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***** Vulnerable Subject Checklist *****

Vulnerable Subject Checklist

Yes	No
N	Children/Minors
N	Prisoners
N	Pregnant Women
N	Fetuses
N	Neonates
N	Educationally Disadvantaged
N	Economically Disadvantaged
N	Cognitively Impaired
N	Other (i.e., any vulnerable subject population(s) not specified above)

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***** Study Sites *****

Study Sites

Select All That Apply :

International

International Site(s) (specify country, region, and township or village)

Local

- X UC Berkeley
UC Davis
UC Irvine
UC Los Angeles
UC Merced
UC Riverside
UC San Diego
UC San Francisco
UC Santa Barbara
UC Santa Cruz

Lawrence Berkeley National Laboratory

Alameda Unified School District (specify schools below)

Berkeley Unified School District (specify schools below)

Oakland Unified School District (specify schools below)

Other (Specify other Study Sites)

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*** General Checklist ***

General Checklist

- | | Yes | No |
|---|-----|--|
| N | | Is the research receiving any federal funding (e.g., NIH, NSF, DOD, etc.) |
| N | | Is another UC campus relying on UC Berkeley for IRB review by means of the UC System Memorandum of Understanding (MOU)? |
| N | | Is another institution relying on UC Berkeley for IRB review by means of an Inter-institutional IRB Authorization Agreement? |
| Y | | Will subjects be compensated for participation? |
-

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*** Funding ***

Funding Checklist

If the research is not funded, check the "Not Funded" box below. If the research is funded, add the funding source to the appropriate table below.

NOTE: Only the Principal Investigator (PI) of the grant or subcontract can add his or her own SPO Funding information in this section. The PI of the grant must also be listed in the Personnel Information section of the protocol in one of the following roles: Principal Investigator or Faculty Sponsor, Student or Postdoctoral Investigator, Co-Principal Investigator, Administrative Contact, or Other Contact. Training Grants can be added by anyone in one of the aforementioned roles. For step-by-step instructions, see Add SPO Funding Quick Guide

Not Funded

SPO - Funding

Funding - Other

Funding Type	Sponsor/Provider	#	Title	Amount	Begin	End	Narrative Description	Lead PI (If different from Protocol PI)
Unrestricted Campus Funds	[REDACTED]							

Funding - Other

Funding Type

Other

Unrestricted Campus Funds

Sponsor/Provider

#

Title

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Amount
Begin
End
Narrative Description
Lead PI
(If different from Protocol PI)

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***** Expedited Paragraphs *****

Request for Expedited Review

An expedited review procedure consists of a review of research involving human subjects by the IRB Chair, or by one or more experienced reviewers designated by the Chairperson from among the members of the committees.

In order to be eligible for expedited review, ALL aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures included in one or more of the specific categories listed below.

If requesting Expedited Review, select one or more of the applicable paragraph(s) below.
(DO NOT select any paragraph(s) if your protocol does not qualify for expedited review. Protocols that do not qualify for expedited review will be reviewed by the full (convened) Committee.)

1. Clinical studies of drugs and medical devices only when conditions (a) or (b) are met.
 - a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b) Research on medical devices for which
 - i) an investigational device exemption application (21 CFR Part 812) is not required; or
 - ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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3. Prospective collection of biological specimen for research purposes by non-invasive means.

Examples:

- a) hair and nail clippings in a non-disfiguring manner;
- b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- c) permanent teeth if routine patient care indicates a need for extraction;
- d) excreta and external secretions (including sweat);
- e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- f) placenta removed at delivery;
- g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth
- j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

- a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject of an invasion of the subject's privacy;
- b) weighing or testing sensory acuity;
- c) magnetic resonance imaging;
- d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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6. Collection of data from voice, video, digital, or image recordings made for research purposes.
- X 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
- a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b) Where no subjects have been enrolled and no additional risks have been identified; or
 - c) Where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
-

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***** Purpose, Background, Collaborative Research *****

Old CPHS # (for Protocols approved before eProtocol)

Study Title

Curiosity, Memory, and Learning in Adult Attention Deficit Hyperactive Disorder

Complete each section. When a question is not applicable, enter "N/A". Do not leave any sections blank.

1. Purpose

Provide a brief explanation of the proposed research, including specific study hypothesis, objectives, and rationale.

The purpose of this study is to examine intrinsic motivation, ie. curiosity and interest, and its influence on memory and learning, in young adults diagnosed with Attention-Deficit Hyperactivity Disorder (ADHD). ADHD is commonly characterized by difficulty with memory and attention; interventions to increase memory in this population are needed. There exists a plethora of research on the relation between dysregulated external motivation/reward processes and impaired learning/memory in children with ADHD. However, much less is known regarding the internal/intrinsic motivation processes in ADHD, and even less of their influence on learning and memory. The current proposal seeks to shed light on this understudied topic with the long-term goal of improving intervention techniques. Pilot data from this current project should inform later developmental investigations. We hypothesize that ADHD participants will demonstrate lower overall interest/curiosity. We also predict an interaction effect; participants with ADHD will show lower recall overall for information they are not curious about, and improved recall for information they are curious about, compared to adults without ADHD.

2. Background

Give relevant background (e.g., summarize previous/current related studies) on condition, procedure, product, etc. under investigation, including citations if applicable (attach bibliography in Attachments section).

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most common and chronic developmental disorders occurring across the life span (Boyle et al. 2011; Froehlich et al. 2007). The disorder, traditionally thought to be driven by inattention and impaired memory, has been shown to be associated with reduced academic and vocational achievement among those diagnosed when compared to their typically developing peers (Kuriyan et al., 2013). Newer models of ADHD posit that dysregulated motivation and reward responsivity may be one of the core features of the disorder, of which inattention and impaired memory are merely secondary symptoms (Volkow et al. 2011). There exists a plethora of research on the relation between dysregulated external motivation/reward processes and impaired learning/memory in children with ADHD. Extant psychobiological literature has consistently shown that individuals with ADHD demonstrate more frequent sensation and novelty-seeking than typically developing peers (White 1999;

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Gill et al. 1997), require stronger incentives to complete tasks than peers, and prefer smaller immediate rewards over delayed larger rewards (Plichta & Scheres, 2014). Taken together, these findings suggest that the interest threshold required for engagement with material is higher for those with ADHD than for their peers without the disorder. Whereas a plethora of research exists examining the effect of extrinsic motivators on behavior and learning in ADHD, much less work has investigated the role of intrinsic motivation, or curiosity, in the disorder. Even less is known of the influence of curiosity on learning and memory. This study, [REDACTED] aims to examine intrinsic motivation, ie. curiosity and interest, and its influence on memory and learning, in young adults diagnosed with ADHD.

Extant literature has demonstrated consistent motivational impairment in children with ADHD. Children with ADHD have been shown to require stronger incentives to modify their behavior than peers (Kollins et al., 1997); these findings have led to the development of several external reinforcement-based interventions to improve learning and broad task performance in young children and adolescents with ADHD. External reward-based interventions, however, become inappropriate and unsustainable as adolescents with ADHD enter tertiary education and the workforce, though demands on memory and learning remain high or increase. Curiosity, a malleable intrinsic motivator, has been shown to enhance academic achievement and aide learning in the general population (Gruber et al., 2014). Extensive focus has been placed on the effect of external motivators on performance in ADHD; little is known about the role that trait-based intrinsic motivators--like curiosity--play in the overall presentation of the disorder.

A growing body of research suggests that curiosity enhances declarative memory for trivia facts in children (Walín, O'Grady, & Xu, 2016; O'Grady, Simmons & Xu, in prep) and adults (Kang et al. 2009; Gruber, Gelman, & Ranganath, 2014; Dubey & Griffiths, 2017). In the typical version of such tasks, participants are presented with trivia questions from a variety of domains and asked to rate how confident they feel that they already know the answer as well as how curious they are to know the answer. Importantly, this task involves sustained attention to internally cued information. While research using the Continuous Performance Task (CPT) yields consistent deficits in sustained attention for people diagnosed with ADHD, these tasks are often understimulating, evoke little intrinsic motivation, and require a response to an externally cued piece of information. In several ways, the trivia question task is the exact opposite. The cue to the information is provided internally by the participant's subjective curiosity and task motivation.

We chose to focus on young adults with ADHD due to growing demand within this population for non-pharmacological therapies (Rutledge et al., 2012); findings from the present study may have implications for the development of cognitive therapies (e.g. mindfulness and gratitude based interventions) shown to enhance trait-based curiosity.

3. Collaborative Research

- a) If any non-UCB institutions or individuals are engaged in the research, explain their human research roles and what human subjects training they have/PI has planned to provide.

NA

- b) If any non-UCB institutions or individuals are collaborating in the research, complete the table below and

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attach any relevant IRB approvals in the Attachments section.

4. Qualifications of Study Personnel

- a) Explain expertise of Principal Investigator, Student/Postdoc Investigator, Faculty Sponsor (if applicable), any Co-Investigators or other key personnel listed in the application, and how it relates to their specific roles in the study team.

[REDACTED]

[REDACTED]

[REDACTED]

- b) In case of International research, describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, training). Also, explain your knowledge of local community attitudes and cultural norms, and cultural sensitivities necessary to carry out the research. See CPHS Guidelines on Research in an International Setting

N/A

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***** Subject Population *****

5. Subject Population

- a) **Describe proposed subject population, stating age range, gender, race, ethnicity, language and literacy.**

We plan to recruit a maximum of 38 participants between the ages of 18 and 40 from a larger and well-characterized sample of adults with ADHD. An additional 38 age- and gender- matched comparison participants will be recruited from the UC Berkeley RPP. Subjects will be excluded from participation in the control sample if they do not meet criteria for ADHD, based on responses to the ASRS.

All subjects will be required to be fluent and literate in English.

- b) **State the maximum number of subjects planned for the study. This number should account for all subjects to be recruited, including those who may drop out or be found ineligible. Explain how number of subjects needed to answer the research question was determined.**

The maximum sample size to be recruited is 76. A-priori power analyses suggest a required sample size of 30 per group, totaling 60 participants. Given estimated and predicted drop/out and ineligibility rates of 25% (based on prior studies), we plan to recruit an additional 16 participants in order to meet our required sample size of 30 per group, totaling 76 participants.

- c) **If any proposed subjects are children/minors, prisoners, pregnant women, those with physical or cognitive impairments, or others who are considered vulnerable to coercion or undue influence, state rationale for their involvement.**

N/A

6. Recruitment

- a) **Explain how, where, when, and by whom prospective subjects will be identified/selected and approached for study participation. If researcher is subject's instructor, physician, or job supervisor, or if vulnerable subject groups will be recruited, explain what precautions will be taken to minimize potential coercion or undue influence to participate. See CPHS Guidelines on Recruitment for more information.**

Prospective ADHD group subjects will be recruited from a pool of subjects who have previously participated in research studies conducted in the [REDACTED] Lab. These subjects have consented in the past to being contacted in the future for follow-up studies. The IRB#s for the studies in which participants previously participated and in which they consented to being contacted in the future for follow-up studies are: [REDACTED]. This second IRB is a multi-institutional study, UCLA IRB was responsible for the overall direction of the study at other institutions (UC MOU) and served as the IRB of record for the UC Berkeley site.

