Semantic Learning Deficits in School Age Children with Developmental Language Disorder

NCT04508699

May 1, 2020

SAN DIEGO STATE UNIVERSITY

Graduate and Research Affairs
Division of Research Affairs San Diego Statue University 5500 Campanile Drive San Diego, CA 92182-1933 Phone 619-594-6622
irb@sdsu.edu

Expedited Approval

01-May-2020

Principal Investigator:	**Abel, Alyson**
Department:	**Speech, Language and Hearing Sciences**
Protocol Number:	**HS-2020-0108**

Title: Semantic learning deficits in school age children with developmental language disorder

Dear Alyson,

The above referenced protocol was reviewed and approved on 01-May-2020 under expedited procedures in accordance with SDSU's Federal Wide Assurance (FWA) with the Department of Health and Human Services as well as federal requirements pertaining to human subjects protections within the Code of Federal Regulations (45 CFR 46) and relevant subparts. This approval applies to the conditions and procedures described in your protocol. As the study was reviewed under expedited review procedures at 45 CFR 46.110, annual continuing review is not required.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subjects research study. Principal Investigators are responsible for assuring final approval from other applicable school, department, center, or institute review committee(s) or boards has been obtained. If any of these other committees require changes to the IRB-approved protocol and informed consent/assent document(s), the changes must be submitted to and approved by the SDSU IRB prior to beginning the research study.

Important:

1. Research is to be conducted according to the proposal approved by the IRB.
2. Changes to the protocol or related documents are to be reviewed and approved before any changes are implemented unless those changes are to ensure the safety of the research participants. In the event that changes are enacted for the safety of research participants without prior IRB approval, you must promptly notify the IRB within 5 days.
3. Unanticipated problems, protocol deviations or adverse events are to be reported to the IRB within 5 days of occurence. Serious adverse events (e.g. life-threatening, death, hospitalization, significant disability or incapacity) must be reported within 48 hours of the event.
4. Participants are to receive a copy of the consent form, unless the IRB waives the requirement to obtain informed consent per 45 CFR 46.116(d).
5. Regulatory requirements as well as California State University Executive Order 1031, require that IRB records be maintained for the duration of the activity and at least an additional three years after completion. https://www.calstate.edu/recordsretention/documents/RSP.pdf Important: If your

research study is funded, the funding agency may have more stringent record retention requirements.

6. All CITI Human Subjects training for all study team members must be kept current to be in compliance.

For questions related to this correspondence, please contact the Human Research Protection Program office at 619-594-6622 or at irb@sdsu.edu.

Sincerely,

Rick Gulizia
Asst. Vice President of Research Support Services
San Diego State University

SAN DIEGO STATE UNIVERSITY

Updated By: **Alyson Abel @ 30-Apr-2020 09:05:11 PM**

STUDY TEAM INFORMATION

Contact Information for this Protocol Submission

Principal Investigator:
Abel, Alyson

* Academic Status:
Faculty

* Department:

* Work Phone:
619-594-4694

Alternate Phone:
678-592-8755

Alternate Email Address:(*SDSU email on file*)
alyson.abel@sdsu.edu

Funding Details

* Is your study funded?
☐ Yes ☑ No

STUDY PERSONNEL

Personnel - Review(Add Personnel - Review)

Personnel - Review

Name	Primary Investigator	Start Date	End Date	Role
Abel, Alyson	☑	27-Apr-2020		PI

☑ CITI Human Subjects Training Complete

* Please Upload Training Completion Report

☑ This individual will be involved with the administration of informed consent.

STUDY PERSONNEL CONTINUED

Non-SDSU Affiliated or Undergraduate Study Personnel

Use the table below to list study team members who do not have InfoEd accounts

Full Name	Email	Start Date	End Date	Upload CITI Training Certificates	Role	This individual will be involved with the administration of informed consent.
Cristy Sotomayor	csotomayor@sdsu.edu	27-Apr-2020	31-May-2022		Other Study Personnel	Yes
Ashlie Pankonin	apankonin3092@sdsu.edu	27-Apr-2020	31-May-2022		Other Study Personnel	Yes

HUMAN SUBJECTS RESEARCH QUESTIONNAIRE

HS or NHSR?

