East Carolina University

Date: Wednesday, April 21, 2021 4:30:37 PM Print Close

ID: MS1_UMCIRB 20-001021 **MS1_UMCIRB 20-001021**

View: 1 - Study Identification Information

Study Identification Information

This is the first step in your Human Research Application. You will automatically be guided to the appropriate page views needed to complete your submission. If a question is not applicable to your study, you may state this as your response. Please read the help text located on the right side of the page throughout this application.

1.0 * **Study Name (Short):**
Teacher Mindset and ADHD Intervention

2.0 **Study Name (Long):**
TEACHER MINDSET AND ACCEPTABILITY OF CLASSROOM INTERVENTIONS FOR STUDENTS WITH ADHD

3.0 * **Summary of Research in Lay Terms:**
There is a large research-to-practice gap when it comes to school-based interventions for both academic and behavioral needs. Students with ADHD are one group of students for whom this gap is problematic. Understanding which evidence-based interventions are accepted and used by teachers provides more information to help encourage their use and to promote development of new interventions that teachers will find favorable. Past research has suggested that teachers will not use interventions unless they are trained to use them and find them acceptable. However, the question remains as to whether teachers' perceptions of possible growth, their mindset, will influence their acceptance and use of interventions for students with ADHD. Using survey methodology with practicing middle school teachers, we will examine whether having a growth mindset influences their perceived acceptability and feasibility of three main school-based interventions for students with ADHD.

4.0 * **Principal Investigator:**
Christy Walcott

5.0 **Faculty Investigator** (Serving as the responsible individual in the oversight of the research study when the PI is a student, resident, fellow or visiting faculty.)

Faculty Investigator IRB Certification Renewal Deadline:

6.0 **Study Coordinator or Contact Individual:**
Alicia Day

7.0 **Contact Individual(s) (if different from Study Coordinator or Principal Investigator):**

Last Name	First Name	Organization	Profile	IRB Certification Renewal Deadline

There are no items to display

8.0 **Sub-Investigators:**

Last Name	First Name	Organization	Profile	IRB Certification Renewal Deadline

Last Name	First Name	Organization	Profile	IRB Certification Renewal Deadline
Day	Alicia	Psychology, Department of	Alicia Day's Profile	7/21/2020

9.0

Other Study Staff - (Read-Only):

Last Name	First Name	Organization	Profile	IRB Certification Renewal Deadline

There are no items to display

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View: 1.1 Study Staff Roles and Responsibilities

Study Staff Roles and Responsibilities

1.0 * **Click on the UPDATE button beside each person's name to provide the responsibilities for each study staff member:**

	Name	Role	Responsibilities
View	Christy Walcott	Principal Investigator	Data management, Communicates with IRB
View	Alicia Day	Sub-Investigator	Screens potential participants, Obtains Informed Consent, Data management, Communicates with IRB, Conducts surveys/interviews

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View: 1.2 IRB Researcher Training Records

IRB Researcher Training Records

The following information is taken from your researcher profile.

1.0 Principal Investigator's Training

IRB CITI Modules Completion Date:
5/1/2018

IRB CITI Modules Renewal Deadline:
5/1/2021

2.0 Study Coordinator IRB CITI Modules Renewal Deadline:
7/21/2020

3.0 Other Relevant Training:

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Study Funding Information

1.0 * **Select the appropriate funding type for this study:**

	Funding Type
☐	Federal Funding
☐	Industry
☐	Non-Profit
☐	State or Local Funding
☐	Internally Funded (ECU)
☐	Other University or College
☑	**No Funding**
☐	Other
☐	International Funding

If other, provide the name of the type of funding source:

2.0 **Provide your RAMSeS/eTRACS application number, if applicable:**

3.0 * **Does the research include any monetary inducements, compensation or reimbursement for participation in this research study?**

○ Yes ● **No**

4.0 **Will the sponsor/funding agency reimburse the participant for any items or procedures or supply any items at no cost involved in this research study?**

○ Yes ● **No**

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Disclosing Real or Perceived Conflict of Interest (COI)

