

Human Subjects: IRB approval form has been submitted to The University of Southern Mississippi's Internal Review Board. Submission documents can be found below.



INSTITUTIONAL REVIEW BOARD
HUMAN SUBJECTS RESEARCH APPLICATION FORM

HUMAN RESEARCH APPLICATION PROCEDURES

Use this form to apply for IRB review. IRB approval is required before human subjects research can begin.

- In order to complete this form you will need both CITI certificates for all investigators, completed consent forms, and any survey instruments and funding permission letters. All of these documents must be attached as **loose** (see instructions at the bottom of this form) in order for this application to be accepted.
- Before completing this form, review the information included on the sample consent forms and FAQ section of the IRB website: <http://www.usm.edu/research/institutional-review-board>.
- Student researchers must send the completed form with all attachments to Research Advisors (Honor's Thesis Advisor, Master's Thesis Director, or Dissertation Director) for review. Faculty researchers should send the form directly to department chairs.
- Student Research Advisors must review the form, attach their own CITI certifications, and provide authorization where indicated before sending the application to departmental chairs.
- Department chairs must review the completed form, provide authorization where indicated, and submit completed versions of this form and all necessary authorizations to irb@usm.edu using their Southern Miss email address.

Last Edited September 14th

SECTION 1: INVESTIGATOR INFORMATION

1. Project Title: An Educational Audiology Model for Mississippi: Telepractice Plus Direct Service Provision

2. Principal Investigator: Kimberly Ward 3. Phone: 601-266-5257 4. UGM Email: kimberly.ward@usm.edu

5. Campus ID: w183580 6. College: Health 7. Department: Speech and Hearing Sciences 8. Department Phone: 601-266-5216

9. Purpose (check one):

<input type="checkbox"/> Undergraduate project	<input type="checkbox"/> Honors Thesis Project	<input type="checkbox"/> Graduate project	<input type="checkbox"/> Faculty or staff research
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10. Name:	Student Research Advisor (if applicable)	Funding Agency/Sponsor (if applicable)
11. Phone:		13. Organization:
12. USM Email:		14. Grant #:

15. Describe your expertise and qualifications related to this research:

Kimberly Ward, Au.D., is an audiologist and an assistant professor in the Department of Speech and Hearing Sciences. She currently teaches a wide variety of undergraduate and graduate courses in audiology. She provides educational audiology consultation services to several school districts within the state.

16. List other USM affiliated investigators: completion of CITI Common and Human Subject Research Courses must be attached.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Name	University or Institution	Project Role
Rebecca Lowe	University of Mississippi	Co-Investigator

17. List all Non-USM affiliated investigators:

18. If other individuals will be involved in data collection, describe their role and their training.

SECTION 2: RESEARCH PROCEDURES

19. Briefly describe the project and its goal(s) in two to three paragraphs.

Educational audiology plays a vital role in both the educational and healthcare success of children with hearing loss. Educational audiologists provide a full range of services to children, as part of a multidisciplinary team, to facilitate "listening, learning and communication access via specialized assessments, monitor personal hearing instruments, recommend, fit and manage hearing assistance technology, provide and recommend support services and resources, and advocate on behalf of the students." In addition, "Educational audiologists provide evidence for needed services and technology, emphasize access skills and supports, counsel children to promote personal responsibility and self-advocacy, maintain student performance levels, collaborate with private sector audiologists, help student transitions and team with other school professions to work most effectively to facilitate student learning" (Educational Audiology Association, 2018). Literature has suggested over numerous years that educational audiology services are valuable and produce efficacious outcomes for students with hearing loss (Stewart & Funaki, 1988; Digi, 2003).

However, the state's educational audiology is severely lacking and the children of Mississippi deserve these services in order to be successful. In the state of Mississippi, there are currently two full-time educational audiologists- one of which is employed solely by the DeLido County School District and the other which is employed by the Children's Center. Unfortunately, these educational audiologists serve only the children within their schools and are not available for other children in the state. The authors of this grant do contract occasionally to local area schools as needed, but because of jobs and time commitments, it is extremely infrequent and inadequate service as a whole. The hearing impaired children of Mississippi deserve to have access to educational audiology services as do the schools deserve the support from the educational audiologists to help them help the children become the most successful educationally. This grant will serve as a pilot study for an educational audiology model in which both telepractice and direct educational audiology service provision are delivered to one school district within the state. Outcomes of this project will be analyzed and combined for state and national presentations as well as publications. It is the authors' hopes that the project identifies a new model for educational audiology service provision which will work for the state until we can reach the level of educational audiology in which other states have long achieved.

20. Are any of the subjects under 18 years of age?
 Yes No **Note: Parental consent is required for participants under the age of 18.**

21. Describe subject population, number of subjects to be included, and criteria for selection.

The school utilized for educational audiology telepractice and direct service provision will be determined if funding from the Educational Audiology Association is received. Without this funding, the project is not possible. If funding

is obtained, the researchers will obtain permission from one school district within the state to provide services and collect data on regarding educational audiology services.

