

# Protection of Human Subjects

## Risks to the subjects

Through Co-PI Allen's previous speech perception research, it has been established by the University of Illinois IRB committee that the risk to the subjects in this experiment is minimal. The most serious concern would be high levels of sound delivered over earphones. This possibility is easily avoided by hard-limiting the upper level. By its very nature, the upper levels of the laptop computers used in these experiments do not put out high levels of sound (max of 1 volt RMS). High levels of sound are not required for the experimental conditions, which are all presented in quiet. Furthermore, the sound level is monitored by a trained experimenter running each session.

**Human subjects involvement and characteristics:** The parameters of the human subject involvement is spelled out in some detail in the IRB forms. Specifically, all participation will be strictly voluntary and will follow written informed consent from children's parents/guardians and potential child subjects. Subjects and their families will be free to stop participating or withdraw at any time without penalty or prejudice to their relations with the University of Illinois or the Reading Group center. Participation will require approximately 19 sessions (3 assessment sessions, and two 8-block experimental sessions), each of which will be one hour in duration (broken into 10-min blocks of trials, with 5 min play breaks between blocks). The child's comfort with the experimental tasks will be monitored throughout a session.

The test signals will be played using the high quality earphones. Participants will be asked to adjust the level of signals that they hear over earphones so that it is at a "comfortable listening" level.

**Potential risks:** None are known.

## Adequacy of protection against risks:

The upper levels of the sound are limited by the sound card in the laptop computer and by the type of earphones used. We instruct the subject that if they feel the sound is too loud, to stop the experiment and inform the person running the experiment. The same is true if the child becomes tired of the task.

Assessment batteries for reading, speech, language, hearing, and nonverbal cognition will be administered by clinically trained, speech-language pathologists, who hold Masters degrees in the field.

**Recruitment and informed consent:** Standard IRB procedures have been followed in Co-PI Allen's previous speech perception research and our preliminary studies for the proposed project, and will continue to be followed. The University of Illinois Beckman Institute and Dept. of Speech and Hearing Science and our collaborator, The Reading Group center, will be fully informed on the necessary approvals from the University IRB committee, as required. Written informed consent will be obtained from children's parents/guardians and potential child subjects.

**Protection against risk:** The subjects are instructed to stop the experiment if they find the sounds too loud, and not to proceed. This is in the written instructions, and verbally explained to the subjects. All data collected (including original assessment data forms) will be identified only by an assigned name and subject number and kept in the locked laboratories of the PIs, in the Dept. of Speech and Hearing Science, and the Beckman Institute. The key linking the subject to her or his identification label will be destroyed at the end of the study.

## Potential benefits of the proposed research to the subjects and others

There are several potential benefits: (a) results of the assessment battery may help the child's family understand the child's reading disability, (b) the experimental training condition may result in improved speech perception and possibly benefit the child's reading, (c) 20 concurrent reading lessons at The Reading Group will be funded by this research and may also result in reading improvement for the child, and (d) the control subjects will receive a small amount of remuneration (\$10 per session, for 23 sessions).

## Importance of the knowledge to be gained

If successful, it may be possible to help with reading intervention during the experiment, since we will be testing for this possibility. The knowledge gained from the study is intended to improve our understanding of aural sensory difficulties that may underlie poor phonemic awareness and, ultimately, reading disabilities.

## **Inclusion of Women and Minorities**

The studies have a special and small population (children with reading disabilities). Because of the small size of the population, it is not always possible to strike an ethnic balance in the test population. It is well known that children with reading disabilities have a more frequent representation in the low income, minority population. Thus we expect, and have already experienced, a larger than average minority population in our preliminary experiments.

There is no language requirement in these experiments, thus the subjects' first language or dialect does not impact their ability to participate.

### **Inclusion of women**

By design, half of our subjects will be male, and half female.

### **Inclusion of minorities**

No subject will be eliminated on the basis of race or ethnic group.