Prospective control group subjects will be recruited via the UC Berkeley Research Participation Program (RPP).

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In order to match subjects, subject recruitment will not be random, but based on gender, age, comorbid disorders, and current and past stimulant medication use, as much as is possible.

- b) Describe any recruitment materials (e.g., letters, flyers, advertisements [note type of media/where posted], scripts for verbal recruitment, etc.) and letter of permission/cooperation from institutions, agencies or organizations where off-site subject recruitment will take place (e.g., another UC campus, clinic, school district). Attach these documents in Attachments section. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information.

There will be a simple script for verbal or email recruitment of subjects. Scripts are attached in the Attachments section.

- c) Will anyone who will be recruiting or enrolling human subjects for this research receive compensation for each subject enrolled into this protocol? If yes, please identify the individual(s) and the amount of payment (per subject and total).

No, no research personnel in this study will receive compensation per subject enrolled.

7. Screening

- a) Provide criteria for subject inclusion and exclusion. If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for restrictions.

All subjects in the recruitment database will be contacted and invited to participate in the present study, as they previously met all basic eligibility for the current study when they were enrolled in the database. Updated information will be obtained during the phone screen to confirm that subjects are still eligible.

Inclusion Criteria for ADHD subjects:

- 1) Prior participant in research at UC Berkeley
- 2) Between ages of 18 and 40 at time of study participation
- 3) Physically and mentally able, in the opinion of investigator, to complete all required study procedures
- 4) Fluent in English

Additional Inclusion criteria for ADHD subjects:

- 1) Diagnosed with ADHD at time of prior research study participation

Exclusion Criteria for Control Subjects:

- 1) Control subjects that meet criteria for ADHD during screening will be excluded

- b) If prospective subjects will be screened via tests, interviews, etc., prior to entry into the "main" study, explain how, where, when, and by whom screening will be done. NOTE: Consent must be obtained for screening procedures as well as "main" study procedures. As appropriate, either: 1) create a separate "Screening Consent Form;" or 2) include screening information within the consent form for the main study.

Prospective subjects will be screened by completing the ASRS with project staff via phone. Project staff

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will complete a brief phone call with each interested participant prior to their inclusion in the study to confirm that the individual does not meet any of the exclusion criteria listed above. Project staff will not have any identifying information of the individual at this time other than the phone number which participants interested in being contacted for research provided; other than this phone number they will only have the individual's de-identified subject ID from prior research participation. [REDACTED], the graduate student investigator (who was in contact with this subject pool during their prior study participation and will be the only staff member with access to the subject pool database) will coordinate phone screening.

8. Compensation and Costs

a)

Describe plan for compensation of subjects. If no compensation will be provided, this should be stated. If subjects will be compensated for their participation, explain in detail about the amount and methods/ terms of payment.

Include any provisions for partial payment if subject withdraws before study is complete.

When subjects are required to provide Social Security Number in order to be paid, this data must be collected separately from consent documentation. If applicable, describe security measures that will be used to protect subject confidentiality.

If non-monetary compensation (e.g., course credit, services) will be offered, explain how

Participants will receive monetary compensation (\$40) OR RPP credits (3 credit hours) for their time.

b) **Discuss reasoning behind amount/method/terms of compensation, including appropriateness of compensation for the study population and avoiding undue influence to participate.**

The present study is expected to take 2.5 hours of the participants time. In order to compensate at a rate comparable to California minimum wage, we will compensate participants at a rate of \$16/hr. Participants participating for RPP credit will be compensated in 3 credit hours.

c) **Costs to Subjects. If applicable, describe any costs/charges which subjects or their insurance carriers will be expected to pay. (If there are no costs to subjects or their insurers, this should be stated.)**

There is no other cost to subjects.
There is no cost to subjects' insurers.

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***** Study Procedures, Alternatives to Participation *****

9. Study Procedures

- a) Describe in chronological order of events how the research will be conducted, providing information about all study procedures (e.g., all interventions/interactions with subjects, data collection procedures etc.), including follow-up procedures. If any interviews, questionnaires, surveys, or focus groups will be conducted for the study, explain and attach one copy each of all study instruments (standard and/or non-standard) in the Attachments section. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information. If the proposed research involves use of existing data/specimens, describe how data/specimens will be acquired.

We plan to recruit 25-30 participants from a larger and well-characterized sample of adults with ADHD. ADHD group participants will be recruited from a larger pool of individuals participating in a larger and ongoing longitudinal study of ADHD. An additional 25-30 age- and gender- matched control group participants will be recruited from UC Berkeley's Research Participation Program (RPP).

For all participants, there will be a phone session with a screening. We will use the Adult ADHD Self-Report Scale V1.1 (ASRS) measure to make sure all ADHD participants meet criteria for ADHD in the ADHD group, and to make sure that control participants do not meet criteria for ADHD. Once eligibility is confirmed, participants will be scheduled for their research visits. Consenting will be done by approved study team members [REDACTED].

