

**From:** umcirb@ecu.edu  
**Subject:** RX: Your Exempt study has been approved  
**Date:** November 21, 2024 at 9:21 AM  
**To:** fitzgeraldca23@ecu.edu



**EAST CAROLINA UNIVERSITY**  
**University & Medical Center Institutional Review Board**  
Willis Building · Mail Stop 682  
600 Moyer Boulevard · Greenville, NC 27834  
Office 252-744-2914 · Fax 252-744-2284 · [rede.ecu.edu/umcirb/](https://rede.ecu.edu/umcirb/)

## Notification of Exempt Certification

**From:** Biomedical IRB  
**To:** Caitlin Fitzgerald  
**CC:**  
**Date:** 11/21/2024  
**Re:** UMCIRB 24-001769  
Trauma ECMO

I am pleased to inform you that your research submission has been certified as exempt on 11/20/2024. This study is eligible for Exempt Certification under category # 4c.

It is your responsibility to ensure that this research is conducted in the manner reported in your application and/or protocol, as well as being consistent with the ethical principles of the Belmont Report and your profession.

This research study does not require any additional interaction with the UMCIRB unless there are proposed changes to this study. Any change, prior to implementing that change, must be submitted to the UMCIRB for review and approval. The UMCIRB will determine if the change impacts the eligibility of the research for exempt status. If more substantive review is required, you will be notified within five business days.

| Document                                                                       | Description                         |
|--------------------------------------------------------------------------------|-------------------------------------|
| AASTEOMOMCTV1.docx(0.01)                                                       | Study Protocol or Grant Application |
| Application-for-Waiver-or-Alteration-of-HIPAA-Authorization-4-4-2022.pdf(0.01) | HIPAA Documentation                 |
| ECMOMCTDataCollectionSheet.doc(0.01)                                           | Data Collection Sheet               |
| HIPAA-Research-on-Decedents-Information-Form-Revised-8-10-2022.pdf(0.01)       | HIPAA Documentation                 |

For research studies where a waiver or alteration of HIPAA Authorization has been approved, the IRB states that each of the waiver criteria in 45 CFR 164.512(i)(1)(i)(A) and (2)(i) through (v) have been met. Additionally, the elements of PHI to be collected as described in items 1 and 2 of the Application for Waiver of Authorization have been determined to be minimal necessary for the specified research.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418  
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418

Study.PI Name: