eHIRB Electronic Homewood Institutional Review Board

Date: 1/5/2015, 11:16:30 AM   [Print] [Close]

New Application
PI: Carley Emerson
HIRB00002551

1 - General Information

1.0   *** Principal Investigator**

*PI must be faculty or senior staff. Click **Select** to choose a PI, or **Update** to modify the PI.*

Carley Emerson

PI's HSR Training Date: 7/27/2009

PI's HSR Training Certificate:
IRB Training.pdf

2.0   *** Full Study Title**

Working memory ability in children

3.0   *** Type of submission**

New

5.0   *** Briefly describe your proposed project**

Include the overall objectives, general description of the procedures, and a description of the subject population or the types of data or specimens to be studied. You will be asked to provide more details later in the application.

Many forms of problem solving in children's everyday lives require them to remember information and manipulate these memories over short periods of time. For example, when playing "hide-and-seek", the child has to remember in which locations he has already searched and which ones remain and this information has to be constantly updated as the child continues his search. The goal of the present study is to investigate the relationship between working memory capacity in the auditory and visual domains in 4-10-year-old, typically developing children by developing novel behavioral methods to assess working memory capacity.

6.0   *** Select amount of risk involved with this study**

Minimal

xxx

3 - Research Personnel

1.0 *** Is this research being submitted as a student research project?**

yes

1.1

* Describe and outline the plan for the PI's supervision and oversight of this project, including regular meetings and communication between the student and PI.

The PI has helped the student design the study and will also meet with the student on a weekly basis to discuss the progress of the study and if any issues arise. The PI will often be present during the conducting of the research and overseeing the research.

2.0 **Team Members**

*Click **Add** to add all Student Investigators and Study Team Members. Click **Update** to modify existing people on this list.*

NOTE: You do not have to list the PI again on this list. If you are not the PI, you must add yourself here or you will not have access to the application when you click "Continue" to go to the next page.

	First Name	Last Name	Degree	Title	Receive Notifications	Role	HSR Training Date	HSR Certificate Uploaded
View	Carley	Emerson		Sr. Policy Associate	yes	Student Investigator	7/27/2009	Yes

xxx

4 - Conflict of Interest

1.0 *** Does the PI, any study team member (or their spouse, domestic partner, or dependent children), or any other person responsible for the design, conduct, or reporting of this research have a financial or economic interest (e.g., royalty, equity, consulting, employment) or fiduciary relationship (e.g., board service, office role, director role) with the sponsor and/or manufacturer of products used in this researcher with an outside entity whose financial interests could reasonably appear to be affected by the research?**

no

xxx

5 - Research Sites

1.0   *** Will the research involve collaboration with a non-Hopkins entity?**

yes

1.1   *** Enter the names of the non-Hopkins entities that are involved in the research, a description of their involvement in the research, as well as a contact person at the entity. You will be asked to provide their entity's or institution's IRB approval later in this section.**

University of Maryland is also conducting this study. The JHU researchers are collaborating with a UMCP researcher. UMCP will recruit their own participants. They are currently seeking IRB Approval. The UMCP researcher is Dr. Neal Brian and can be reached at nbrian@umcp.edu.

2.0   *** Where will the JHU researchers recruit participants for the research?**

Check all that apply.

- ☑ **Johns Hopkins University Homewood campus**
- ☐ **School of Advanced International Studies (SAIS)**
- ☐ **Applied Physics Lab (APL)**
- ☐ **Carey Business School**
- ☐ **Kennedy Krieger Institute (KKI)**
- ☐ **Peabody Institute**
- ☐ **Johns Hopkins School of Medicine (SOM)**
- ☐ **Johns Hopkins School of Nursing (SON)**
- ☐ **Johns Hopkins School of Public Health (JHSPH)**
- ☐ **Schools or Classrooms**
- ☐ **Community or Community Centers**
- ☐ **International**

- ☑ **Internet/email**
- ☑ **Telephone**
- ☑ **Mail**
- ☑ **Other sites where another PI will conduct the research**
- ☐ **Only data analysis of pre-existing data**
- ☐ **Other**
- ☐ **N/A**

3.0   *** Will JHU serve as the lead site, or data coordinating center or receive the primary funding for this study?**

yes

4.0   *** If JHU will serve as the lead/coordinating center, it is the JHU PI's responsibility to address the following issues. Please explain how the following will be done:**
- If federally-funded research, confirmation that each participating site has on file an FWA with

OHRP
- Plan for review of each site's IRB approval documents and consent forms, and submission of the external approvals to the HIRB
- Method of assuring that all centers have the most current version of the protocol and amendments to the protocol will be communicated to all centers
- Plan for collection and management of data from all centers, including adverse events and protocol deviations
- Plan for review of each site's IRB approval documents and consent form

Sites are collaborating but JHU is not the lead site. Each site will have their own protocols and processes, as well as go through their own IRB.