We plan to follow a three-stage (screening, study, and recall) task paradigm outlined in Gruber et al. (2014). Task instructions will be given both verbally and in writing and trivia questions will be presented on a MacBook Air laptop running the Matlab programming language with the psychophysics toolbox. The same pool of 375 trivia questions presented in Gruber et al. (2014) will be used in the current study. In the screening stage, a set of high- and low-curiosity trivia questions are selected for each participant from a larger pool of questions based on self-report ratings of both confidence (i.e. "How likely is it that you know the answer?") and curiosity (i.e. "How curious are you about the answer?"). Both of these questions will be presented along with a likert scales from 1 to 6 and participants will be instructed to press the number key on a keyboard to indicate their response. The screening phase will continue until responses have been collected for 56 'high curiosity' questions (curiosity rating 4-6) and 56 'low curiosity' questions (curiosity rating 1-3). Questions that a participant rates as a '6' on the confidence scale will be excluded from this categorization scheme, as this response indicates that they already know the answer. Once the participant has responded to 112 included questions (56 'high' and 56 'low') they will take a 1-2 minute break and will then proceed to the study phase. We expect that the screening phase will last for 30 minutes to 1 hour due to the self-paced nature of the task.

During the study phase, participants will be asked to study these questions selected during the screening phase. In the study phase, participants will be presented with the same 112 included questions from the screening phase in randomized order. Each question will be presented for 4 seconds after which the participants will view a fixation cross for an additional 4 seconds followed by the answer presented for 1 second followed by an additional fixation cross for 4 seconds. We expect that the study phase will take 25 minutes to complete (13 seconds X 112 questions). After a delay of 22-24 hours, participants will be asked to return to the lab in order to complete the recall phase of the experiment. In the recall phase participants will be provided with a list of the trivia questions from the study phase in randomized order and will be ask

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will be provided with a list of the trivia questions from the study phase in randomized order and will be asked to spend 20 minutes to provide the answers to as many questions as they can remember.

After completion of the recall phase, participants will also be asked to complete the Five-Dimensional Curiosity Scale Revised (5DCR) and the PHQ-9, and Mental Health History Form (all attached). All questionnaires will be completed on paper. These measures will be used to assess general levels of curiosity as a trait, current levels of depressive symptoms, and overall mental health history.

b) Explain who will conduct the procedures, where and when they will take place. Indicate frequency and duration of visits/sessions, as well as total time commitment for the study.

Experimental procedures will be conducted by project staff who are pursuing BA-level degrees in psychology or a related field or who are graduate students in the Clinical Science program at UC Berkeley. Currently, this includes the project coordinator, [REDACTED], and research assistant [REDACTED].

Phone Screening is expected to last a maximum of 15 minutes.

Study visit will take place in the Berkeley Way West Building at UC Berkeley, in a small lab room.

In total, time commitment for this study is a maximum of 2.5 hours.

c) Identify any research procedures that are experimental/investigational. Experimental or investigational procedures are treatments or interventions that do not conform to commonly accepted clinical or research practice as may occur in medical, psychological, or educational settings. Note: if the study only involves standard research or clinical procedures, enter "N/A" here.

N/A

d) If any type of deception or incomplete disclosure will be used, explain what it will entail, why it is justified, and what the plans are to debrief subjects. See CPHS Guidelines on Deception and Incomplete Disclosure for more information. Any debriefing materials should be included in the Attachments section.

N/A

e) State if audio or video recording will occur and for what purpose (e.g. transcription, coding facial expressions).

No photographing, audio, or video recording will occur.

10. Alternatives to Participation

Describe appropriate alternative resources, procedures, courses of treatment, if any, that are available to prospective subjects. If there are no appropriate alternatives to study participation, this should be stated. If

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the study does not involve treatment/intervention, enter "N/A" here.

NA

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***** Risks and Discomforts *****

11. Risks and Discomforts

- a) Describe all known risks and discomforts associated with study procedures, whether physical, psychological, economic or social (e.g., pain, stress, invasion of privacy, breach of confidentiality), noting the likelihood and degree of potential harm.

There are no known risks associated with the behavioral procedures used in the present study.

The PHQ-9 is a standardized and objective clinical measure used to assess degree of depression severity via questionnaire, and includes questions probing thoughts of self-harm. All PHQ-9 questions are needed in order to determine depression severity, and as such participants will be asked about thoughts of self-harm and death. This may pose some risk/discomfort.

Current episode of major depressive disorder is a major and known influencer on memory, and as such the researchers in the present study will need to ensure that any results are not driven by current depression. The PHQ-9 will be used to confirm the absence of a current episode. In order to correctly score this clinical measure, follow standardized clinical protocol, and obtain an accurate score in order to determine absence or presence of depression, all questions must be administered (please see attached PHQ-9 for scoring procedures).

Should a participant endorse these thoughts via questionnaire, lead project coordinator and MA in Clinical Psychology, [REDACTED], will be contacted immediately, and will complete a clinical risk assessment with the participant to categorize participant's risk before termination of study participation. [REDACTED] will follow up as appropriate and determine appropriate course of action, based on results of risk assessment. If risk is deemed immediate (i.e. intent, plan, and means are endorsed) [REDACTED] will contact authorities. Mental Health resource sheet (attached) will be provided to all participants.

The other foreseeable risk, as in any study, is unintentional breaching of confidentiality. However, procedures to minimize such risk will include secure storage of paper and computerized data. Paper forms will be kept in filing cabinets in locked offices and deidentified so they do not contain any subject identifying information. Computerized data will be stored on password protected lab computers, and spreadsheets containing subject data will be encrypted. The master spreadsheet linking the subject's name and ID number will be stored with a different password, which only the PI and the grad student project coordinator, [REDACTED] will know.

- b) Discuss measures that will be taken to minimize risks and discomforts to subjects. In terms of minimizing a confidentiality breach, simply refer to section 13 (Confidentiality).

Subjects will be informed that they may terminate the session whenever they feel discomfort for any reason.

Paper forms will be deidentified (i.e. all subject names and identifying information will be removed, only the subject ID number will remain) and stored in filing cabinets in locked offices in PI's lab space.