Principal Investigator (PI)

The PI must answer the following questions:

1.0 * **Do you or a member of your immediate family have a financial interest consisting of consulting fees, honoraria, royalties, salaries or other payments, ownership of stocks or other interests in any external entity related to this research?**

○ Yes ● **No**

2.0 * **Do you or a member of your immediate family have an executive position or serve as a board member of any external entity related to this research?**

○ Yes ● **No**

3.0 * **Do you hold or plan or hold any claims to intellectual properties, licenses or pending patents on technology that will result from conducting this research study?**

○ Yes ● **No**

4.0 * **Will you receive any incentives or bonuses based on the number or speed in which you enroll human subjects?**

○ Yes ● **No**

5.0 * **Will you or any key study personnel receive any incentives or bonuses, based on the outcome of the research study?**

○ Yes ● **No**

6.0 * **Will any related persons participate on the project?**

○ Yes ● **No**

7.0 **If you have answered "Yes" to any of the questions above, you may have either a real or perceived COI. If you have not already done so, you must contact the** Office of Research Integrity & Compliance (ORIC) **for a determination of whether there is a COI. Please upload ORIC's COI determination and/or, if required, a fully executed COI management plan below.**

Name	Version	Document

There are no items to display

Provide any additional details regarding the financial or intellectual relationship:

Key Study Personnel Other Than the PI (Study Coordinators, Sub-Investigators, Other Study Team Members, etc.)

1.0 * **Do any of the key study personnel (or their immediate family/significant other) have a financial and/or intellectual property interest in the sponsor or products used with this project?**

○ Yes ● **No**

2.0 **If you have answered "Yes" to the question above for any of the key study personnel (KSP) they may have either a real or perceived COI. Each East Carolina University KSP for whom this response is "Yes" must complete a project specific COI disclosure in AIR at ecu.myresearchonline.org/air/. If ORIC determines a COI exists, ORIC will notify the respective KSP of the need for a management plan. A fully executed management plan, if required, must be uploaded below for each KSP for whom a COI is identified.**

Name	Version	Document

There are no items to display

ID: MS1_UMCIRB 20-001021 **MS1_UMCIRB 20-001021** View: 1.5 Study Locations

Study Locations

1.0 Select the Research Facilities where this study will be conducted locally:

	Name
☐	Carolina East Medical Center
☐	Vidant East Carolina Health-Beaufort, Inc.
☐	Physicians East, PA
☐	Vidant Medical Group
☐	Orthopaedics East, Inc.
☑	**East Carolina University**
☐	Vidant Medical Center
☐	Albemarle Hospital Authority
☐	Vidant Duplin Hospital
☐	Vidant Bertie Hospital
☐	Vidant Chowan Hospital
☐	Vidant Edgecombe Hospital
☐	Vidant Health Access, Inc.
☐	Vidant Surgicenter Services of Pitt, Inc.
☐	Vidant Roanoke Chowan Hospital

2.0 Other Study Locations (if not captured in the list above):

	Name
View	Cumberland Co Schools

3.0 Upload letter(s) of support/agreement from the research facility/site/school unless research will be conducted at ECU or Vidant Medical Center.

Name	Version Number
County Support Letter(0.01)	0.01

4.0 * **Describe the research setting, listing any safeguards in place for participant safety:**
Teachers will be recruited from the co-PI's internship district, Cumberland Co Schools, where she is working as a school psychologist intern. For those who agree to participate in this anonymous survey, they will receive a link to an online survey that they can complete where ever they so choose. If they choose to complete the survey via paper copy, one would be provided

5.0 * **Is this a multi-site study being conducted at other sites national or internationally?**
◯ Yes ● **No**

6.0 * **Will an external IRB act as the IRB of record for this study?** ◯ Yes ● **No**

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Required Reviews

1.0 * **Requested Review Type:**

Name
● **Exempt**
○ Expedited
○ Full IRB Review

2.0 **Required Department Approvals:**

Department/School	College/School	Division/Institution
Psychology, Department of	Harriot College of Arts & Sciences	Academic Affairs