## Targeted/Planned Enrollment

A total of 69 subjects will be required for this study.

Participants will be 39 children having a documented reading disorder, and 30 control children (good readers). All participants will be 8 to 12 years old, to ensure that they have had a number of years of reading instruction and have adult-like articulation, and to optimize the chances that they can do our experimental tasks.

The 39 participants with documented histories of reading difficulties (RDs) will be recruited from The Reading Group center. Parents will be asked to fill out an extensive questionnaire about the child's physical, speech-language, and reading development; vision, hearing, and health; and educational history.

The 30 control children will be recruited from local schools and other community facilities, lab web site postings, and local newspaper announcements. Their parents should report no history of reading difficulties or any remedial services for reading.

For both the RD and control groups, two to three sessions will be devoted to a battery of standardized tests or protocols for hearing screening, reading, speech, language, phonetic awareness and nonverbal intelligence.

co-PIs: Allen, Jont B. & Johnson, Cynthia

## Targeted/Planned Enrollment Table

Study Title: Children with Reading Disabilities – years I/II, 8-12 years old

Total Planned Enrollment (I/II): 39

<b>Ethnic Category</b>	Females	Males	Total
Hispanic or Latino	0	0	0
Not Hispanic or Latino	20	19	39
<b>Ethnic Category: Total of all subjects</b>	20	19	39
<b>Racial Categories</b>	Females	Males	Total
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
Black or African American	10	10	20
White	10	9	19
<b>Racial Categories: Total of All Subjects</b>	20	19	39

Study Title: Normal Reading Control Children – years I/II, 8-12 years old

Total Planned Enrollment (I/II): 30

<b>Ethnic Category</b>	Females	Males	Total
Hispanic or Latino	2	2	4
Not Hispanic or Latino	13	13	26
<b>Ethnic Category: Total of all subjects</b>	15	15	30

  

<b>Racial Categories</b>	Females	Males	Total
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
Black or African American	5	5	10
White	10	10	20
<b>Racial Categories: Total of All Subjects</b>	15	15	30

## **Inclusion of Children**

This research entirely about reading in children, thus by design, children necessarily comprise 100% of subject population.

## Multiple PI Leadership Plan

This study has two co-PIs, Prof. Allen and Prof. Johnson.

We have been working together on preliminary research for the proposed study since 2005 (7 years), and there has never been any conflict. We know each other well enough that we are sure there will be no conflict in the future. The two PIs have one common goal: to create deep insight into reading disorders in children. Our working relationship is mutually supportive.

Prof. Johnson manages the data collection and processing for the experiment with the children, with the help of her Speech and Hearing Science graduate and undergraduate students. Consequently the major portion (\$178,605) of the Total Direct Costs is allocated to her, primarily as support for a GRA and a group of undergraduate students who will assist in running the 39 subjects (23 sessions each).

Prof. Allen manages the programming of the computers, required to present the stimuli, and take and analyze the data; and does a major part, but not all, of the data analysis. Some of the finer statistical points of the analysis are performed by Prof. Johnson. The speech database is managed by Allen, as are the computer programs to collect and analyze the data. Consequently, \$96,395 of the Total Direct Costs is allocated to him, primarily as support for a GRA to assist with computer programming.

Most of the time the PIs are attending to the graduate students involved in the project. Once a week we all meet to review the status of the project. These meetings are always professional and productive. It is in these weekly lab meetings that we reach consensus and make decisions on scientific direction for the project. Based on the last 7 years of closely working together, there is no sign of a need for a conflict management plan. This working relationship has always been very smooth and is a relationship built on trust and respect.