Computerized data will be stored on password-protected lab computers and using subject ID numbers, no

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Computerized data will be stored on password-protected lab computers and using subject ID numbers, no identifying information will be used. There will be a password protected master spreadsheet linking subject names and ID numbers, and only the PI and project coordinator will know the password.

- c) **Discuss plans for reporting unanticipated problems involving risks to subjects or others, or serious adverse events, to CPHS. (This applies to all types of research.) See Adverse Event and Unanticipated Problem Reporting.**

Any unanticipated problem or serious adverse event (as defined in the CPHS Policies & Procedures) will be reported to the Director of the Office for Protection of Human Subjects as soon as possible (by fax, mail/delivery, phone, or email), but within no more than one week (7 calendar days) of the Principal Investigator learning of the incident. The Principal Investigator will submit a written incident report (via eProtocol), within no more than two weeks (14 calendar days) of learning of the incident.

- d) **Describe plans for provision of treatment for study-related injuries, and how costs of injury treatment will be covered. If the study involves more than minimal risk, indicate that the researchers are familiar with and will follow University of California policy in this regard, and will use recommended wording on any consent forms (see CPHS Informed Consent Guidelines).**

The study does not involve more than minimal risk. However, the PI is familiar with and will follow the University of California policy regarding treatment and compensation for injury.

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***** Benefits, Confidentiality *****

12. Benefits

Describe any potential benefits to the individual subject, group of subjects, and/or society. If subjects will not benefit directly from study procedures, this should be stated.

NOTE: Do not include compensation/payment of subjects in this section, as remuneration is not considered a "benefit" of participation in research.

There are no direct benefits to the subjects for participation in this research. Subjects will be made aware that even though there is no direct benefit to them personally, their participation may bring insights into the cognitive processes underlying learning, specifically in adults with ADHD.

13. Confidentiality and Privacy

NOTE: See CPHS Data Security Policy and Guidelines before completing this section.

a) What identifiable participant data will you obtain? Note: Audio, photo, and video recordings are generally considered identifiable unless distinguishing features can be successfully masked.

Signed consent forms will be obtained from subjects. These will be stored in a locked file cabinet in the PI's laboratory offices. The labeling of all materials is safeguarded so that a subject's identity is never made public. Some raw data will be stored on paper forms, on which only the identification number would be recorded. These would be stored in a file cabinet in an off-master-keyed room in the PI's laboratory offices.

The key linking names and identification numbers will be in the possession of only the Principal Investigator and lead graduate student ([REDACTED], graduate student in CS in Dept. of Psychology), in secure computerized form (i.e., on the project's computers in the PI's lab, in an encrypted password protected spreadsheet for which only the PI and [REDACTED] know the password).

Although any breach of confidentiality cannot be completely eliminated, our research group has never had such a breach and all relevant protections would be deployed to minimize such risk.

b) If obtaining existing data/specimens, will you have access to identifiers? Please see The Industry Alliance Office website for requirements when receiving existing data/specimens for research.

N/A

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c) Explain how the confidentiality of subject information will be maintained. Include:

i. Who will have access to study records/specimens?

Only trained research staff will have access to deidentified study data (records/specimens) and the key linking names and deidentification numbers.

ii. How the records will be secured (e.g., password-protected computer, encrypted files, locked cabinet). Response should be consistent with CPHS Data Security Policy.

Deidentified study data (records) will be secured on password-protected computers (for electronic/computerized data) and in file cabinets (for paper data) in locked offices in the PI's laboratory offices. The key linking names and identification numbers will be stored in an encrypted file on password-protected computers in the PI's lab offices, and only trained study staff will have access to this encrypted file.

iii. How long study data will be retained, including signed consent forms. Data retention specifications should adhere to the regulatory requirements applicable to the study (e.g. DHHS, OCR [HIPAA], FDA, etc.).

The data will not be destroyed at the end of the study; they will be stored for 10 years in computerized form in locked offices. Only trained project staff will have access to the data. The identifier key, to which only the PI and lead grad student, will have access, will be kept for as long as the data are kept: for 10 years in computerized form after the completion of the study.

Screening data for subjects who are screened and determined to be ineligible will be destroyed immediately after the screening phone call. Subject pool database will be updated stating simply that this participant was ineligible for the present study. A separate document, without identifying information or subject IDs, will be created to track reasons for exclusion (e.g., 3 individuals were above 40 years of age at time of contact and were therefore excluded from participation). This will be kept for 10 years in computerized form after completion of the study, along with study data.

iv. When audio/video recordings will be transcribed and when they will be destroyed (if ever).

N/A

d) Identifiers should be removed from data/specimens as soon as possible following collection, except in cases where the identifiers are embedded (e.g., voices in audio or faces in video recordings). If data are coded in order to retain a link between the data and identifiable information, explain where the key to the code will be stored, how it will be protected, who will have access to it, and when it will be destroyed.

N/A

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- e) Describe how identifiable data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit (e.g., prior encryption). If not applicable, enter N/A.

All identifiers linked to data would be separated on the day of study participation (this pertains primarily to self-report survey data). For all data, including computerized data, a password protected file that links identifiers to ID numbers would be stored only on computers of the PI and the lead grad student, in locked offices. This information will be kept for future reference if these subjects are recruited for future research projects.

- f) Will subjects be asked to give permission for release of identifiable data (e.g., for publications or presentations), now or in the future? If so, explain here and include appropriate statements in the consent materials. See Media Records Release Form template for guidance.

Individual subjects will never be identified in any presentation of the data.

- g) Explain how subject privacy will be protected (e.g., conducting interviews in a discreet location).

All procedures (phone screening, questionnaire completion) will be conducted in a private laboratory office to ensure subject privacy.