The following items do not fall under the purview and authority of the IRB:

- Scholarly and journalistic activities (e.g. biography, literary criticism, legal research, and historical scholarship;
- Public health surveillance activities for the purposes of identifying, monitoring, assessing, or investigating potential public health signals, onsets of disease outbreaks or conditions of public health importance; or
- The collection and analysis of information, biospecimens or records by or for a criminal justice agency for activities authorized by law or court order for criminal justice or criminal investigative purposes

If your project solely involves one or more of the three bullet items above, check “no” to the answer to Question 1 below:

* 1. Does your project involve a systematic investigation and is intended to develop or contribute to *generalizable knowledge* (e.g. publication, presentation at a conference, or thesis)?
☑Yes ☐No

* 2. Does your research involve obtaining data from or about living individuals through interaction with them, or through an intervention?
☑Yes ☐No

Identifiable Information

* 3. Will any study team member receive, possess, or have access to any of the following identifiers listed below
☑Yes ☐No

- Name
- Geographic subdivision smaller than a state unless according to currently publically available data from the Census Bureau the geographic unit formed consents more than 20,000 people.
- Telephone Numbers
- E-Mail addresses
- Social Security Numbers
- Medical Record Numbers
- Health Plan Beneficiary numbers
- Account Numbers
- All elements of date (except for year) directly related to an individual (e.g. birth date, admission date, discharge date, date of death), all ages over 89, and elements of dates (including year) indicative of age, except such as ages and elements may be aggregated into a single category of age 90 or older
- Certificate / license number
- Vehicle identifiers (e.g. serial number, VIN, license plate number)
- Device identifiers & serial numbers
- Biometric Identifiers including voice and fingerprints
- Full face photographic images and any comparable images
- Video and voice recordings
- Any other unique indentifying number, characteristic or code
- Access to the key to the code allowing you to link the data to the identity of study participants

* 4. Is your project a clinical trial?
NIH defines a clinical trial as: "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." Interventions include drugs, medical devices, procedures, vaccines, as well as noninvasive approaches such as surveys, education, and interviews.
☐Yes ☑No

5. Cancer Related Research

* Does your study involve cancer patients under current treatment or with evidence of current disease; target cancer survivors, or participants which may be at high risk for cancer?
☐Yes ☑No

* Does your study involve participants from a healthy population but are at a high risk for cancer or is cancer a study outcome?
☐Yes ☑No

IDENTIFIERS

Select any PHI identifiers you will be accessing (i.e., using), recording (i.e. collecting), or disclosing (i.e. sharing outside of SDSU) among the following:

* Use the "+" symbol to add additional rows and select applicable PHI Identifiers

* PHI Identifier	Accessing	Recording	Disclosing
Names	☑	☐	☐
Telephone numbers	☑	☑	☐
E-mail addresses	☑	☑	☐
Any other unique identifying number, characteristic, or code	☑	☑	☐
Access to the key to the code allowing you to link the data	☑	☑	☐

BASIC STUDY INFORMATION

Investigator(s) Experience

* List relevant experience of all study team members as it pertains to this research.
Dr. Alyson Abel developed the research skills that allow her to collect, process, analyze and interpret behavioral and EEG data through her doctoral and postdoctoral training. Dr. Abel received her PhD in Child Language from the University of Kansas in 2012 and a postdoctoral training in EEG research at the University of Texas at Dallas in 2014. She also holds a degree in clinical speech-language pathology. Dr. Abel is an expert in child language development and disorders and EEG analyses of on-line language processing. She has years of experience testing children from infancy through adolescence and adults. As director of the Language Learning Lab in the School of Speech, Language, and Hearing Sciences, Dr. Abel has access to equipment and software necessary to complete this research.

