment, that are performed for research purposes.*

☐ **Yes** ☐ **No**

b. Will you obtain data through **interaction** with living individuals? *This includes communication or interpersonal contact between researchers and subjects, including indirect interaction such as via a web-based survey.*

☐ **Yes** ☐ **No**

c. Will you obtain (i.e., access, observe, use, or record) **Identifiable Private Information** about living individuals?

Private Information *includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical or education record).*

Private Information *means that the identity of the subject is or may readily be ascertained by the investigator or associated with the information. Note: When data or specimens are coded, and the investigator has access to the key or another means to re-identify, the data is identifiable. Consult with the IRB Office for questions on this topic.*

☐ **Yes** ☐ **No**

3. Is the activity "**human subjects research**" as defined by DHHS ("Yes" to 1(a) and (b) and "Yes" to 2(a), (b), or (c))?

☐ **Yes.** The proposed activity is or includes human subjects research. Do not submit this form, an application for an exempt determination or IRB review is required. Please contact the IRB office with any questions.

☐ **No.** The proposed activity is not human subjects research according to the Common Rule. Proceed to Section V to evaluate whether the proposed activity is research subject to FDA regulations.

V. FDA DETERMINATION

1. Does the activity include the evaluation of an **"FDA-regulated test article"**?

a. Does the activity evaluate a **DRUG or BIOLOGIC**? *(A chemical or biological substance – other than food – that achieves its primary intended purposes through chemical action within or on the body or which is dependent upon being metabolized for the achievement of any of its primary intended purposes.)*

☐ **Yes** ☐ **No**

b. Does the activity evaluate a **MEDICAL DEVICE**? *(An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory that is one of the following:*

- *Recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them*
- *Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals*
- *Intended to affect the structure or any function of the body.)*

☐ **Yes** ☐ **No**

c. Does the activity evaluate a human food additive, nutritional supplement, color additive, radiation-emitting electronic product, or other article subject to FDA regulation?

☐ **Yes** ☐ **No**

2. Does the activity involve **Human Subjects** as defined by the FDA?

Human subject *means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. In the case of a medical device, a human subject also includes any individual on whose tissue specimen an investigational device is used or tested. [Note: This definition does not require that the specimens are identifiable.]*

☐ **Yes** ☐ **No**

3. Does the activity include a **clinical investigation** as defined by the FDA?

Clinical investigation means any experiment that involves a FDA-regulated test article and one or more human subjects.

For drugs, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

For medical devices, it is limited to experiments involving one or more human subjects (or specimens) to determine the safety or effectiveness of a device.

☐ **Yes** ☐ **No**

4. Is the activity subject to approval by the FDA (e.g., as an IND, IDE, or HDE) or are the results intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit?

☐ **Yes** ☐ **No**

5. Does the activity involve an FDA-regulated test article ("Yes" to 1(a), (b), or (c)), one or more human subjects ("Yes" to 2), an experiment or clinical investigation ("Yes" to 3), and is subject to approval or inspection by the FDA ("Yes" to 4)?

☐ **Yes.** The proposed activity involves human subjects research subject to FDA regulations. IRB approval is required.

☐ **No.** The proposed activity does not involve human subjects research subject to FDA regulations. Submit this form to the IRB office if you are seeking an official determination and documentation that IRB approval is not required.

Investigator Statement:

I will conduct the activities identified above in the manner described on the attached narrative. If I decide to make any changes, I will submit the proposed changes to the TWC Institutional Review Board, for confirmation that the activity remains "not human subjects research".

_____

Investigator Signature Date

IF THE INVESTIGATOR IS A STUDENT OR RESIDENT, A FACULTY ADVISOR/DEPT CHAIR/DEAN/DIRECTOR MUST SIGN BELOW: I have read this application and approve of this project.

_____

Faculty/Resident Advisor Signature Date

HRPP/IRB USE ONLY

1. **Reviewer Conflict of Interest**
   Do you have any interests, financial or otherwise, related to this submission that could present a conflict of interest?
   ☐ Yes. Please do not conduct this review, contact the IRB office so that this submission can be reassigned.
   ☐ No
2. **Determination**
   ☐ The activity **does not** involve human subjects.
   ☐ The activity **is not** research.
   ☐ The activity **does** involve human subjects research per the: ☐ Common Rule ☐ FDA An application to the IRB is required.
   ☐ Additional information is needed (see below)

Changes, Modifications, and Clarifications

Reviewer Name:	**Date:**