5.0   Upload IRB approvals from other sites, if available at this time. You will be required to submit the approvals from the other places conducting the research before you can receive final approval.

*Click **Add** to upload a new document. Click **Upload Revision** to upload a revised version of the existing document. Do <u>not</u> delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

Name	Description	Modified Date
There are no items to display		

5.1   If you do not have the documents at this time, please explain where you are in the process of getting the approvals.

UMCP is waiting for approval. We will send it to the HIRB once received.

xxx

6 - Support Information

1.0   * What is the funding status of this research?

Not funded

2.0   Enter any additional information regarding funding.

xxx

7 - Exempt Determination

You chose minimal risk research. You will have the option to choose an exempt category below, although the IRB will make the final determination of exemption. If your research does not fall into one of the exempt categories, check the last box and proceed to the next page.   ⑦

If your research involves any of the following, it cannot be exempt. Therefore, click **Continue** and proceed to the next section:

- Clinical studies of medical devices, procedures, treatments, or drugs.
- Pregnant women, fetuses, neonates, or human in vitro fertilization.
- Prisoners.
- Surveys or interviews that include minors (i.e., children) as participants.
- Collection or study of data (prospective study) if the information is recorded in such a way that participants can be identified, either directly or through identifiers linked to the participants and disclosure of the participants' responses outside the research could reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.
- Study of existing data (retrospective study) if the information is recorded in such a way that participants can be identified, either directly or through identifiers linked to the participants.
- Research techniques or activities that expose participants to discomfort or risk beyond that encountered in daily life.
- Deception of research participants.
- Classified research.

Choose ONE or MORE Exempt Categories from the list below. If your study meets NONE of the below listed criteria, leave the answers BLANK and click the Continue button:

☐ **Category 1** - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2** - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. Note: Research under this category cannot involve children or other vulnerable populations such as prisoners.

☐ **Category 3** - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are United States elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ **Category 4** - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. PLEASE NOTE: According to the Office for Human Research Protections (OHRP), to qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins. The principle

behind this policy is that the rights of individuals should be respected; subjects must consent to participation in research.

☐ **Category 5** - Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ **Category 6** - Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

✅ **The research does not meet any exempt category, or I am unsure if the research falls into one of the exempt categories.**

xxx

8 - Protocol Information

1.0   * **Type(s) of research this study involves:**   🔵

no **Chart/record review or analysis of data that's already been collected for another purpose**
no **Classified**
no **Devices**
no **Drugs/Biologics**
no **Focus group/group discussion**
yes **Intervention or testing: Neuropsychological/ cognitive/ psychosocial/ behavioral/ educational**
no **Interviews**
no **Specimen/sample collection or banking**
no **Survey/Questionnaire**
no **Use of existing banked specimens**
no **Other**

2.0   **Describe the purpose and goals of the study.**   🔵

Many forms of problem solving in children's everyday lives require them to remember information and manipulate these memories over short periods of time. For example, when playing "hide-and-seek", the child has to remember in which locations he has already searched and which ones remain and this information has to be constantly updated as the child continues his search. This ability to actively hold information in mind and manipulate it is commonly referred to as "working memory". According to Baddeley's model of working memory (Baddeley & Hitch, 1974), it is comprised of three components: a phonological loop that stores phonological information, a visuo-spatial sketchpad that stores visual and spatial information, and a central executive that directs information to the two other components. The phonological loop and the

visuo-spatial sketchpad undergo dramatic changes during development: Working memory capacity in both domains increases dramatically between 4 and 11 years of age (Gathercole, 1998; Alloway, Gathercole, Pickering, 2006). Previous research also indicates that memory capacity across components is correlated but that this association decreases with age (Alloway et al., 2006). The goal of the present study is to further investigate the relationship between working memory capacity in the phonological and visuo-spatial domains across childhood by developing novel methods to assess working memory capacity.

