EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board
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rede.ecu.edu/umcirb/

Notification of Initial Approval: Expedited

From: Social/Behavioral IRB
To: Alexa Clatfelter
CC: Cari Autry
Date: 3/31/2025
Re: UMCIRB 24-002432
The Role of RT in Transition Services for Individuals with IDD

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) occurred on 3/31/2025. The research study is eligible for review under expedited category # 6,7. The Chairperson (or designee) deemed this study no more than minimal risk.

As the Principal Investigator you are explicitly responsible for the conduct of all aspects of this study and must adhere to all reporting requirements for the study. Your responsibilities include but are not limited to:

1. Ensuring changes to the approved research (including the UMCIRB approved consent document) are initiated only after UMCIRB review and approval except when necessary to eliminate an apparent immediate hazard to the participant. All changes (e.g. a change in procedure, number of participants, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the UMCIRB before they are implemented;

2. Where informed consent has not been waived by the UMCIRB, ensuring that only valid versions of the UMCIRB approved, date-stamped informed consent document(s) are used for obtaining informed consent (consent documents with the IRB approval date stamp are found under the Documents tab in the ePIRATE study workspace);

3. Promptly reporting to the UMCIRB all unanticipated problems involving risks to participants and others;

4. Submission of a final report application to the UMICRB prior to the expected end date provided in the IRB application in order to document human research activity has ended and to provide a timepoint in which to base document retention; and

5. Submission of an amendment to extend the expected end date if the study is not expected to be completed by that date. The amendment should be submitted 30 days prior to the UMCIRB approved expected end date or as soon as the Investigator is aware that the study will not be completed by that date.

The approval includes the following items:

Name	Description
Alexa Clatfelter Final Thesis Proposal with Edits 2.24.25.pdf	Study Protocol or Grant Application
Alexa Clatfelter-Thesis IRB Protocol.pdf	Study Protocol or Grant Application
Informed Consent-Alexa Clatfelter.docx	Consent Forms
Interview Guides	Interview/Focus Group Scripts/Questions
Letter of Support copy.pdf	Additional Items
Participant Recruitment Script Final- Alexa Clatfelter.docx	Recruitment Documents/Scripts

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 the minimal necessary for the specified research.

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