3.0 **Research Type:**

☐ Clinical Trial
☐ Qualitative Research
☑ **Quantitative Research**

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View: 2.0.1.1 Exempt Study Population

Study Population

1.0 * **Indicate what your primary targeted population will be:**

Study Population

Adults (18 years of age and older)

If other, list below:

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View: 2.0.12 Exempt Study Population Summary

Study Population Summary

1.0 * **What is the maximum number of participants you plan to recruit for this site? For record/chart reviews, please provide the number you plan to review.**

100

2.0 **If you are enrolling human participants, provide the number of individuals you may need to approach for recruitment in order to enroll the number above:**
150

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View: 2.1.5 Exempt Qualification for Jan 2019

Exempt Study Qualification

If your study meets any of the criteria below, it may qualify for EXEMPT review status under federal guidelines. Please note that some of these categories, once selected, will have additional sub-categories that will appear and need to be selected.

*** Exempt Review Categories:**

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

*** Exempt Sub Categories 2:**

a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects, e.g. coding numbers.

b. Any disclosure of the human subjects' responses outside the research would not reasonably place the individual at risk of criminal or civil liability or be damaging to the person's financial standing, employability, educational advancement or reputation.

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Study Summary

1.0 * **Expected Start Date:**
6/1/2020

2.0 **Expected End Date:**

3.0 * **Describe the study objectives.**

The implicit theories about achievement result in either fixed or growth mindsets. When a person believes that they (or others) can change by learning new strategies and putting forth additional effort, they adhere to a growth mindset. Those who believe that one is born with certain abilities and no amount of effort or learning will change them adheres to a fixed mindset (Haimovitz, & Dweck, 2017).

To our knowledge there is no research that looks at teachers' mindsets and the influence on their likelihood of using evidence-based interventions. Based on the idea that those with fixed mindsets are more likely to attribute difficulties to personal characteristics that are unlikely to change, teachers may attribute ADHD problems to be stable and unchangeable. If that is the case, then the assumption is that they will favor medical interventions over evidence-based behavioral approaches, as behavioral interventions focus on changing the environment and response to behaviors.

Past research has suggested that teachers will not use interventions unless they are trained to use them and find them acceptable. However, the question remains as to whether teachers' perceptions of possible growth, their mindset, will influence their acceptance and use of interventions for students with ADHD. Our research questions are:

1. After controlling for degree type, years of teaching experience, and experience with ADHD students, does having a growth mindset influence teacher ratings of **acceptability** of three main behavior interventions for students with ADHD?
2. After controlling for degree type, years of teaching experience, and experience with ADHD students, does having a growth mindset influence teacher ratings of **perceived feasibility** of three main behavior interventions for students with ADHD?

4.0 **UPLOAD your study protocol here. A protocol is required for review by the convened IRB committee.**

For student projects, UPLOAD your professional paper proposal, thesis, or dissertation proposal.

Name	Version	Document
Thesis Proposal(0.02)	0.02	Thesis Proposal(0.02)

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Recruitment Methods

1.0 * **Select recruitment methods used on this study:**

- [ ] Advertising such as flyers, letters, or ads (newspaper, TV, radio)
- [x] **Email Campaign (provide language to be used in email)**
- [ ] Web Site (provide language to be used on website)
- [ ] Phone Solicitations
- [ ] Referral by independent source
- [x] **Pre-existing relationship with participants**
- [ ] Selected from pre-existing records
- [ ] Selected from investigators clinic/patient population
- [ ] Treating provider will share PHI of potential participants with study team (also requires Application for Alteration of Authorization form)
- [ ] Treating provider shares contact information of study team with potential participants to allow self-referral, no PHI is shared and no form required.
- [ ] Social Media (Facebook, Twitter, Blogs, Forums, etc)
- [ ] Other

2.0 **What are the "other" methods selected above:**

3.0 **Upload all recruitment documents or scripts that need approval:**

Name	Version Number
Recruitment Script(0.01)	0.01

4.0 **If recruitment will use PHI from a designated health care component of ECU or Vidant Health, please describe how the PI and/or study team members are affiliated with that health care component (check all that may apply).**
There are no items to display