Conflict of Interest

* Does anyone on the research team have a conflict of interest (significant financial interest, financial relationship, governance or administrative affiliation with any entity that is providing funds for or which has rights to intellectual property resulting from this study.) SDSU COI
☐ Yes ☑ No

Background & Significance

* Discuss relevant background information and literature reviewed to provide the rationale for the proposed research.
Semantic knowledge, or knowledge of a word's meaning, has strong ties to reading comprehension and long-term academic outcomes, particularly in the school years. Children with developmental language disorder (DLD), language impairment in the absence of any causal factors, often show deficits in semantic knowledge and acquisition. It is generally accepted that these deficits are driven by difficulty with the process of adding meaning to a new word with repeated exposures to the word, or configuration. What is unknown is what underlies deficits in configuration and whether these deficits vary across the DLD profile. The goal of this project is to elucidate the semantic learning deficits in DLD. Toward this goal, this project uses a combined electroencephalogram (EEG) - behavioral methods approach to examine the cognitive and linguistic processes engaged during semantic learning in school-age children with and without DLD. The inclusion of EEG will allow for a real-time examination of semantic learning and associated cognitive and linguistic processes. 10-12 year old children with and without DLD will complete a behavioral assessment battery and semantic learning task while their EEG is collected. Behavioral data will be analyzed for semantic learning group differences (Aim 1) and the types of errors that children make when they are unable to retrieve a correct meaning (Aim 2). EEG data will be analyzed in two ways. The event-related potential (ERP) analysis will examine changes in semantic processing, indexed by the N400, during learning (Aim 1). Time frequency analysis of the EEG will examine the engagement of neural processes associated with lexical retrieval (theta) and attention/inhibition (alpha) during learning (Aim 1). Behavioral and EEG methods will be combined to examine individual differences related to semantic learning outcomes and fine-grained differences in N400 learning effects across groups (Aim 2). Taken together, findings will inform our understanding of the nature of the semantic learning deficits in school-aged children with DLD. This understanding is prerequisite for targeted intervention that would help these children learn how to learn.

* Please provide a list of references to support the information found in the background and significance section.
Ouellette, G.P. (2006). What's meaning got to do with it: The role of vocabulary in word reading and reading comprehension. Journal of Educational Psychology, 98(3), 554. Milton, J., & Treffers-Daller, J. (2013). Vocabulary size revisited: the link between vocabulary size and academic achievement. Applied Linguistics Review, 4(1), 151-172. Bishop, D.V., Snowling, M.J., Thompson, P.A., Greenhalgh, T., Consortium, C., Adams, C., . . . Bellair, J. (2017). Phase 2 of CATALISE: A multinational and multidisciplinary Delphi consensus study of problems with language development: Terminology. Journal of Child Psychology and Psychiatry, 58(10), 1068-1080. Watkins, R.V., & Rice, M.L. (1994). Specific Language Impairments in Children: ERIC. Leonard, L.B. (1998). Children with Specific Language Impairment. Cambridge, MA: MIT Press. Gray, S. (2003). Word learning by preschoolers with specific language impairment. Journal of Speech, Language, and Hearing Research, 46, 56-67. Gray, S. (2004). Word learning by preschoolers with Specific Language Impairment: Predictors and poor learners. Journal of Speech, Language, and Hearing Research, 47, 1117-1132. Gray, S. (2005). Word learning by preschoolers with Specific Language Impairment: Effect of phonological or semantic cues. Journal of Speech, Language, and Hearing Research, 48, 1452-1467. Windfuhr, K.L., Faragher, B., & Conti-Ramsden, G. (2002). Lexical learning skills in young children with specific language impairment (SLI). International Journal of Language & Communication Disorders, 37(4), 415-432.

Study Abstract

Briefly complete the following Study Abstract components:

* 1. Purpose/objective:
Children with developmental language disorder (DLD) have deficits in semantic learning, or learning the meaning of new words. However, the nature of the deficit remains elusive. Understanding why children with DLD fall short in semantic learning is prerequisite for targeted intervention that would help these children learn how to learn.