Project Title: Aural Confusions of Consonants and Vowels in Children with Reading Disabilities

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GRANT NUMBER:1 R21-XXX

## Project Narrative

The proposed study explores whether poor sensory (phonetic) perception for speech underlies poor phonemic awareness and reading disability (RD). The study measures how well 8 to 12 year old children with RD can perceive all English consonants and vowels in nonsense syllables, in a series of experiments that increase the auditory memory load, add print to the auditory signal, and provide training for phonetic perception. Preliminary work suggests that although children with RD do not experience severe confusions, they do experience moderate confusions for many sounds, significantly more often than good readers. Cumulatively, this increased level of syllable confusions could result in considerable difficulty with reading.



## Facilities and Equipment

Beckman Laboratory, UIUC: *Speech Lab*: This room in Beckman contains office space for 5 graduate students. This is where speech testing is done on student subjects for psychophysical tests. The room contains computers for the students (one computer per desk), equipment for stimulus generation and computation, software for presentation of stimuli, network, earphones, etc. A BW printer is available in the room. Each student has a laptop computer along with a desktop, for general purpose computing, with Matlab networked via the central facilities at Beckman. *Computers*: All of our computers are networked together using a Linux network. Wideband Internet services are provided by the Beckman Institute at no extra charge. The speech lab runs a local subnet so that laptops may be easily connected into the backbone without going through central services, Support personnel for maintenance of computers is available, however the PI does his own computer support.

Office: Office space is provided for the PI and the graduate students at Beckman. Phone service and computer services are provided. Prof. Allen's office is across from the Speech Lab.

Office: Office space is provided for PI Johnson and her graduate students in the Speech and Hearing Science Bldg.

Child Language Lab: Prof. Johnson has a three-room lab suite in the Speech and Hearing Science Building. The lab contains a computer that research assistants can use, statistical analysis software, earphones, video and audio recording equipment, and data storage cabinets and shelves. Additionally, there are two rooms set up for data collection with school-age subjects. Prof. Johnson also has a second five-room lab suite at The Children's Research Center (CRC) building on campus. That suite has a large office space for Prof. Johnson, an office for research assistants, a large data collection room set up like a classroom (for running small groups of research subjects), a small waiting room for the families of research participants, and a data analysis room. The CRC suite is only 2 blocks from the Speech-Language Clinic, run by the Dept. of Speech and Hearing Science.

Speech-Language Clinic: The Speech-Language Clinic offers complete diagnostic, intervention, and consultation services to a few hundred children and adults annually, and aids in clinical investigations conducted by faculty of the Dept. of Speech and Hearing Science. This resource would be available to the proposed project for subject recruitment and data collection. The clinic is located in the Research Park section of the University, and occupies the north half of a recently constructed building shared with Chesterbrook Academy (a preschool day-care program). The clinic has a number of clinical/research spaces for data collection, which are equipped with state-of-the-art video and audio recording technology. There also is a waiting room for families, a home living area (with a combined kitchen-living room), rooms for working with young children, and a large playroom equipped for multisensory stimulation. Office space is available for researchers and their assistants.

Department of Speech and Hearing Science, UIUC: The Department is housed in its own building, the Speech and Hearing Science Building, which was designed specifically for the discipline. The Speech and Hearing Science Building was completed in 1977 and includes many of the classroom, office, clinic, and laboratory spaces that are utilized by the program. Most laboratory space is located in the Speech and Hearing Science Building, but two large additional spaces outside of the building have also been assigned to the Department. Laboratory spaces include the Evoked Potential Laboratory, the Auditory Perception and Neuroscience Laboratory, the Auditory Neural Coding and Auditory Plasticity Laboratory, the Language Development Laboratory, the Child Language and Literacy Laboratory, the Discourse Analysis Laboratory, the Child Language Laboratory, the Speech Anatomy Laboratory, the Swallowing Research Laboratories, the Visual Processes Laboratory, the Auditory-Visual Perception Laboratory, the Signed Languages Laboratory, the Data Analysis Laboratory, the Multicultural Studies and Child Language and Traumatic Brain Injury Laboratory, the Medical Imaging Research Laboratory, and the Stuttering Research Data Acquisition Laboratory. The Department also houses an Audiology Clinic and a Speech-Language Pathology Clinic.