If any study team member accessing or using PHI for recruitment is not a workforce member of the health care component from which the PHI will be accessed, or as noted above in Question 1.0, please upload the Application for Alteration of Authorization for Recruiting by Research Team Members Who Are Not Health Care Component Workforce Members.
There are no items to display

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View: 3 Methods & Procedures: Behavioral Research/Data Collection

Methods & Procedures: Behavioral Methods/Data Collection

1.0

Select all behavioral/data collection methods and procedures which apply to this study:

	Procedure
☑	**Surveys/Questionnaires**
☐	Interview/Focus Groups
☐	Videotaping/Audio Recording/Photography
☐	Intervention or Experimental Procedure
☐	Public Observation
☐	Standardized/Non-standardized tests
☐	Deception
☐	Creating a Databank
☐	Use of Existing Datasets
☐	Teacher Inquiry
☐	Chart Review
☐	Other social science, behavioral, or educational procedures

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View: 3.4 Surveys and Questionnaires

Surveys & Questionnaires

1.0 * Upload Surveys or Questionnaires that will be used in this study:

Name	Description
TEACHER MINDSET AND ACCEPTABILITY OF CLASSROOM INTERVENTIONS FOR STUDENTS WITH ADHD Survey(0.02)	Surveys and Questionnaires

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View: 7.01 Exempt Informed Consent Determination

Informed Consent

1.0 * **Indicate the types of consent that will be involved in this study (check any or all that apply):**

Informed Consent Category

Online/Verbal consent or written information sheet (If research is Expedited or needs Full board review, a Waiver of Documentation of Written or Signed Consent is required).

2.0 * **Do you plan to include non-English speaking participants in this research study?** ◯ Yes

● **No**

3.0 **How will you accommodate a potential participant who does not speak English?**

Name

There are no items to display

If other, please describe:

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View: 7.02 Exempt Consent Forms & Process of Consent

Consent Forms & Process of Consent for Studies Certified Exempt

1.0 **If needed, there are several different types of consent form templates provided. You may use any of these to develop consent documents or information sheets.**

Instructions:

1.1) Download the applicable consent form template to your computer and modify this where applicable.

- Consent Template for Benign Behavioral Interventions (ONLY for use in Exempt Category #3 research)
- Consent Template: Consent Letter for Expedited Survey Research
- Consent Template: Consent Paragraph for Exempt Survey Research
- Consent Template: More Than Minimal Risk Research
- Consent Template: No More Than Minimal Risk Research
- Genetic Testing Consent Template
- Local Boilerplate Language for NCI-CIRB Approved Consents Only
- Local Boilerplate Language for NCI-CIRB Approved Youth Information Sheets (Assents)
- Local Boilerplate Language for Sponsor's Consent Template (does not apply to NCI-CIRB approved studies)
- Minor Assent Template
- Parent Consent to Use Child's Data for Research Purposes (ONLY for use in Exempt Category #1 research)
- Parent Permission Form Template: No More than Minimal Risk Research

*** 1.2) Upload consent forms, assent forms, or information sheets here:**

Name	Modified	Version
survey consent paragraph(0.01)	5/27/2020 9:14 PM	0.01

1.3) Upload Tracked Changes versions of consent forms, assent forms, or information sheets here:

Name	Modified	Version

There are no items to display

2.0 *** Describe how, when, and where the consent process will be initiated:**
WIth approval of the school principals, emails will be sent by Alicia to teachers at three schools, two

of which Alicia worked at as an Intern, inviting them to participate in the survey study (see recruitment script) and providing a survey link. This process will begin upon IRB approval (late April) and continue through the end of this school year (June 2020). If we fail to recruit enough participants by June, we will initiate the process again in August 2020 at the new school year.

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View: 8.01 Exempt Data Privacy & Confidentiality August 2017

Data Privacy & Confidentiality

1.0 * Will you view, collect, generate or analyze protected health information (PHI) from any source (not limited to ECU or Vidant data) as part of your research study?