* 2. Methods:
This study will use brain processing measures in conjunction with traditional behavioral measures to evaluate the process of semantic learning in real-time

* 3. Subjects
10-12 year old children, both those with typical language development and those with DLD, will serve as participants for this research. DLD is defined as impairment with language and no other deficit (e.g. neurological impairment, intellectual deficit, ADHD, autism, etc.) affecting language abilities.

* 4. Planned analyses:
Data analyzed will include behavioral performance on a semantic learning task (percent correct and analysis of incorrect responses) and EEG data time-locked to the novel word being learned. To compare behavioral semantic learning performance, behavioral data will be subjected to a one-way ANOVA to evaluate a possible effect of group (DLD, TL) on accuracy and the error analysis. To evaluate changes in brain processing of the novel word during

learning and potential group differences in neural processing, a 2 group (DLD, TL) x 3 presentation (1st sentence, 2nd sentence, 3rd sentence in the set) ANOVA will be run on the EEG data.

* 5. Potential benefits:
There are no direct benefits to the participants. Researchers will learn more about the nature of the semantic learning deficits in children with DLD.

* 6. Potential risks:
Participants will be exposed to very minimal risks. Due to the length of the assessments and semantic learning task, participants may experience some boredom and stress, which will not exceed the levels they experience in everyday life and breaks will be provided to alleviate any fatigue or boredom participants may experience. The EEG cap may be a little stressful for some participants and may seem itchy or uncomfortable. The risks and inconveniences associated with the assessments are reasonable in relation to the anticipated benefits discussed above.

* 7. Risk management procedures:
Participants will be informed about the procedure and the minimal risk. If at any time the participant does not feel comfortable with the EEG process, the experiment will be terminated. To help alleviate fatigue or boredom, breaks will be provided throughout the assessment session. To maintain confidentiality, a code number will replace participants' names on all of the information collected from them. All data will be marked with a participant code number only. Research records will be kept confidential to the extent allowed by law and stored in a locked filing cabinet at the Language Learning Lab and only personnel associated with this research will have access.

Research Design and Methods

* Specify aims of the research that include the hypotheses to be tested, research questions to answer, data to be gathered and tested.
The central hypothesis of this research is that children with DLD engage cognitive and linguistic processes at different points during configuration compared to their typical peers, resulting in poorer semantic learning outcomes. Aim 1. To investigate the cognitive and linguistic processes underlying configuration in children with DLD and typical language (TL) peers. Aim 2. To investigate individual differences in configuration in children with DLD and TL peers. Toward these aims, we will administer a series of behavioral assessments to establish language status and a semantic learning task, during which we will collect EEG. See below for details.

* Use this space to provide a detailed list of every step you will take to test your hypothesis. Beginning with recruitment strategy, data collection , to analysis of research results.
Participant Recruitment: The PI has experience recruiting children with DLD and has established relationships with community agencies and professionals who work with these children, including local speech-language clinics, school districts, and literacy centers. Participants, both DLD and TL, will be recruited from these and other locations/professionals by way of flyers and in-person recruitment, when possible. General procedures: All participants will be screened over the phone or via email for language history, handedness, medication use and history of neurological disorders or dysfunction. Upon arriving at the lab, participants will complete a behavioral test battery including nonverbal cognition, receptive and expressive vocabulary, general language and verbal working memory measures. For the EEG task, an electrode cap, similar to a lycra swimcap, will be placed on the participant's head. The EEG caps used in the PI's lab are designed for research conducted with infants, children, adolescents, and adults. The EEG cap is being used as described for use with children according to the instructions for use document provided by the manufacturer. The researcher will apply a small amount of saline solution to each electrode (total: 64 on the scalp, another two above and below the left eye). The solution enables the small sponge in each electrode to expand and make contact with the scalp. When this contact is made, the measured impedance (measurement of resistance) decreases, and the impedance values can be observed on a computer monitor visible to the researcher. When the impedance level is decreased on most electrodes, the experiment can begin. Participants will be seated in an electrically-shielded room in the Language Learning Lab. The electrode cap will collect electrical activity from the brain as participants complete the semantic learning task, as described below. Participants will silently listen to naturally-paced sentences presented in sets of 3 sentences. The last word of each sentence will be a nonsense word. After each set of 3, the participant will be asked to provide the meaning of the nonsense word, if possible. An experimenter, sitting in the room but out of sight of the participant so as not to distract them, will write down the word provided by the participant. The participant will be asked to sit as still as possible while the stimuli are being presented, with the exception of when they are asked to define the nonsense word. Participants will be given breaks as needed. Following completion of the semantic learning task, participants will complete a word recognition task where they hear 200 nonsense words one at a time and push a button to indicate whether they've heard it before or not. Data analyzed will include behavioral performance on the semantic learning task (percent correct and incorrect responses for error analysis) and EEG data time-locked to the nonsense word in each sentence. To compare behavioral semantic learning performance and errors, behavioral data will be subjected to a one-way ANOVA to evaluate a possible effect of group (TL, DLD). To evaluate changes in brain processing of the novel word during learning and potential group differences in neural processing, a 2 group (TL, DLD) x 3 presentation (1st sentence, 2nd sentence, 3rd sentence in the set) ANOVA will be run on the EEG data.