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***** Potential Financial Conflict of Interest *****

14. Potential Financial Conflict of Interest

Individuals who have independent roles in projects and who are responsible for the design, analysis, conduct, or reporting of the results of research performed (or to be performed) under a human subjects protocol must disclose whether or not they have a financial interest in or association with a sponsor, a company supplying or manufacturing materials, drugs, or devices being tested under the protocol, or any intellectual property used in the project. This checklist pertains to the entire project team working under the protocol. Any individual who has such an interest and/or potential conflict must comply with University regulations and procedures for disclosure of financial conflict of interest.

See Conflict of Interest Committee Website for more information.

Please answer the following questions:

Does any member of the project team (defined as UCB or non-UCB personnel working under the protocol) with substantive responsibility for the design, conduct, or reporting of activities under the protocol, or any member of their immediate family (defined as spouse, dependent child or registered domestic partner) have any of the following:

1. N Positions of management (e.g., board member, scientific advisor, director, officer, partner, trustee, employee, consultant) at a non-UC entity financing the research to be done under the protocol or at a non-UC entity supplying or manufacturing materials, drugs, or devices being tested under the protocol.
2. N Equity interest (e.g., stock, stock options, investment, or other ownership) in a non-UC entity financing the research to be done under the protocol or in a non-UC entity supplying or manufacturing materials, drugs or devices being tested under the protocol.
3. N Intellectual property used in the protocol, such as rights to a pending patent application or issued patent to any invention(s), or license rights or copyright for software that has a direct relationship to the project proposed.

If the answer to any of the above is Yes, then each individual with any "Yes" response(s) must submit a Human Subjects Financial Conflict of Interest Form and include it in the Attachments section of the protocol.

NOTE: When review by the COI Committee is required, CPHS approval of protocols will be contingent upon the disclosure and resolution of all financial conflicts of interest, as determined by the COI Committee.

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***** Informed Consent *****

15. Informed Consent

Add the consent documents and/or waivers needed for this research using the table at the bottom of the page, including any translated versions. For any translated consent, include an affirmation of the translation's accuracy, indicating who is affirming the accuracy (PI, Co-PI, or Student Investigator), in the Consent/Waiver Description or in the Attachment section. Describe the consent process and provide justification for any waivers for each consent document, translation, and/or waiver. The various consent/waiver options are described below.

Note: DO NOT include child assent documents, parent permission documents or waivers here (these are addressed in the next section).

Altered and Unsigned Consent - A consent document that has omitted required information and does not include a place for a participant's signature. This means that CPHS is being asked to waive one or more elements of consent in addition to the requirement for documented consent.

Altered Consent Form - A consent form that has omitted required information. This means that the CPHS is asked to waive one or more required elements of informed consent. For example, if the purpose of the study will not be disclosed to participants in order to avoid bias, this option should be selected because disclosure of the "purpose" is a required element of informed consent. The form must include a signature line and date line for the individual to sign if he or she agrees to participate.

Consent Form - A standard consent document that embodies all of the required information (elements of informed consent) designed to help an individual make an informed decision about whether or not to participate in the research. The form must include a signature line and date line for the individual to sign if he or she agrees to participate. The Consent Form can also be presented as a "short form" document stating that the required elements of informed consent have been presented orally to the participant. When the short form method is used, a "summary" of the information that is presented to the participant must also be provided for CPHS approval and there must be an impartial witness to the oral presentation. The witness must sign the summary as well as the short form and the participant must sign the summary. The "short form" method may be used in circumstances where oral presentation of consent is preferable or necessary, e.g., subjects are illiterate in English or their native language.

Consent Waiver - No consent will be sought at all. This means that the CPHS is asked to waive the requirement for informed consent. This option is often appropriate for research that involves use of existing data or samples

Unsigned Consent - A document that embodies all of the required information (elements of informed consent), but does not include a place for a participant to indicate with a signature that he or she agrees to take part in the research. This means that the CPHS is asked to waive the requirement for documented (signed) consent. For example, if consent will be obtained verbally or using a button on the web, this option

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should be selected.

- Informed Consent Guidelines, Templates and Sample Forms
- Informed Consent Policies and Procedures

Informed Consent

Consent/Waiver Description	Consent Document
Consent Form	CONSENT FORMV1

Informed Consent

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)

Consent Type	Consent Form
Attach Consent Document (in PDF format)	X Consent Document CONSENT FORMV1

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Consent will be obtained from trained study personnel in private lab spaces. No vulnerable subject groups are involved.

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***** Child Assent & Parent Permission *****

16. Child Assent and Parent/Guardian Permission

Add each child assent document, parent/guardian permission document, and/or waiver needed for this research using the table at the bottom of the page, including any translated versions. For any translated consent, include an affirmation of the translation's accuracy, indicating who is affirming the accuracy (PI, Co-PI, or Student Investigator), in the Consent/Waiver Description or in the Attachment section. Describe the consent process and provide justification for any waivers for each consent document, translation, and/or waiver. The various consent/waiver options are described below.

Altered and Unsigned Parent/Guardian Permission Form - A parent permission document that has omitted required information (elements) and does not include a place for a parent to indicate with a signature that he or she agrees to permit the child's participation. This means that CPHS is being asked to waive one or more elements of consent in addition to the requirement for documented consent.

Altered Parent/Guardian Permission Form - A permission form that has omitted required information (elements). This means that the CPHS is asked to waive one or more required elements of informed consent. However, the form must include signature and date lines for the parent(s)/guardian(s) to sign if the child is permitted to take part in the research.