3.0	*** Describe the design and the methodology of the study.**

The study will employ a cross-sectional experimental design in which we are planning on recruiting 250 children between the ages of 4 and 10 years. Children will be asked to play a series of different memory games that assess different aspects of working memory (see details below). Tasks will be administered in randomized order to avoid any order or practice effects.

4.0	*** Describe the importance of the knowledge expected to result from the study.**

Working memory is a fundamental cognitive skill that is developing throughout childhood and linked to academic achievement. Understanding more about the mechanisms behind this development will have implications for teaching and education.

5.0	**Describe the study's procedures and activities that participants will be asked to perform or take part in, including the number and duration of sessions. If the study involves surveys, tests, interventions, or tasks, please describe them in detail here. If the study involves interviews or focus groups, explain the topics to be covered. You will be asked to upload these documents next.**

Children will be asked to complete three different tasks: a working memory (WM) span task, a Corsi block task, and a Flicker task. In the WM span task, the experimenter will read a sequence of letters or numbers increasing in length and the children will be asked to repeat the letters or numbers back in exactly the same order or backwards. In the Corsi block task, children will be shown an arrangement of nine blocks and the experimenter sequentially taps an increasing number of blocks. Children are then asked to repeat the tapping of the blocks in the same order or backwards. In the WM span and the Corsi block task, the initial sequence length will be two items and two trials of each sequence length will be administered until the child fails to produce the correct sequence for both trials of a given length. Each task will take about 5 minutes to complete. In the Flicker task, children will see images of different numbers of cartoon characters such as blue and yellow smiley faces on a computer screen that will flicker at a steady rate (e.g. 500 ms on-screen followed by 300 ms of blank screen). One of these faces will e.g. change its color between images and children are asked to detect this change and point to it as fast as possible. A total of 24 trials with varying numbers of characters will be administered to each child resulting in about 5 minutes of testing time for this task. Thus, total testing time will be about 15 minutes. On all three tasks, children will be praised for the completion of each trial but not be provided with feedback on their performance.

In addition, as an index of cognitive and verbal development, children's parents will be asked to complete the Developmental Vocabulary Assessment for Parents. This survey is an experimentally validated index of children's productive vocabulary, and will allow us to ask whether children's verbal working memory is related to their language development.

Parents will also be asked to complete a survey at the end of the study.

6.0	**Upload a copy of all assessments, surveys, questionnaires, tests, tasks, interview questions, or focus group questions. Please assign them a clear title.**

*Click **Add** to upload a new document. Click **Upload Revision** to upload a revised version of the*

*existing document. Do <u>not</u> delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

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Survey	History		1/5/2015 11:16 AM

7.0   *** Will any participants be audio recorded, video recorded or photographed?**

yes

8.0   *** Type of Recording:**

yes **Still Photography**
yes **Video**
yes **Audio**
no **Other**

xxx

9 - Deception

1.0   *** Do any of the research procedures, including tests and tasks, involve deception of any of the participants?**

no

xxx

13 - Recruitment and Participants

1.0   *** Who will recruit participants for this study?**

Check all that apply.

☑ **PI**
☑ **Study Team Member(s)**
☐ **Student Investigator**
☐ **No recruitment (Data analysis of existing data ONLY)**

☐ **Other**

2.0   *** Will you be specifically recruiting ANY of the following populations?**

Check all that apply.

☑ **Children (individuals under 18 years of age)**
☐ **JHU Students (all at least 18 years old. If you are unsure if all students will be 18, please select 'Children' as well)**
☐ **Johns Hopkins Employees**
☐ **Non-English Speakers**
☐ **Emancipated Minors**
☐ **Wards of the State**
☐ **Cognitively Impaired/Impaired Decision Making Capacity**
☐ **Pregnant Women**
☐ **Critically Ill or Injured Patients**
☐ **Prisoners**
☐ **Homeless or Economically Disadvantaged**
☐ **None**

3.0   *** Choose one of the following that applies to your research as it relates to children.**

☐ **The research presents no greater than minimal risk.**
☑ **The research presents greater than minimal risk but presents the prospect of direct benefit to the individual participants.**
☐ **The research presents greater than minimal risk and no prospect of direct benefit to the individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition.**

