MERCER UNIVERSITY

Office of Research Compliance

AFFILIATED FACULTY
CONTINUING RESEARCH INVOLVING HUMAN SUBJECTS

(Minimal Risk Studies Involving Human Subjects)

The information provided should address a specific project in its entirety. For assistance in determining whether your project is considered research, please review Mercer's IRB website at the following link: http://orc.mercer.edu/irb/

PLEASE **TYPE YOUR ANSWERS** TO ALL QUESTIONS AND ANSWER AS COMPLETELY AS POSSIBLE

Principal Investigator: Dr. Karyn A. Allee-Herndon — Degree: PhD

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Co-Principal Investigator(s):

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  3001 Mercer University Drive, Atlanta, GA 30341; (678) 547-6338; marsh_rj@mercer.edu
- Name, Degree(s); School/College Institution; Department or Affiliation with Mercer University; Campus/Institution Address; Phone Number; Email

Project Title: Kinesthetic Classroom Pilot Study

Assigned Protocol No.: **H2007189** Year of Study: **02**

Sponsoring Agency:
Sponsor Agency Name
Sponsor Mailing Address

Anticipated Project Start Date: 06/01/2021
Anticipated Project End Date: 07/31/2022

OFFICE USE ONLY:	**OFFICE USE ONLY:**
Institutional ID Number _____	☐ **Protocol Narrative**
Reviewers _____	☐ **Informed Consent Document on Mercer Letterhead**
Date Received _____	☐ **Assent Document (if minor subject included)**
Date Approved _____	☐ **Data collection instrument (survey/questionnaire/etc.)**
Not Approved _____	☐ **Data collection as word doc for online survey set up**
Withdrawn _____	☐ **Advertisement, Recruitment Materials, Scripts**
Expedited Category _____	☐ **Letter of Permission for Administration (e.g., school)**
Exemption Category _____	☐ **IRB Approval from Applicant Institution**
	☐ **Online Survey Informed Consent Document**
	☐ **Request waiver of written consent Needed:** _____

Is the project initiated by the Principal Investigator (PI)?	☒ Yes	☐ No	
Is the project initiated by the Sponsor or Sponsoring Agency?	☐ Yes	☒ No	
Will Sponsor pay for Serious Adverse Events (SAEs)?	☐ Yes	☐ No	☒ NA
Does Sponsor offer indemnification?	☐ Yes	☐ No	☒ NA

Which status applies to this application? ☒ Research ☐ Teaching ☐ Training

☒ Renewal without changes ☐ Renewal with changes

If this is application is for joint protocol research or requires review from an external institution's IRB, please visit http://orc.mercer.edu/external-research/institutions/ and ensure that you are using the appropriate application for your collaborative research.

All IRB training is required every three (3) years. **For CITI Training:** http://www.citiprogram.org/

***Accepted Training with DHHS/PHS funding – NIH: Provide copy of NIH certificate to ORC.**

Provide date of last training certification: 11/11/2019

Please complete the following items using BRIEF descriptions written in easily understandable LAY TERMINOLOGY.

NOTE: A scientific abstract from a grant application using highly technical terms is NOT acceptable

1. Study Objectives and Relevance

Are there any proposed modifications/amendments to your protocol objectives and/or relevance of the study?

(This does not include any modifications already submitted and approved)

☐ Yes ☒ No If **YES**, please provide a description of any changes to the protocol

2. Subject Enrollment

(a) ***How many participants are currently enrolled in the study?*** 0

(b) ***How many remaining participants are to be entered into the study?*** ~60 (All)

(c) ***If participants not entered in the study, please explain why.***

We delayed the launch of our survey this study because of the COVID-19 pandemic. We did not feel we should overburden our participants, and we worried about how the pandemic would affect the data we collected if we had proceeded. We will pick back up next academic year.

(d) ***How many participants completed the study?*** 0

3. Is the study still active?

☒ Yes, Expected Completion Date: **07/31/2022**

☐ No, Date Study Closed: **MM/DD/YYYY**

4. Does this study involve ongoing online survey research?

☐ Yes ☒ No Start Date: MM/DD/YYYY End Date: MM/DD/YYYY

Were Mercer's ORC SurveyMonkey services used to create your survey(s)?

☐ Yes ☐ No, online survey software used: Name of Online Survey Software

5. Research Methodology and Procedures

Briefly describe any changes to your research methods and/or procedures that involve human subject participation.

We have no changes to our research methods or procedures.