22. How will participants be recruited?

Class announcement Oral Announcement E-mail announcement
 Posted campus advertisement Television, Radio or Newspaper ad Advertising Agency
 Other (explain): Participants will be school district employees and students. Employees will be asked to complete a questionnaire via email upon the conclusion of this project. Student records will be reviewed only.

23. For adult subjects, how will you verify that individuals are over 18?

Survey or interview
 No adults will be participating in this research
 Other (explain): consent form

24. Indicate consent procedures (check all that apply):

Information letter
 Oral presentation & Short Consent Form
 Long Consent Form
 Assent form (children or subjects with disabilities)
 Request for waiver of consent
 Not applicable

25. Detail procedures for obtaining participants' consent or justify request for waiver.

Potential participants will express voluntary interest in participating in the project. The project and any potential risks or benefits will be explained to the participant through the long consent form. If willing, the participant will then sign the long consent form.

26. How many interactions will be required with each subject?

1
 2 - 3
 4 - 9
 10 or more

27. Maximum length of each interaction

less than 10 minutes
 less than an hour
 less than three hours
 three hours or more
 No direct interaction with subjects

28. Where will interactions take place? (check all that apply):

On campus
 Off campus
 Online

29. Indicate means of data collection (check all that apply):

Personal Interview Questionnaire or survey
 Audio or video recording Behavioral Observation
 Focus Group Inquiry Other (explain below):
 Student outcome measures

30. Do any of the following apply to your study?

Use of human biological samples Yes No
 Use of physical exercise Yes No
 Medical examinations or procedures Yes No
 Use of drugs or biological products Yes No

31. Give a step by step explanation of human subjects data collection procedures.

Selection of School System
 One school district will be selected to pilot this hybrid model in the Hattiesburg area. The school will be selected based upon the following criteria: willingness to work with the investigators and comply with outcome measures; number of hard-of-hearing children; lack of appropriate audiology services; willingness to house and use telepractice equipment following all HIPAA standards.

Assessment of School District-An initial needs assessment of the school district at large, to the services already provided, the services needed, and the budget available will be assessed through an in-person interview and electronic questionnaire.

Assessment of each child with hearing loss-The audiograms, audiology reports, previous year's grades and current IEP/504 of each student with hearing loss in the school district will be reviewed and a needs assessment on services for each student will be implemented.

In-service training of school personnel- All members of the team working with each HOH student will receive in-service training on the following topics:
 a) The needs of hard-of-hearing children,
 b) The role of the educational audiologist,
 c) A multidisciplinary approach using an educational audiologist in meeting the needs of children with hearing loss,
 d) The new hybrid program being implemented, and

e) The coordination of communication with each investigator.

Housing and training of telepractice equipment-A secure, quiet office will be identified in the school to house the telepractice equipment and at least two school personnel will be trained on its usage.

Outcome measures obtained- a) Measurements of School Personnel- Quarterly assessments (every nine-weeks) will be given to the school personnel involved with the hard-of-hearing children to derive outcome measures identifying the effectiveness of the hybrid nature of the educational audiology services. With each assessment, any challenges noted will be addressed immediately and subsequent changes to this program implemented so as to improve the programming structure as "issues" arise. b) Measurements of Children Served- Likewise, grades of each student served by the educational audiologist will be reviewed every nine weeks and compared with the previous year's grades corresponding to that point in time. Understanding that all variables influencing grades cannot be controlled for, at this point, the investigators still plan to use the grades of the students as one outcome measure for the effectiveness of the services provided.

6) Programmatic structure - The hybrid program will be implemented initially following the structure described below. If changes are necessary or other services implemented during the year, those will be executed and described in the final report.

a) One investigator will be onsite in the school to perform the following services:
 i. Measurement of noise levels in classrooms and provision of recommendations for environmental modifications ii. Management of the selection, purchase, installation, and evaluation of any large-area amplification systems. iii. Monitoring of personal hearing instruments including hearing aids, cochlear implants and FM technology. This includes but is not limited to: recommending, fitting, evaluation and programming the hearing assistance technology iv. Oversight of the administration of hearing screening programs in school, training non-audiologists to perform hearing screening in the educational setting. v. Diagnosing, treating and managing any children with hearing problems. vi. Meeting with each child, providing counsel and advocacy training as needed.

b) The second investigator will implement the following services via tele-practice:
 i. Provision of individual training for professionals on the team when needed. ii. Participation in the development of an Individual Education Program (IEP) or a Section 504. iii. Provision of in-service programs for school personnel iv. Consultation to educators as members of interdisciplinary teams about communication management, educational implications of hearing loss and other auditory problems, educational management, classroom acoustics, and FM technology for children with hearing loss. v. To help with student transitions and "team with" school personnel to facilitate student learning.

7) Final outcome measure-A final outcome measure will be taken at the end of the school year assessing the overall structure of the program with the necessary changes made throughout the school year. All school personnel will be assessed individually. Overall grades will be assessed for each child served in the program. A final report will be written as to the benefits and challenges of the hybrid nature of the program, the ongoing changes made during the year to better improve the services, and future direction for the implementation of this model in the state of Mississippi.