4.0   *** Sex of participants**

☑ **Male**
☑ **Female**

5.0   **Describe your participant population and how you will recruit them for the study.**

Healthy, typically developing children between the ages of 4 and 10 years will be included in this study.
Participants will be recruited according to the general procedures of the Johns Hopkins University Cognitive Development Laboratory. Brochures advertising the lab's activities will be posted in public places (public bulletin boards, pediatrician's offices (with permission), bookstores (with permission). We will also give brochures to the Maryland Vital Statistics Administration who will mail letters out on our behalf (*Note: we will not receive any confidential information through this process - we will only be able to speak to parents who are interested and contact us). Interested parents can send back a form (postage pre-paid) with their contact information. Once we receive this form, we will enter the child's name in our database and contact the parent(s) by phone. We will thoroughly describe our interests and activities, and answer any questions the parent(s) might have. If the parent(s) are interested in visiting the lab and their child is the right age, we will schedule them for a one-time visit (lasting approximately 45 minutes to 1 hour). If the parent(s) are interested in visiting the lab but their child is not of an age that we are currently testing, we will explain that we will call them back as soon as their child is of age. Parents will also be asked to participate in a brief survey.

Additionally, commercial mailing lists of parents of infants will be purchased from Experian. We will send letters of introduction to these parents, along with a response form they can send back, postage pre-paid, if they are interested in having their child participate in the lab's research We will telephone parents who have sent back these response forms in order to further explain the lab's interests, answer questions, and schedule an appointment if the parent wishes to do so and if the child is of an appropriate age. We will also try to telephone parents who have not mailed back a response form, in order to ask whether they are interested in hearing more about the possibility of scheduling their child for an appointment at the lab. If they are interested, we will follow the procedures described above for explaining the interests of the lab and scheduling an appointment. If the parent indicates that they do not wish to participate, or if they have been contacted in error (for instance, if they do not have children), we will move their names to a separate database of people whom we will not contact again. By cross-checking this database with our database of parents who are interested in participating, we can be more confident that we do not bother people who have already indicated that they do not wish to be involved with the laboratory's activities.

We also plan to share our list of interested parents with the Language and Cognition Lab, located in the Department of Cognitive Science and run by Dr. Barbara Landau. The Landau Lab already has IRB approval to test subjects. The main purpose of this sharing of names is to be sure that the two labs are not calling the same parents. By cross-checking our subject database with their subject database, we can better coordinate the recruitment efforts of the two developmental labs. If our databases do indeed contain some of the same subjects, we will discuss ways to make sure that the parents of these subjects are called only at reasonable intervals.

6.0   *** Provide the maximum number of participants to be enrolled.**

200

6.1   *** Provide justification for recruiting the above number of participants.**

sample size power analysis explanation

7.0   *** Describe measures that will be implemented to avoid participant coercion or undue influence.**

Parents always receive a full explanation of the experimental procedure prior to giving consent. Parents will be told that they can end the testing session at any point if their child becomes fussy or uncomfortable. This will also be written in the consent form which parents sign prior to the experiment.

8.0   *** List the criteria participants must meet to be <u>included</u> in the study. Please describe how you will verify that participants meet this criteria and how this will be documented in your study files.**

All healthy, typically developing children between the ages of 4 and 10 years will be included in this study. Parents of children within this age range will also be participants.

9.0   *** List the criteria for <u>excluding</u> individuals from the study.**

Children with known developmental delays or disabilities will be excluded from the study since we are trying to understand the trajectory of typical working memory development.

10.0   **If the participant is responsible for any research-related costs, identify and estimate the dollar amount.**

11.0   **Will participants receive payment (money, gift certificates, coupons, etc.) or be offered incentives (entered into a drawing, class credit) for their participation in this research?**

yes

12.0   **Describe payment and/or incentives to participants.**

Children will receive a small gift

13.0   *** Are you using recruitment materials/scripts?** 🔵

yes

14.0   **Upload recruitment materials here, including flyers, posters, email scripts, phone scripts, etc.**

Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)

Name	Description	Modified Date
View ASD_Parent_new.pdf		1/5/2015 11:08 AM

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14 - Risk, Benefits and Confidentiality

1.0   *** Describe the risks to participants and the steps for minimizing the risks. Please include risks that would be associated with loss of confidentiality and privacy.** 🔵

All data will be maintained separately from any identifying information by assigning each participant a number upon arrival in the lab. Any link between the participants name and their data will be maintained via this number in a secure file, and will only be maintained until the data have been adequately recorded.