Assent Document - A form or script of the information that will be conveyed to the child about the study. In general, researchers must obtain the affirmative agreement of children ages seven years and older for their participation. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of children, more than one assent form may be needed (i.e., an assent form suitable for a 15 year old is not usually suitable for a 7 year old child).

Assent Waiver - No child assent will be sought at all. This means that CPHS is asked to waive the requirement for child assent. Among other circumstances, this option is appropriate when the capability of the child to understand the research is too limited or when the research holds out a prospect of direct benefit that is important to the health or well being of the child.

Parent/Guardian Permission Form - A document that embodies all of the required information (elements of informed consent) designed to help the parent/guardian of a child make an informed decision about whether or not to permit the child's participation in the research. The form must include signature and date lines for the parent(s)/guardian(s) to sign if the child is permitted to take part in the research.

Permission Waiver - No parent/guardian permission will be sought at all. This means that the CPHS is asked to waive the requirement for parent/guardian permission. This option, for example, is often appropriate for research designed to study conditions in children or a study population for which parental

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permission is not a reasonable requirement to protect the children (e.g., neglected or abused children).

Unsigned Parent/Guardian Permission Form - A parent permission document that embodies all of the required information (elements of informed consent), but does not include a place for a parent to indicate with a signature that he or she agrees to permit the child's participation. This means that the CPHS is asked to waive the requirement for documented (signed) consent.

- **Child Assent and Parent Permission Guidelines, Templates, and Sample Forms**

- Policies and Procedures on Child Assent and Parent Permission

Documents and Waivers

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*** Attachments ***

17. Attachments

Add appropriate attachments (e.g., advertisements, data collection instruments, IRB approvals from collaborating institutions, etc.) in this section. Attachments MUST be in PDF format. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information.

CITI Certificate(s)

Document Type	Document Name	Attached Date	Submitted Date
CITI Certificate(s)	[REDACTED] 6	11/15/2019	11/15/2019
CITI Certificate(s)	[REDACTED]	11/15/2019	11/15/2019
CITI Certificate(s)	[REDACTED]	11/15/2019	11/15/2019

Other

Document Type	Document Name	Attached Date	Submitted Date
Other	375 Trivia Questions	11/15/2019	11/15/2019
Other	Mental Health Resources	11/15/2019	11/15/2019

Questionnaire(s)

Document Type	Document Name	Attached Date	Submitted Date
Questionnaire(s)	PHQ - Questions	11/15/2019	11/15/2019
Questionnaire(s)	ASRS.Questionnaire	11/15/2019	11/15/2019
Questionnaire(s)	Mental Health History Form	11/15/2019	11/15/2019
Questionnaire(s)	Curiosity-5DCR-measure	11/15/2019	11/15/2019

Recruitment Script(s)

Document Type	Document Name	Attached Date	Submitted Date
Recruitment Script(s)	EmailRecruitment.V1	11/15/2019	11/15/2019
Recruitment Script(s)	Verbal.Recruitment.V1	11/15/2019	11/15/2019

Document Type
Document Name

CITI Certificate(s)
[REDACTED]

Document Type

CITI Certificate(s)

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Document Name

[REDACTED]

Document Type
Document Name

CITI Certificate(s)

[REDACTED]

Document Type
Document Name

Other
375 Trivia Questions

Document Type
Document Name

Other
Mental Health Resources

Document Type
Document Name

Questionnaire(s)
PHQ - Questions

Document Type
Document Name

Questionnaire(s)
ASRS.Questionnaire

Document Type
Document Name

Questionnaire(s)
Mental Health History Form

Document Type
Document Name

Questionnaire(s)
Curiosity-5DCR-measure

Document Type
Document Name

Recruitment Script(s)
EmailRecruitment.V1

Document Type
Document Name

Recruitment Script(s)
Verbal.Recruitment.V1

Phone/Verbal Recruitment Script

Hello! My name is _____ from the [REDACTED] at UC Berkeley. I'm calling to let you know that we are conducting a new research study that we think you might be eligible to participate in. During your previous study participation you indicated an interest in being contacted about future research. I'd like to give you some information about our new study, and find out if you might be interested in participating. Is now a good time?

[If no] Okay. If you are interested in hearing about this opportunity, when might be a better time for us to call you back?

[If not interested] Okay, thank you for your time! Have a great day!

[If yes] Great! The purpose of this study is to examine the relationship between curiosity and memory in those with ADHD. If you agree to participate in this study, you will be asked to come in to the research lab twice over a period of 48 hours, and complete a set of memory tasks. We ask that you not take any ADHD medication on the day of your visit, and encourage you to discuss this possibility with your doctor. You will be paid a total of \$40 for your time.

Please keep in mind that you are in no way obliged to participate in this study, and whether or not you choose to participate will have no bearing on your relationship with [REDACTED], or UC Berkeley. Your participation is entirely voluntary and even if you decide to do this now and later change your mind that is perfectly ok.

Might you be interested in participating? Do you have any questions for me?

[If yes] Great! Do you have about 10 minutes available to answer some eligibility questions, and schedule a time for your visit?

[If unsure] Okay. Can I answer any questions for you? **[If no]** Okay, thank you for your time! Please call us back if you decide you might be interested in participating.

[If no] Okay, thank you for your time. Feel free to call us back if you change your mind!

Email Recruitment Template

<Dear *Participant Name*>

We hope this email finds you well! My name is [REDACTED], and I am a researcher with the [REDACTED] at UC Berkeley. During your previous study participation with us you indicated an interest in being contacted about future research. We are emailing you at this time to let you know that we are conducting a new research study that we think you might be eligible to participate in.