Confidentiality of Subjects:

Establishing Confidentiality: All information attained from the questionnaires, assessments, or activity trackers will be held in strict confidence. Individual results will remain confidential and only be relayed to the parent of the participant upon request. All psychosocial and activity data, as well as data collection sheets, will be coded immediately after collection to a de-identified system and stored electronically in a password protected computer accessible only by the PI. As soon as the identifiable data has been recoded and de-identified, the identifiable data will be destroyed. De-identified data will be held for five years in the same password protected computer. Participant folders will be marked with a randomly generated de-identified ID number to protect against a breach of confidentiality. All de-identified information will be destroyed five years from the end of the study and not used for other research purposes. The results of this study will be submitted for publication in peer-reviewed scientific journals. No individual results will be published or shared with any person or party, although aggregated classroom data will be shared with the appropriate teachers and overall study data will be shared with the principal to inform their instructional and social-emotional work at Hopkins Elementary School.

Maintaining Confidentiality: No individually identifying information will be shared with the co-investigators, study participants, or members of the academic community.

6. Research Design and Data Collection

Briefly describe any changes to your research design, data collection strategies, and specific factors such as independent variables, conditions, or groups in your study as well as any changes to the control conditions or the setting in which the interaction occurs.

The only changes to our study is delaying it by one academic year out of deference to everything P-5 educators in Georgia are dealing with during the COVID-19 pandemic. This is a naturalistic, quasi-experimental study with purposive sampling, which uses a pretest-posttest, non-equivalent control group design. While the assignment to condition will be done at the classroom level, analyses will be done at the student level. During a brief, 4-week period of the study (one academic year), we will also conduct a single case-study design experiment to explore students' on-task behaviors during a specific instructional period in the treatment classroom.

7. Human Subject Populations

Briefly describe any changes to characteristics of the subject population

There are no proposed changes to the characteristics of the subject population. Title I Elementary school teachers and their students in one of two classrooms at Hopkins Elementary School (or similar) with similar student demographics, instructional goals and approaches, and academic assessments will be recruited to participate.

Inclusion Criteria: All individuals satisfying the study characteristics are eligible to participate in the study.

Exclusion Criteria: Teachers who do not foresee teaching at Hopkins Elementary School the entire 2021-2022 academic year or who do not teach a typical general education class as the teacher of record (i.e., resource teacher, self-contained exceptional student education teacher) will be excluded from this study. The purpose of the study is to compare two like Title I elementary classrooms in the same grade level, with similar student demographics, and the same instructional standards and assessments. There are no other reasons why a teacher at Hopkins Elementary School would be excluded from this study. Students would be excluded if they do not have parental consent to participate or are not members of one of the participating classes.

8. Informed Consent

Are there any proposed modifications/amendments to the Informed Consent?

(This does not include any modifications already submitted and approved)

☐ Yes ☒ No If **YES**, please explain the reasons for these changes

9. Risk

(a) ***Were there any problems or complications in the study which altered the projected risk to the subject or to other individuals?***

☐ Yes ☒ No If **YES**, please provide a COMPLETE description

(b) ***How do Adverse Events (AEs) or Serious Adverse Events (SAEs) affect the risk of the study?***

While it is impossible to state that participants will unequivocally not be exposed to any risks, any potential risks are minimal.

(c) ***Did any AEs or SAEs result in participants withdrawing from the study?***

☐ Yes ☒ No If **YES**, please explain

(d) ***Are any changes to the protocol being contemplated based on the Adverse Events (AEs)?***

☐ Yes ☒ No If **YES**, please explain

10. Results

(a) ***Has the study resulted in any publications?*** ☐ Yes ☒ No

Titles: If **YES**, please list all titles of resulting publications

(b) ***Briefly summarize any preliminary results obtained to date.***

N/A

(c) ***Should the study be terminated by the IRB?*** ☐ Yes ☒ No

If **YES**, please explain

11. Required Attachments

Please check the attachments included with your submission. **Items in BOLD (if applicable) MUST accompany your application or it will be returned.**

☒ **Protocol Narrative** (a paragraph or two describing goals, objectives, and methodology)

☒ **Informed Consent Document on Mercer University Letterhead** (unless exempt, closed to enrollment, or requesting waiver of written consent)

☒ **Assent Document** (if minor subjects will be included)

☒ **Data Collection Instrument** (surveys, survey invitation letter, questionnaires, data log sheets, etc.)

☒ **Letter of Permission or IRB Approval from Off-Site Institution/Off-Site Research Agreement**

☒ **Advertisement, Recruitment Materials, Scripts**

☒ Request for Research Use of Student Records (If requesting student information)

NOTE: ***If you already know that there are items you will need to submit for this protocol that are not yet available (e.g., letters of permission from external institutions, data collection instruments, advertisements, etc.), please describe your anticipated timetable for obtaining and/or developing these documents below.***

We are submitted our Gwinnet County Public Schools IRB in March 2020. The district meets bi-monthly with an anticipated decision on or around June 1, 2021 This decision has been delayed because of COVID-19. Dr. Garcia's letter of permission from the University of Central Florida would be forthcoming upon the initiation of the study.