The only anticipated risks are the frustration that can accompany more difficult cognitive tasks and the fatigue and boredom associated with long or repetitive testing. The participants (and parents of minors) will be clearly advised of these risks and their right to stop participation at any time. These tasks reflect standard procedures in cognitive psychology, however, and have been used extensively in adults and children.

2.0   *** Describe the potential benefit(s) to <u>participants</u>. If none, state this.**

The only benefit to the participants is that they generally enjoy visits to the lab, which involve friendly experimenters, bright playrooms, and engaging toys.

3.0   * **Describe the potential benefit(s) to <u>society</u>. If none, state this.**

The benefit to society is an improved understanding of cognitive development. In the case of the present project, we hope to more accurately characterize the development of children's working memory abilities. Although no pedagogical implications have been outlined at this point in time, understanding such aspects of cognitive development has the possibility of educational implications at a later point in time.

4.0   * **Will research data be identifiable, meaning linked to participants' identifiable information through a code or other way at any point in the study? (If audio recording, video recording, or still photography of participants will take place as part of the study, then the data are likely to be considered identifiable so please select "yes".)**

yes

5.0   * **Once all research data are collected, will research data be de-identified (no links or codes maintained)?**

yes

6.0   * **Describe how and when data or specimens will be de-identified, whether any links will be kept by anyone involved with the study, and who will have access to the links.**

Once we have confirmed that the correct data have been associated with each other, all reference to the participant's identify will be deleted. The only remaining identifier will be on the consent form, which will be stored securely and not contain information that can link that participant name back to the data.

7.0   * **Where will research data be kept and how will data be stored and secured? Describe security measures used to protect study data from loss or inappropriate use (locked office, password protection, restricted access to database, database backup etc.).**

All pencil-and-paper data are stored in a locked lab room, separated from the main laboratory. All electronic data files are stored on a secure server that is accessible only by password. The electronic data are also backed up on separate hard drives, stored securely in the laboratory. The laboratory remains locked at all times, and individuals can only access the computers using their personalized access accounts.

8.0   * **Indicate who will be responsible for collection and storage of data. Who will have access to research data?**

he PI and study team members will be responsible for data collection. The PI and senior graduate student in the lab will monitor all data storage. Only the research team members associated with a particular experiment will have access to the data. This will include team members who are responsible for running the experiments, scoring tests, and analyzing data.

9.0   * **How long do you plan to store the data? Please note that data must be kept by the PI for at least three years after the completion of the research. Describe how and when you plan to destroy the data.**

Data are stored for a minimum of three years following the publication of the results. In many cases, we store de-identified data for additional years because it allows us to do large, cross-experiment assessments in a large project like this one. When the three year limit is passed and data are no longer being tracked over the longer term of the project, all pencil-and-paper tests will be shredded, files will be securely deleted from computers, and dedicated hard drives will be destroyed.

10.0   **If the information being collected or analyzed is highly sensitive, do you plan to obtain a Certificate of Confidentiality?**

N/A

xxx

15 - Informed Consent and Consent Waivers – Adults

Please note that this section is only asking about informed consent from an ADULT who is participating in the research. If this is a study is involving <u>ONLY</u> CHILDREN, select 'None of the above' below. You will answer questions about assent and parental permission later.

1.0   *** Select all types of participant informed consent and/or waivers requested for this study.**

yes **Written Informed Consent**
no **Waiver of Written Consent (Oral Informed Consent)**
no **Waiver of Informed Consent or Alteration of Informed Consent**
no **Survey/questionnaire research (Exempt research only: Consent text added to beginning of survey rather than participants filling out a separate consent form)**
no **None of the above**

2.0   *** Describe the process for obtaining written informed consent/permission, including:**

        - where and when consent will be obtained
        - time allotted for obtaining consent
        - procedure to assess participants' understanding of the research
        - how information will be provided if non-English speakers may be enrolled.

At the time of the experiment, the study investigator will explain, to the participant, in very plain terms that the purpose of the study, The study investigator will then remind them that the study is voluntary, and provide the participant, at that time, with the Informed Consent form (attached). The participant will be given as much time as they need to read the form and, if they wish, sign the form. The study investigator will ask the participants if they have any questions before getting started.