The purpose of this study is to examine the relationship between curiosity and memory in those with ADHD. If you agree to participate in this study, you will be asked to come in to the research lab twice over a period of 48 hours, and complete a set of memory tasks. We ask that you not take any ADHD medication on the day of your visit, and encourage you to discuss this possibility with your doctor.

You will be paid a total of \$40 for your time.

Please keep in mind that you are in no way obliged to participate in this study, and whether or not you choose to participate will have no bearing on your relationship with [REDACTED], or UC Berkeley. Your participation is entirely voluntary and even if you decide to do this now and later change your mind that is perfectly ok.

If you are interested in participating, please give us a call at XXX-XXXX or reply to this email with a few good times for us to call you.

Thank you for your time, and we hope to see you again soon!

**CONSENT TO PARTICIPATE IN RESEARCH***Curiosity, Memory and Learning in Adult Attention-Deficit Hyperactivity Disorder***Principal Investigator:** [REDACTED]**Graduate Student Investigator:** [REDACTED]**Key Information**

- You are being invited to participate in a research study. Participation in research is completely voluntary.
- The purpose of the study is to examine the role that curiosity plays in learning for adults with and without ADHD.
- This study will take up to 2.5 hours of time in the lab: one 2-hour lab visit and one 20-minute visit the next day. You will be presented with and asked to recall factual information (i.e. trivia) and you will be asked to complete questionnaires.
- Risks and/or discomforts may include discomfort sharing personal information about health and behavior, discomfort or cognitive fatigue, and the risk of breach of confidentiality.
- There is no direct benefit to you. The results from the study may help researchers develop behavioral interventions for adults with ADHD.

Introduction

[REDACTED] a faculty member in the Department of Psychology at the University of California, Berkeley, is currently conducting a research study. You are being invited to participate in this study because you either 1.) have participated in research with us previously, and indicated an interest in being contacted about future opportunities, or 2.) you have signed up to be a research participant through the Research Participation Program. Your participation in this research study is voluntary.

Purpose

The purpose of this study is to examine the relationship between curiosity and memory in those with ADHD. We hope to understand the role intrinsic motivators like curiosity play in ADHD to shed light on potential avenues of treatment and better understand ADHD itself.

Procedures

If you agree to participate in this study, you will be asked to come in to the research lab twice over a period of 48 hours. The procedures of each visit are outlined below.

Visit 1

At your first visit, you will be asked to learn a set of 112 trivia questions, beginning with a screening phase to measure curiosity. Then there will be a five minute break, followed by a learning phase to learn the questions. This session will take place in a lab room in the Berkeley Way West building. If you are diagnosed with ADHD and take medication for focus/attention difficulty you will be asked to not take your medication for both the 24 hours before the first visit, AND the 24 hours before the second visit (and

can resume right after the second visit if you'd like). All tasks will be administered via computer. These tasks are expected to last for about 2 hours, including breaks as needed.

Visit 2

You will be asked to return to the research lab approximately 24 hours after your first visit, and asked questions about the trivia facts learned during Visit 1. You will also be asked to complete a set of questionnaires. This will last about 30 minutes. After this component is complete, you will be reimbursed for your participation or provided with your RPP credit.

Study time: Participation in this study will take up to a total of 2.5 hours of your time.

Study location: All study procedures will take place in Berkeley Way West at UC Berkeley.

Benefits

You will not directly benefit from your participation in the research. However, the results of the research may help develop behavioral interventions for learning and memory in adults with ADHD.

Risks/Discomforts

- If you are asked to refrain from taking medications prior to a study visit, you may notice that your attention and behavior may be slightly more difficult to manage that day (i.e., your ADHD symptoms may increase). There are no known serious side effects from abstaining from the type of medications relevant to this study, however please contact your physician regarding any questions you may have about this medication washout request.
- You may be uncomfortable responding to questions about your mental health and behavior and/or become fatigued during the learning phase of the study. If you desire, a mental health resources sheet can be given to you at the end of your visit.
- **Breach of confidentiality:** As with all research, there is a chance that confidentiality could be compromised; however, we are taking precautions to minimize this risk.

Confidentiality

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used.

Any information that is obtained in connection with this study and that can identify you will remain as confidential as possible. It will be disclosed only with your permission or as required by law. To minimize the risks to confidentiality, information will be maintained by using an alpha-numeric code, instead of your name, in labeling all data and information collected from you during the experiment. Any paper questionnaires and the secret alpha-numeric code will be stored in locked cabinets in the laboratory that only the primary investigator will be able to access.

We will keep your study data as confidential as possible, unless it is certain information that we must report for legal or ethical reasons, such as child abuse, elder abuse, or intent to hurt yourself or others.

Retaining research records: When the research is completed, study records will be saved for up to 10 years for possible use in future research. The same measures described above will be taken to protect confidentiality of this study data.

Clinically relevant research results, including individual research results, will not be disclosed to subjects.

Compensation/Payment

You will be compensated \$40 for your participation in this study. If you are participating in this study through the Research Participation Program (RPP), you will be awarded 3 credits.

Study Name: Curiosity and Memory

Study Type: Standard (lab) study

This is a standard lab study. To participate, sign up, and go to the specified location at the chosen time.

Duration: 2.5 Hours

Credits: 3 credits

Abstract: This is a memory task designed for adults to examine how curiosity impacts learning.

Description: On the first day, participants will rate their curiosity about trivia facts, then will learn the trivia facts (approximately 2 hours). On the second day, participants will complete a short recall task and complete some survey questionnaires about their behavior and health (approximately 30 minutes).

Preparation: Study Location: [REDACTED] Berkeley Way West Building (2121 Berkeley Way). Please arrive on time (not Berkeley time).