Audiology Clinic: The Audiology Clinic has two double-walled commercially produced sound-treated booths. The booths house two clinical diagnostic audiometers (GSI 16 and AC 40), CD players, supraaural and insert earphones, bone conduction transducers, talkback systems and participant response devices, and two real ear hearing aid test units (FP40D). The clinic has two acoustic immittance devices (an AE 206 screener and a Zodiac 901), and two additional hearing aid test units, a Frye Fonix 6500 and a Frye FP40D. Also in the clinic are two computers with a HI-PRO box and cables and NOAH and cables, an ultrasonic cleaner device, and otoscopes and ear canal examination and cerumen management supplies. An Earmold Room contains a video otoscope, earmold materials, earplugs, a drill and buffer, a third immittance screener (American 85 AR impedance screener), and hearing aid repair materials. An Assistive Listening Devices room contains a VCR, assorted assistive listening devices (for television and telephone, alerting devices), computers, and a NOAH with cables.

# Budget Justification

## Personnel Budget Justification

### Senior Personnel:

Cynthia Johnson-PI (1.4 academic months 15% buyout): Co-PI Johnson will be responsible for overall conduct of the research program, including supervision of all subject recruitment, all data collection, lab procedures, and data analysis.

Jont Allen-PI (1.0 summer month): Co-PI Allen will be responsible for overall conduct of the research program as well, including management of the computer programming required to present the stimuli and take the data, data analysis, and management of the speech database.

### Other Personnel:

*GRA-TBA* (5.5 calendar months) As a part of the requirements for an advanced degree in the Dept. of Speech and Hearing Science, this GRA will work closely with Professor Johnson and will be responsible for recruiting subjects, subject scheduling, data collection, supervision of 20 hourly undergraduate student employees who also will assist in data collection, and assisting in data preparation and analysis.

*GRA-TBA* (3.85 calendar months) As a part of the requirements for an advanced degree in the Dept. of Electrical and Computer Engineering, this GRA will work closely with Professor Allen and will be responsible for writing special purpose scripts in Matlab, to present stimuli, take data, manage the speech database, and analyze the data.

*Student Hourly:* Twenty students over the two years, 7 in year 1 and 13 in year 2 2 hrs/wk for 50 weeks \$10/ hour. These undergraduate students will help run the child subjects in the data collection sessions for 24 subjects in Year 1 and 45 subjects in Year 2.

### Fringe Benefit:

- the Fringe Benefit rate of 42.97% is assessed on salary for all Academic Salaries
- the Fringe Benefit rate of 6.25% is assessed on salary for all GRADs
- the Fringe Benefit rate of 7.79% is assessed on salary for all Students

**Tuition remission:** This is assessed on all Graduate Research Assistant salaries at a rate of 62%.

## **Additional Budget Justification**

We have requested one extra module for Year 2. With a budget maximum of \$275,000, it is not possible to have equal modules for both years. Therefore, the budget for Year 2 includes an extra module (\$25,000), primarily to cover the increase in subjects.

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To NIH:

The title of the grant is:

*Aural Confusions of Consonants and Vowels in Children with Reading Disabilities*

This grant is about reading disability (RD) in children. The abilities of children with RD to perceive the full repertoire of English consonants (C) and vowels (V) have yet to be examined. In two preliminary studies, we compared 11 children with RD to 6 control children who were good readers. We found that while children with RD do not experience severe aural confusions for Cs and Vs, they do experience moderate confusions for many speech sounds, to a significantly greater degree than control children. Cumulatively, this increased level of CV confusions could well result in considerable reading difficulties. The proposed study is designed to further explore our preliminary work, by investigating the impact of perceptual confusions on auditory memory, the integration of auditory perception and print, and the effect of training on auditory perception.

We have no restrictions regarding who may review this grant.

Sincerely,

Jont B. Allen