32. Does your research involve only the collection of anonymous data?
 Yes No
 Note: "Anonymous" means that investigators cannot associate the data with individual subjects and vice versa. Electronic surveys must be conducted via websites that do not link responses to e-mail addresses or other identifiers. Personal interviews are not anonymous.

33. Does your research involve sensitive information?
 Yes No
 Note: Sensitive information may include (but is not limited to) information about sexual activity, drug usage, criminal behavior, financial or medical data, and religious views.

34. Does your research involve hidden video or audio recordings or deception?
 Yes No
 Note: Deception includes any information or procedure that misleads a subject intentionally.

SECTION 3: RISKS AND BENEFITS

35. Indicate all potentially vulnerable subjects involved in the study.

Children Mentally ill patients
 Nursing home patients Pregnant females
 Prisoners HIV positive individuals
 Other Not applicable

36. Detail the methods that will be employed to protect vulnerable subjects.

Students' personal files will be reviewed. Only interaction with students would be amplification troubleshooting.

37. If your research involves prisoners, explain how it directly relevant to prisoners or the prison system (check all that apply):

the causes and/or effects of incarceration
 the process of incarceration
 prisons as relational structures
 the conditions of prisons or prisoners
 procedures for improving the wellbeing of prisoners
 Other (explain):

Note: All research involving prisoners requires compliance with federal regulations pertaining to biomedical and behavioral research involving prisoners as listed in [28 CFR Subpart C](#). Research must be directly relevant to prisons or prisoners (e.g. the effects of incarceration, criminal behavior, prison infractions, etc.). Completion of the CITI Research with Prisoners Module is also required.

38. How will you maintain confidentiality?

Anonymous data
 Electronic data will be password protected
 Physical data will be locked in a file drawer
 Public/non-confidential data
 Other (explain):

39. Describe final disposition of data.

Numerical and statistical data organized by identification numbers will be maintained in the researchers' offices until no longer needed for research or publication purposes. At that time, all data collection and summary forms will be disposed of in an appropriate manner consistent with university guidelines. Access will be granted only to the principal investigators, research advisor, and co-investigators. In addition, HIPAA compliance software will be utilized for telepractice.

40. Risks, inconveniences, or discomforts subjects are likely to experience (check all that apply):

Physical Legal
 Psychological Social
 Financial Other
 Occupational None

41. Detail potential risks, inconveniences and discomforts subjects are likely to experience, if any.

None anticipated.

42. Describe the methods that will be employed to mitigate any potential risks, inconveniences or discomforts.

There are no anticipated risks.

43. Describe any potential benefits subjects may gain as a result of participation.

Anticipated benefits may be increased teacher knowledge on hearing loss and amplification devices and improved student outcomes.

44. List all incentives subjects will receive for their participation.

None.

Note: If class credit will be given for participation, describe what other options exist for nonparticipants to receive the same credit.

45. If individuals are unwilling or unable to complete their participation, how will their incentives be distributed?

Not Applicable (no incentives will be offered)
 They will still receive all incentives.
 They will be informed that they will receive no incentives.
 They will receive partial incentives (explain):

SECTION 4: CHECKLIST AND AUTHORIZATION

46. The following documents must be attached to this form:

CITI Common Course Certificate (mandatory for all investigators and student advisor)
 CITI RE Course Certificate (mandatory for all investigators and student advisor)
 Research proposal approval from dissertation or master's thesis committee (if applicable)
 Study recruitment documents (if applicable)
 Survey questionnaires (if applicable)
 Permission letter from external organization participating in the project (if applicable) on official letterhead
 Assent form for minors (if applicable)
 Consent forms (long or short, if applicable) and any related documents (mandatory)
 Letter to parents (if applicable)

Instructions for Attaching Documents:

- Place the cursor where you want the attachment to appear.
- Select the "Insert" tab at the top of MS Word.
- Select "Object" located on the far right of the tool bar (PC) or the bottom of the list (MAC)
- Select the "Create from File" tab and **check the box that states "Display as icon."** Note: Do not check the box that says "link to file."
- Browse to the location of your document, and double click on it.
- Repeat these steps for each document to be attached.

Note for Mac Users: Word for MAC is unable to attach .pdf files, so you will have to first save the CITI certificates or any other .pdf files you intend to attach as a .doc or .rtf file before attaching them. There are several ways to accomplish this. You may use Adobe to open the file and then select "File" and "Save as" and change the file type to an .rtf or .doc format. Alternatively, you may also download or create your own .pdf to .doc application or simply save the application and then open the file on a PC to attach them as instructed above.

Attach all relevant documents in this section:

WordCITI.pdf EdAudconsentform.doc

47. Instructions for Authorization:

- Type your name and date in the appropriate box.
- Students should email the form to their advisors, who should add their name and then send it to department chairs for review. Department chairs should add their name and send the finalized form to jm@uwm.edu.

By typing my name below, I acknowledge that I have read, understood, and approve of the information contained herein.

Kimberly Ward _____
 Principal Investigator

Student Research Advisor (if applicable) _____
 Department Chair

March 25, 2018 _____