We have no plans to enroll non-english speakers or individuals who are unable to provide their own consent.

3.0   *** Upload all of your Written Consent Forms for approval in Microsoft Word only.**

Please make sure your documents are clearly labeled and contain a title that accurately describes the type of consent to be obtained with the document. Under no circumstances should copies of these versions be distributed to participants. When this research submission is approved by the IRB, your consent forms will contain an IRB stamp.

*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do <u>not</u> delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

Name	Description	Modified Date
View AdultConsent		1/5/2015 11:12 AM

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16 - Assent and Parental Permissions - Children

1.0   *** Select the type of assent requested for this study.**

Assent should be obtained by means of a written form that the child signs, if appropriate given the child's age and abilities. If written assent is not appropriate, an oral assent procedure may be used, unless the child is too young to give assent, in which case a waiver should be requested.

yes **Written assent**
yes **Oral assent or Waiver of written documentation of assent**

* Justify the request for oral assent
As described in the application for review, this research involves no more than minimal risk to participants. Children are young and may not be able to sign their name but can be expected to give verbal permission.

no **Waiver or alteration of assent**
no **Other**

2.0   *** Describe the process for obtaining assent, including:**

- who will discuss the research with the child
- information that will be discussed
- how you will assess the child's understanding of the study
- any other information deemed to be important

The experimenter will read along with the child in the presence of the parent. The child will be given the general information about the project as well as the details for the specific experiment. The experimenter will ask the child to repeat what he/she is going to be doing and will emphasize to parent and child the right to stop at any point.

4.0   *** Assent form**

Please make sure your documents are clearly labeled and contain a title that accurately describes the type of consent to be obtained with the document. Under no circumstances should copies of these versions be distributed to participants. When this

research submission is approved by the IRB, your consent forms will contain an IRB stamp.

*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

Name	Description	Modified Date
View Assent_		1/5/2015 11:13 AM

5.0   *** Oral assent script**

Please make sure your documents are clearly labeled and contain a title that accurately describes the type of consent to be obtained with the document. Under no circumstances should copies of these versions be distributed to participants. When this research submission is approved by the IRB, your consent forms will contain an IRB stamp.

*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

Name	Description	Modified Date
View Assent_		1/5/2015 11:05 AM

6.0   *** Select the type of parental permission requested for this study.**

yes **Written parental permission**
no **Oral parental permission or Waiver of written documentation of parental permission**
no **Waiver or alteration of parental permission**
no **Other**

7.0   *** Describe the process for obtaining written parental permission, including:**

- where and when parental permission will be obtained
- time allotted for obtaining parental permission
- procedure to assess participants' understanding of the research
- how information will be provided if non-English speakers may be enrolled.

Parental permission will be obtained at the start of the study session. The experimenter will allow the parent to read the consent form, allotting as much time as is needed. The experimenter will encourage the parent to ask any questions and will go over key aspects of the study to ensure comprehension of all study procedures.

8.0   *** Written Parental Permission Form**

Please make sure your documents are clearly labeled and contain a title that accurately describes the type of consent to be obtained with the document. Under no circumstances should copies of these versions be distributed to participants. When this research submission is approved by the IRB, your consent forms will contain an IRB stamp.

*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

Name	Description	Modified Date

Name	Description	Modified Date
View ParentPerm		1/5/2015 11:05 AM

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Finalize Application

Additional Documents

You may upload any documents not requested in the application but which may help with the review process. You may also upload Human Participants Training certificates here.

*Click **Add** to upload a new document. Click **Upload Revision** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

Name	Description	Modified Date
There are no items to display		

To complete this Homewood IRB application:

- Click **Hide/Show Errors** above or below to check the application for completeness. All required fields must be completed in order to submit.
- Click **Finish** below to return to the New Application workspace.
- Finally, click **Submit** on the left side of the workspace.
- NOTE: ONLY THE PI CAN SUBMIT THE APPLICATION.

Study Team Conflict of Interest

1.0　　　**Study Team Member**

Carley Emerson

2.0　　　*** Does this study team member have a conflict of interest?**

3.0   *** Will this study team member serve as a non-conflicted designee?**

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AdultConsent(0.02) | History
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Assent_(0.01) | History
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