PARTICIPANT INFORMATION

Study Population

Instructions: Enter the total number of adults and children you wish to recruit for your study. If you plan on recruiting members of a vulnerable population, indicate using the check boxes below and enter the total number expected for that category.

ADULTS (18+)

0

- ☐ Cognitively Impaired
- ☐ Prisoners
- ☐ Pregnant Women
- ☐ Other

Children

60

- ☐ Cognitively Impaired
- ☐ Prisoner/Detainee
- ☐ Pregnant Women
- ☑ Other

* Population: language impaired

* 30

TOTAL:

60

* Describe how the number of subjects was determined (e.g. statistical significance).

A priori power analyses were conducted with G*Power using preliminary data to determine sample sizes needed for the proposed project. For the behavioral data, the semantic learning accuracy analysis requires 16 participants/group for power=0.95, f=0.6, α=0.05, the error analysis requires 14 participants/group for power=0.95, f=0.6, α=0.05, and the regression requires 24 participants/group for power=0.95, f2=0.35 α=0.05. The ERP analysis requires 18 participants/group for power=0.95, f=0.6, α=0.05. The time frequency analysis requires 12 participants/group for power=0.95, f=0.6, α=0.05. This is consistent with evidence that time frequency analysis is more robust to noise than ERP requiring fewer trials and participants. Therefore, a targeted sample of 25 participants/group should easily provide at least power=0.8 for all proposed variables.

* List the criteria for inclusion and exclusion of subjects in this study.

Participant exclusion criteria include: neurological disorders (i.e., ASD, ADHD), significant neurological history (i.e., head injury, epilepsy), left handedness, medication other than over-the-counter allergy medications, and/or nonverbal IQ less than 70, as measured by the Wechsler Intelligence Scale for Children. Performance on a standardized language omnibus assessment (Clinical Evaluation of Language Fundamentals-5 Core Language Scale; CELF) will be used to classify children as DLD if they earn a standard score of < 80, else they will be classified as TL. The use of a standard score of 80 on the CELF as a cut point for identification of DLD is supported by good sensitivity (0.97) and specificity (0.97). The use of this validated cut score is the best assurance that children will be correctly identified for their respective groups. DLD and TL groups will be equivalent on age, nonverbal cognition, handedness, and gender, as measured by parental responses to a questionnaire administered during participant intake.

If applicable, provide a rationale to support subject exclusion for populations who might benefit from participation in the research.

This age range was selected, in part, because the rate of vocabulary growth in children with DLD further decreases relative to TL peers around age 10.

Subject Recruitment

How will you contact potential subjects for recruitment?

- ☐ Record Review
- ☑ In-Person
- ☐ Classroom
- ☑ Flyer
- ☐ Third Party Referral
- ☐ Paid Advertisements
- ☐ Telephone
- ☑ Email
- ☐ Letter
- ☐ Electronic Participant Pool Recruitment
- ☐ Other

Please upload a copy of any recruitment language that will be used to introduce this study to potential participants.