○ Yes ● **No**

2.0 * **Where will you obtain the data for this research study?**

Generated during the course of the study

3.0 * **Describe how the identity of individuals research data and/or specimens will be recorded (check all that may apply):**

Anonymous (No Identifying Information)

4.0 **List all categories of data to be collected for this research study (e.g., Name, Date of Birth, Age, Disease status, etc) or upload your data collection sheet below:**

If applicable, upload data collection sheet:
There are no items to display

5.0 * **Where will paper and electronic research data be stored? Please specify the physical location (building and room number):**

The anonymous Qualtrics survey data will be downloaded by Dr. Walcott onto an ECU-issued computer and stored on her password-protected ECU computer in her PirateDrive folder.

Note: Data collected and/or generated during the course of the study that includes protected health information (PHI) should have identifiers removed at the earliest opportunity consistent with the conduct of the research and/or clinical needs (if applicable). ***However, regulatory documentation (including signed consent/assent form(s), signed stand-alone HIPAA Authorization(s), documentation of verbal consent/authorization(s), research records documenting that a request for waiver of HIPAA Authorization was approved) must be retained for 6 years following completion of the research.***

6.0 * **How long will data be stored after the study is complete?**
Per APA guidelines, data will be kept for at least 7 years post defense of the thesis project.

7.0 * **How will data be secured to protect privacy, maintain confidentiality, and safeguarded against improper disclosure?**
Data is low risk and anonymous; it will be stored as a single SPSS or Excel file on an ECU password-protected computer within PirateDrive.

8.0 * **Who, other than the specified study team, will have access to the study records or data? Specify their name, role, and affiliation.**

None

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Institutional Ancillary Approval

Based on your answers to the following questions, you may need to answer additional questions.

1.0 * **Will this study generate or require the use of protected health information (PHI) or medical records by any ECU research team member at the research location?**

○ **Yes** ● **No**

2.0 * **Will this study require the use of medical records at Vidant Medical Center (or any other Vidant facility)?**

○ Yes ● **No**

3.0 * **Will this study utilize clinical areas within ECU Physicians, require recruitment of subjects/procedures/tests/medications/surveys or any other study requirements to be performed at ECU/BSOM?**

○ Yes ● **No**

4.0 * **Will this study involve inpatient or outpatient units/staff at a Vidant Health facility, require recruitment of subjects/procedures/tests/medications/surveys or any other study requirements to be performed at a Vidant Health facility?**

○ Yes ● **No**

5.0 * **Will this study take place at the Leo W. Jenkins Cancer Center (LJCC)?**

○ Yes ● **No**

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Additional Material

Please upload any other items for review and approval if not already uploaded on a previous page of this application.
Additional Items for IRB Review and Approval:

Name	Version	Document

There are no items to display

ID: MS1_UMCIRB 20-001021 **MS1_UMCIRB 20-001021** View: SF - Final Page

Final Page

If you have completed your application, click "Finish" to finalize and exit the application. **This action does NOT submit the application for review,** it just means you have finished editing the application at this particular time.

For those studies that are being submitted for review and approval by the UMCIRB:

1. All research personnel/team members must login to ePIRATE and click the "Agree to Participate" button before ePIRATE will allow a study to be submitted.
2. A submission may only be submitted to the UMCIRB by the Principal Investigator. To do this, the Principal Investigator must login and click the "SUBMIT STUDY" button under My Activities for this Study ID:MS1_UMCIRB 20-001021.

For those studies that are being submitted for acknowledgment of the use of an external IRB:

1. Research personnel/team members are not required to "Agree to Participate" before ePIRATE will allow a study to be submitted.
2. A submission may be submitted by any listed team member. To do this, the team member must login and click the "SUBMIT STUDY" button under My Activities for this Study.

You can track the ongoing status of your submission by logging into the study workspace.

Please wait until you receive your final approval/acknowledgement notice prior to beginning your study and feel free to contact the UMCIRB with any questions or concerns.