Advertisisement and Recruitment materials will be developed in coordination with the Hopkins Elementary School (or similar) principal and scheduled for dissemination in August 2021.

The Data Collection Instruments (BRIEF2 and SSIS SEL) are proprietary. Copies of each are unavailable until purchased by the PI. The PI can share a copy with the IRB committee once the IRB is approved and funding secured. The PI does not possess copies of these tools at this time. Additionally, movement data is collected and analyzed using proprietary ActiLife software. The PI can provide sample reports if necessary.

The Request for Research Use of Student Records is implicit in the Gwinnett County IRB application and the parent informed consent forms.

I CERTIFY THAT THE INFORMATION PROVIDED IN THIS APPLICATION IS COMPLETE AND CORRECT.

I CERTIFY THAT I WILL FOLLOW MY IRB APPROVED PROTOCOL.

I ACCEPT ULTIMATE RESPONSIBILITY FOR THE CONDUCT OF THIS STUDY, THE ETHICAL PERFORMANCE OF THE PROJECT, AND THE PROTECTION OF THE RIGHTS AND WELFARE OF THE HUMAN SUBJECTS WHO ARE DIRECTLY OR INDIRECTLY INVOLVED IN THIS PROJECT.

I WILL COMPLY WITH ALL APPLICABLE, FEDERAL, STATE, AND LOCAL LAWS REGARDING THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH.

I WILL ENSURE THAT THE PERSONNEL PERFORMING IN THIS STUDY ARE QUALIFIED AND ADHERE TO THE PROVISIONS OF THIS MERCER CERTIFIED PROTOCOL.

I WILL NOT MODIFY THIS PROTOCOL OR ANY ATTACHED MATERIALS WITHOUT FIRST SUBMITTING AN AMENDMENT TO THE PREVIOUSLY APPROVED PROTOCOL AND RECEIVING SUBSEQUENT IRB APPROVAL AS WELL AS REVIEW AT MERCER UNIVERSITY.

I WILL PROMPTLY REPORT SIGNIFICANT OR UNTOWARD ADVERSE EFFECTS OR UNANTICIPATED PROBLEMS TO THE IRB IN WRITING WITHIN 10 WORKING DAYS OF OCCURRENCE.

I WILL OBTAIN WRITTEN APPROVAL FROM THE DEAN OF MY DEPARTMENT AT MERCER UNIVERSITY.

IN ACCORDANCE WITH 45 CFR 46.112[1], MERCER UNIVERSITY EXPRESSLY RESERVES THE RIGHT TO REVIEW FOR APPROVAL OR DISAPPORVAL RESEARCH APPROVED BY THE IRB.

REQUIRED SIGNATURES: SUBMISSIONS WITHOUT SIGNATURES WILL BE RETURNED.

ALL RESEARCH MUST BE SIGNED BY THE DEAN OR DESIGNEE PRIOR TO IRB SUBMISSION

Karyn A. Allee-Herndon — 3/31/21

Signature of Faculty or Fellow Investigator — **Date**

I AM AWARE OF THE PROPOSED RESEARCH AND THE LEVEL OF INVOLVEMENT WITH THE DEPARTMENTAL FACULTY, STAFF, STUDENTS, AND OR FACILITIES.

I AGREE THAT THIS RESEARCHER CAN ACCESS OUR FACULTY, STAFF, OR STUDENTS.

Lucy Bush — 3/31/2021

Signature of Department Chair / Chair's Designee — **Date**

This project is consistent with departmental objectives; and adequate space, equipment, professional and staff time, and other resources as stated in this application and will be made available if the research is approved.

Robert J. Helfenbein — 04/01/2021

Signature of Dean / Dean's Designee — **Date**

[1] *Review by institution.* Research covered by this policy that has been approved by an IRB may be subject to further appropriated review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

PROTOCOL NARRATIVE

Kinesthetic Classroom Pilot Study

The purpose of this study is to examine the effects of movement on students' executive function, reading and math academic achievement, classroom behaviors, and attendance. A secondary purpose is to examine the indirect effects of movement on academic performance (e.g. movement → better sleep→ increased focus). As part of our data analysis, we would also like to explore whether certain demographic characteristics, such as socioeconomic status (SES), may moderate the relationship between movement and academic achievement. We hypothesize that increased levels of physical activity will have positive effects on learning and other student outcomes, and that there will be a greater increase in these outcomes in students of low-SES and disadvantaged neighborhoods compared to students of higher socioeconomic neighborhoods. As educators and researchers, it is our goal that we increase educational equity for all students. This pilot study in the Atlanta area would be an extension of my dissertation work while also laying the groundwork for future, larger replication studies funded by larger grants. Future studies would add participants from multiple school sites, SES levels, and geographical areas to better analyze any potential benefit from increasing physical activities in classrooms.