Subject Screening

What instrument(s) will you use to determine subject eligibility?

- [x] Survey/Screening/Checklist
- [x] Phone Screen
- [ ] Health Records
- [ ] Other
- [ ] N/A

Survey/Screening/Checklist Detail

- [ ] Mail
- [x] Online
- [ ] SONA
- [x] In-Person
- [ ] Other

* Are you going to obtain informed consent prior to participant screening?
[x] Yes [ ] No

* Explain how consent will be obtained prior to screening.
Consent will be obtained via phone or email, per parent request, following a script which has been uploaded.

Please upload instrument

Phone Screen Detail

* Are you going to obtain documentation of informed consent prior to participant screening?
[x] Yes [ ] No

* Explain how documented consent will be obtained prior to screening?
Consent will be obtained via phone or email, per parent request, following a script which has been uploaded.

Please upload phone screen or phone script

Subject Involvement Expectations

* Describe the tasks in the order that the subject will be asked to complete them. If tasks vary by group, please indicate the group in the description.

Name of Task	Brief Description	Time to Complete
Visit 1	Demographic questionnaire, Edinburgh Handedness Inventory, Wechsler Intelligence Scale for Children, Clinical Evaluation of Language Fundamentals, Nonword Recognition Task, Flanker Inhibitory Control and Attention task	0-5 hours
Visit 2	EEG cap application, semantic learning task, word recognition task	0-5 hours

Research Interviews/Surveys/Questionnaires/Focus Groups

* List all measures used for this study and provide rationale for its use. inidicate if the measure is validated or published:

Measure	Availability	Validation
Demographic questionnaire	Privately Available	PI Developed
Edinburgh Handedness Inventory	Publicly Available	Peer Approved
Wechsler Intelligence Scale for Children	Publicly Available	Peer Approved
Clinical Evaluation of Language fundamentals	Publicly Available	Peer Approved
Nonword Repetition Task	Publicly Available	Peer Approved
Flanker inhibitory control and attention	Publicly Available	Peer Approved
Semantic learning task	Privately Available	PI Developed
Word recognition task	Privately Available	PI Developed

Please upload measures

Research Setting

* Identify the location and describe the setting, include any safety/privacy concerns to study participants
The study will be conducted at Dr. Abel' Language Learning Lab (6505 Alvarado Rd, Suite 100). This laboratory is equipped to administer behavioral measures and collect and record EEG data. The laboratory is typically locked and only accessible to laboratory personnel.

* Will the researcher(s) be traveling to another country to conduct the research?

☐ Yes ☑ No

Payment/Incentives to Participants

What form of payment/incentive will be provided?

Payment/Incentives to Participants Details

(Check all that apply):

☐ Reimbursement	☐ Compensation
☐ Drawing	☐ Small Gift
☑ Cash/Check	☐ Gift Card
☐ Other	☐ None

* Describe each type of payment/incentive checked above.
Participants will be reimbursed with cash at a rate of $15/hour of participation

If applicable, please provide a schedule for any prorated payments or incentives.
The prorated rate is $15/hour of participation, even if participation isn't completed.

CONSENT PROCESS AND PROCEDURES

Informed Consent

How will you obtain informed consent? (Click HERE for Informed Consent Templates and Guidance)

Please Select

- ☐ Comprehensive written
- ☐ Short form
- ☐ Comprehensive oral
- ☐ Legally authorized representative consent
- ☐ Request for alteration or waiver of informed consent requirement
- ☐ Request for waiver of documentation (Signature not Required)
- ☐ Pre-existing consents(s) covers this activity
- ☐ Broad Consent

Minors and Cognitively Impaired Persons Detail

(Check all that apply)

- ☑ Documentation of Assent
- ☐ Request for waiver of documentation of assent
- ☐ Request for waiver or alteration of assent
- ☐ Request for waiver or alteration of informed consent/parental permission/legally authorized representative consent
- ☑ Parental permission or other Legally Authorized Representative in addition to assent

* Will your assent be translated into a foreign language?

