Human Subject Research Determination Form

This form should be completed and submitted for review by the service lines impacted by the work prior to project initiation (including, but not limited to, collection or analysis of baseline data). Projects that are "Not Human Subjects Research" are not required to submit an IRB application in ePirate. To help make that determination, you may utilize the Decision Chart provided by the Office for Human Research Protections along with this worksheet. For any project where there is a question as to whether it qualifies as Quality Improvement or Research, or if certification of "Not Human Subjects Research" is needed for publication, please route to the UMCIRB office via email: umcirb@ecu.edu.

Please check the Office of Clinical Research Website or UMCIRB website to make sure that you have the most recent version of this form.

Project Title	
Project Leader	
Project Leader Contact E-mail	
Department or Unit Affiliation	
Project Advisor (if applicable)[1]	

Additional Faculty, Staff, and Trainees Involved (add more rows if needed):

Name	Department or Unit	Role	Check this box if this team member will access PHI or PII for the purposes of this project.
			☐
			☐
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[1] All student, resident, and fellow projects must have a faculty or unit leader designated as the advisor for the project.

Please answer the following questions to the best of your ability. If the answers to these questions change during the course of the project, please resubmit this form for review:

End Goal / Desired Outcome:

[Please provide a brief overview of the outcomes of this project using the SMART (Specific, Measurable, Achievable, Relevant, and Time-Bound) goal framework. What would be considered success? What question are you trying to answer?]

Methodology / Intervention:

[Please provide a brief overview of how you plan to carry out your project. What methods will be used and what is the proposed intervention for your project? How does this project change current standard of care?]

Data to be collected:

[Please provide a brief overview of what data or variables will collected over the course of the project, where the data will be collected from, where the data will be stored, and how the data will be analyzed.]

Complete the following questions to guide leadership's determination of this project's status:

	True	False
The PRIMARY purpose of the proposed activity or project is limited to: - implementing a standard practice to improve the quality of patient care and to collect data regarding that implementation for clinical, practical, or administrative purposes, and/or - delivering healthcare and measuring and reporting provider performance data for clinical, practical, or administrative uses.	☐	☐
The activity or project would be carried out even if there was no possibility of publication in a journal or presentation at an academic meeting.	☐	☐
The activity or project falls under well-accepted care practices/guidelines and are designed to bring about immediate improvements in health delivery or quality of care. If "true" and the project is related to clinical activity, please provide a citation below as evidence that project activities fall within standards of care. Projects not directly related to clinical activity, such as medical education, do not need to provide a citation.	☐	☐
The activity or project involves "no more than minimal risk" procedures. (i.e., 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).	☐	☐

Please submit this form to your supervisor (or designee) for review and approval. Signature on this form certifies that that the below individual is in support of this project taking place and agrees with the project leader's answers to the above questions:

Supervisor's Name	
Signature	
Date	

For Project Leaders: From the list below, please check the boxes for each service line where interventions may take place or where data may be collected. For each selected area, please route for signature for both the physician leader and administrator (preferably via DocuSign). Send a completed copy of the form to qualityimprovement@ecu.edu.

For Service Line Leaders: Signature on this form certifies that you are in support of this project taking place and agree with the answers to the above questions. If you are not in support of the proposed project, please discuss with the project leader, supervisor, and UMCIRB as needed.

	SERVICE LINE	SIGNATORY
☐	Adult Medicine (Medical Critical Care, Infectious Disease, Hospital Medicine, Pulmonology, Endocrinology, Allergy, Dermatology, & Nephrology)	Paul Bolin, MD
☐	Adult Surgical Service (Anesthesiology, Trauma, ENT, Benign Urology, Plastics, Ophthalmology, Transplant Surgery, & Acute Care Surgery)	Eric DeMaria, MD Wendy Leutgens, MSN
☐	Behavioral Health (Child / Adolescent Psychiatry, Behavioral medicine, & Adult Psychiatry)	Michael Lang, MD Todd Hickey, MHA
☐	Cancer (Breast cancer, Lung cancer, Gynecologic cancer, hematology, GI cancer, Urologic cancer, and Head & Neck cancer)	Emmanuel Zervos, MD Todd Hickey, MHA
☐	Children's Health (Pediatric Surgery, General Pediatrics, Well Newborn, Newborn & Pediatric Critical Care, Pediatric Hem-Onc, Neonatology, Pediatric medicine, Medicine subspecialities, surgical subspecialties)	Matthew Ledoux, MD Tara Stroud, DNP
☐	Emergency Services (Emergency Preparedness, Emergency Management, & Emergency Services)	Leigh Patterson, MD Debra Hernandez, MHA
☐	Heart & Vascular (Interventional Cardiology, Electrophysiology, Cardiac Surgery, Advanced Heart Failure, Cardiac Critical Care, Vascular Surgery, Cardio pulmonary rehab, Structural heart, & Thoracic Surgery)	Mark D. Iannettoni, MD Jay Briley, MHA

☐	Neuro Sciences (Neurology, Neurosurgery, Neuro Degenerative Disease, Neuro Critical Care, Stroke, Neuro Radiology, & Spine)	Stuart Lee, MD Jay Briley, MHA
☐	Nursing	Trish Baise, DNP
☐	Orthopedics (Joints, Orthopedic Surgery, Rheumatology, Sports medicine, Orthopedic medicine, & Orthopedic Trauma)	Deanna Boyette, MD Van Smith, MBA/MHA
☐	Pathology & Lab Services	Craig Steffee, MD Dave Harlow, PharmD
☐	Physical Medicine & Rehab (Rehab, Therapy (OT, PT, SLP), Pain, Wound Care, & Audiology)	Clint Faulk, MD Dave Harlow, PharmD
☐	Primary Care (Family medicine, Med-Peds, General Internal Medicine, Palliative Care, Geriatrics, & Sleep Medicine)	Jonathon Firnhaber, MD Dan Drake, PhD
☐	Radiology	Eric Martin, MD, PhD Dave Harlow, PharmD
☐	Women's Health (Gynecology, Obstetrics, & Maternal Fetal Medicine)	James Whiteside, MD Tara Stroud, DNP
☐	Projects that do not fit in the above service line areas	Niti Armistead, MD Brian Floyd, MBA

Optional Determination:
For any project where there is a question as to whether it qualifies as Quality Improvement or Research, or if certification of "Not Human Subjects Research" is needed for publication, please route to the UMCIRB office via email: umcirb@ecu.edu.

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

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

UMCIRB Office Staff Signature: _____ **Date:** _____

The UMCIRB office will contact you if any further information is needed to make this determination. Please note that if the UMCIRB office determines the activity is not human subjects research, then any presentation, publication, etc. should not refer to the activity as such.