☐ Yes ☑ No

* If the child attains the age of majority during study participation, how will you obtain consent?

N/A

RISK/BENEFIT/DATA MANAGEMENT

Potential Benefits

Are potential benefits specific to the participant (check all that apply)

- ☐ Indirect
- ☐ Direct
- ☑ N/A

Are potential benefits specific to society (check all that apply)

- ☑ Indirect
- ☐ Direct

* Describe benefits indicated above.
There are little to no direct benefits to participants. Participation in this study will advance knowledge about brain representations of semantic learning, particularly differences between TD children and children with DLD. Information gained from this study will inform theories of DLD and potential techniques for semantic learning intervention with these children.

Risk Assessment and Data Storage Safety Measures/ Risk Management

* Select the level of risk:
Minimal Risk

- Minimal Risk: That the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- Greater than Minimal Risk: That the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

* Describe risks other than loss of privacy and breach of confidentiality associated with the minimal or greater than minimal risk research, as indicated above.
Participants will be exposed to very minimal risks. Due to the length of the assessments and semantic learning task, participants may experience some boredom and stress, which will not exceed the levels they experience in everyday life and breaks will be provided to alleviate any fatigue or boredom participants may experience. The EEG cap may be a little stressful for some participants and may seem itchy or uncomfortable. The risks and inconveniences associated with the assessments are reasonable in relation to the anticipated benefits discussed above.

* What procedures are researchers using to protect personal identifiers and human subject research data, remember use of passwords, encryption of data stored, and who will have permission to access the data?
Participants will be informed about the procedure and the minimal risk. If at any time the participant does not feel comfortable with the EEG process, the experiment will be terminated. To help alleviate fatigue or boredom, breaks will be provided throughout the assessment session. To maintain confidentiality, a code number will replace participants' names on all of the information collected from them. All data will be marked with a participant code number only. Research records will be kept confidential to the extent allowed by law and stored in a locked filing cabinet at the Language Learning Lab and only personnel associated with this research will have access.

Data Safety Monitoring Plan (DSMP)

* Will any of the data be released outside of the research study team? (other than to publisher)
☑ Yes ☐ No

* Please explain:
For the purpose of replication, deidentified data may be provided upon request to collaborators and other investigators.

* Will data be provided to a repository as part of a data sharing agreement?
☐ Yes ☑ No

* Will the project require a certificate of confidentiality?
☐ Yes ☑ No

As Data is/ are Collected

- ☑ Confidential (Data contains at least one of the 18 listed HIPAA personal identifiers)
- ☑ Coded and key is linked to the code (or linked to personal identifier(s)) (Code is used on individual data and researchers maintain a key to personal identifier(s))
- ☐ Anonymous/ or Coded With No Key or/ De-Identified (Personal identifiers were never associated with the data or/ personal identifiers are separated from coded data with no key to link to identifiers or / data had personal identifiers then researchers stripped the data of all personal identifiers as an aggregate before analysis)

Coded Details

* Will the information remain coded for the duration of the research?
☑ Yes ☐ No

Data Storage

* How long will data be stored? (Hover over Help Icon for more information)
Data will be stored for 10 years

* When will data be de-identified or destroyed?
Data will be de-identified upon collection.

Division of Research Affairs
Human Research Protection Program
Gateway Center, Rm 3505
San Diego State University
5250 Campanile Dr., MC 1933 San Diego, CA 92182
PHONE: 619-594-6622 **FAX:** 619-594-4109
Email: irb@mail.sdsu.edu

OFFICE USE ONLY

Post-Approval Tracking

q_1	q_2	q_3
Yes	Yes	Yes

Appendix 1

EForm Name: HRPP | INITIAL APPLICATION
Page: Study Personnel
Section: Personnel - Review
Question: Please Upload Training Completion Report
File Name: citiCompletionReport_RCR1_2019.pdf

CITI PROGRAM

Completion Date 22-Sep-2019
Expiration Date 21-Sep-2022
Record ID 32125896

This is to certify that:

Alyson Abel Mills

Has completed the following CITI Program course:

Responsible Conduct of Research (RCR) (Curriculum Group)
Research Involving Human Subjects (Course Learner Group)
1 - Basic Course (Stage)

CITI
Collaborative Institutional Training Initiative

Under requirements set by:

San Diego State University

Verify at www.citiprogram.org/verify/?w209491e0-bf04-43fe-9ae1-10f568d051d7-32125896

Appendix 2

EForm Name: HRPP | INITIAL APPLICATION
Page: Study Personnel Continued
Section: Non-SDSU Affiliated or Undergraduate Study Personnel
Question: Upload CITI Training Certificates
File Name: CITI Research Involving Human Subjects_Sotomayor.pdf

CITI PROGRAM

Completion Date 30-Jun-2017
Expiration Date 29-Jun-2020
Record ID 23668863

This is to certify that:

Cristy Sotomayor

Has completed the following CITI Program course:

Responsible Conduct of Research (RCR) (Curriculum Group)
Research Involving Human Subjects (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

San Diego State University

CITI

Verify at www.citiprogram.org/verify/?wc7b1c7ae-92df-45b6-b95e-649e78260ad4-23668863

Appendix 3

EForm Name: HRPP | INITIAL APPLICATION
Page: Study Personnel Continued
Section: Non-SDSU Affiliated or Undergraduate Study Personnel
Question: Upload CITI Training Certificates
File Name: SDSU RCR citi Completion Report - Ashlie Pankonin.pdf

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Ashlie Pankonin (ID: 6426979)
- **Institution Affiliation:** San Diego State University (ID: 3235)
- **Institution Email:** apankonin3092@sdsu.edu
- **Institution Unit:** Speech Language and Hearing Sciences
- **Phone:** 4024290258

- **Curriculum Group:** Responsible Conduct of Research (RCR)
- **Course Learner Group:** Faculty, Staff and Students
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 32556699
- **Completion Date:** 27-Jul-2019
- **Expiration Date:** 26-Jul-2022
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Authorship (RCR-Basic) (ID: 16597)	27-Jul-2019	5/5 (100%)
Collaborative Research (RCR-Basic) (ID: 16598)	27-Jul-2019	5/5 (100%)
Data Management (RCR-Basic) (ID: 16600)	27-Jul-2019	5/5 (100%)
Mentoring (RCR-Basic) (ID: 16602)	27-Jul-2019	5/5 (100%)
Peer Review (RCR-Basic) (ID: 16603)	27-Jul-2019	5/5 (100%)
Research Misconduct (RCR-Basic) (ID: 16604)	27-Jul-2019	5/5 (100%)
Plagiarism (RCR-Basic) (ID: 15156)	27-Jul-2019	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kc65181d7-8f11-41b5-bbff-d87c89f7fe96-32556699

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Ashlie Pankonin (ID: 6426979)
- **Institution Affiliation:** San Diego State University (ID: 3235)
- **Institution Email:** apankonin3092@sdsu.edu
- **Institution Unit:** Speech Language and Hearing Sciences
- **Phone:** 4024290258

- **Curriculum Group:** Responsible Conduct of Research (RCR)
- **Course Learner Group:** Faculty, Staff and Students
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 32556699
- **Report Date:** 27-Jul-2019
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Plagiarism (RCR-Basic) (ID: 15156)	27-Jul-2019	5/5 (100%)
Authorship (RCR-Basic) (ID: 16597)	27-Jul-2019	5/5 (100%)
Collaborative Research (RCR-Basic) (ID: 16598)	27-Jul-2019	5/5 (100%)
Data Management (RCR-Basic) (ID: 16600)	27-Jul-2019	5/5 (100%)
Mentoring (RCR-Basic) (ID: 16602)	27-Jul-2019	5/5 (100%)
Peer Review (RCR-Basic) (ID: 16603)	27-Jul-2019	5/5 (100%)
Research Misconduct (RCR-Basic) (ID: 16604)	27-Jul-2019	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kc65181d7-8f11-41b5-bbff-d87c89f7fe96-32556699

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org