Date: 11-11-2024

IRB #: FY23-24-62
Title: Utilizing Response Time Assessments of Cognitive Function
Creation Date: 10-23-2023
End Date:
Status: Approved
Principal Investigator: Bryanna Scheuler
Review Board: UTSA IRB
Sponsor:

Study History

Submission Type Initial	Review Type Exempt	Decision Exempt - Limited IRB

Key Study Contacts

Member Bryanna Scheuler	Role Principal Investigator	Contact bryanna.scheuler@utsa.edu
Member Bryanna Scheuler	Role Primary Contact	Contact bryanna.scheuler@utsa.edu
Member Joseph Houpt	Role Co-Principal Investigator	Contact joseph.houpt@utsa.edu

Initial Submission

Getting Started

About Cayuse IRB

Cayuse IRB is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. You do not have to finish the application in one sitting. All information can be saved.

Additional information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark at the top-right corner of each section.

Important: Once you have completed your application, it must be Certified before it is sent to us for review. Your study status will show "Awaiting Certification" if it has not been certified. The study will not be in our queue until the status is "Under Pre-Review" or "Under Review". Please visit Cayuse Certification Steps on how to certify your study.

For more information about the IRB submission Process, IRB Tracking, and Cayuse IRB Tasks, please refer to the Cayuse IRB Procedures Manual.

UTSA IRB

- You must have a formal approval letter from the IRB before beginning data collection.
- The IRB meets on the third Wednesday of each month to review studies that are greater than minimal risk. Applications that need review by the Board should be submitted at least four weeks prior to the meeting.
- Please visit the IRB website for IRB Meeting Dates and Deadlines.

Information to Have Available

Throughout the submission, you will be required to provide the following:

- Detailed and Consistent Study Information
- Informed Consent Form(s)
- Study Recruitment Document(s)
- Questionnaires, Interview Guides, and Other Data Collection Instruments
- Site Approval for Off-Site Studies
- Grant Proposal if Funded

Documents to Upload

- Documents that you attach may be submitted as Word or .pdf documents.
- All documents that will be stamped (e.g., consent forms, recruitment flyers) should be submitted in .**pdf format only**.

*required

I have read the information above and am ready to begin my submission.

✓ Yes

Submission Information

*required

Identify the nature of your research study

Are either or both of these statements true?

1. The research is a systematic investigation, including research development, testing, and evaluation.
2. The activity is intentionally designed to develop or contribute to generalizable knowledge.

✓ Yes

Yes, however I am analyzing a de-identified dataset.

- *Do not select if you are administering anonymous surveys.*

No

I'm not sure.

*required

What type of activity is this submission?

✓ Research Study

Clinical Trial

*required

Do you wish to add the data or materials to a new or existing data repository or data registry?

*Research repositories (also called registries, banks, or libraries) are used to store data and/or biospecimens for **future research use**, either by the research team who collected them or to share with other researchers.*

Yes

✓ No

*required

Is this a multi-institutional study?

Answer yes if you are collaborating with investigators from other institutions.

Yes

✓ No

*required

Study Background

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*Briefly state the purpose, specific aims, or objectives of this research (do **NOT** include a Literature Review).*

Aim 1: Pilot three cognitive tasks in a normal population, providing an avenue for feedback on streamlining and perfecting the assessments.
Aim 2: Fit the response time distributions from the tasks with response time models, to establish typical model parameters.
Aim 3: Use the response time distributions to determine if it is possible to reduce the number of trials while maintaining the stability of results.
Aim 4: Use the feedback and results from this study to inform methodology in future projects assessing cancer-related cognitive impairment in cancer survivors.

*required

Risk to Subjects

Do you consider this research study to be:

✓ Minimal Risk (*Something that a normal person would expect to encounter in his or her daily life.*)

More than Minimal Risk (*This level of risk could place participants at risk of civil or criminal liability; damage their financial standing, employability or reputation; or place them at risk of emotional or physical damage.*)

*required

Potential Benefit to Participants

Do not include compensation here.

None

Direct benefit to participant

✓ Benefit to society

*required

Describe

Piloting these cognitive tasks with the current population is a crucial first step to utilizing these methods to assess cancer-related cognitive impairment in cancer survivors.

Other

Research Status

*required

What is the principal investigator's status at UTSA?

Faculty

✓ Student

*required

Undergraduate Student

✓ Graduate Student

Staff

Other

Study Personnel

Note: If you cannot find a person in the people finder, please email IRB@utsa.edu.

*required

Principal Investigator

Provide the name of the Principal Investigator of this study.

Name: Bryanna Scheuler
Organization: HCAP PSYCHOLOGY
Address: , San Antonio, TX 77573-6287
Phone:
Email: bryanna.scheuler@utsa.edu

*required

Primary Contact

Provide the name of the Primary Contact of this study.

Name: Bryanna Scheuler
Organization: HCAP PSYCHOLOGY
Address: , San Antonio, TX 77573-6287
Phone:
Email: bryanna.scheuler@utsa.edu

*required

Faculty Sponsor

Provide the name of your Faculty sponsor.

Name: Joseph Houpt
Organization: HCAP PSYCHOLOGY
Address: One UTSA Blvd , Fair Oaks Ranch, TX 78249-1644
Phone: 2104587558
Email: joseph.houpt@utsa.edu

Co-Principal Investigator(s)

Provide the name(s) of Investigator(s) for this study.

Other Personnel

Provide the name(s) of other personnel for this study.

Note: All study personnel will need to complete the following:

1. *The human subjects training course: "Social/Behavioral Research" or "Biomedical Research" course offered through CITI. See instructions. Must be taken at least within the last three years.*
2. *Conflict of interest training. Must be up-to-date for this calendar year.*
3. *Disclosure of financial interests Must be up-to-date for this calendar year.*

Studies will be approved only after each study personnel has completed all three requirements.

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*required

Study Personnel Affiliation

Are all personnel affiliated with a university?

- ✓ Yes
- No

*required

Study Site(s)

Please select the location(s) of the study.

- ✓ On UTSA campus
- External Collaborating Site(s) (e.g. Schools, Hospitals, etc.)
- External Public Site(s) *(e.g., Starbucks)*

Provide the name(s) of the site(s).

- ✓ Online

Provide the platform (e.g. MTurk, Qualtrics, etc.)

Pavlovia

*required

Funding Status

Is the research funded?

Yes

✓ No

Participant Information

*required

Participant Description

List inclusion criteria, such as: "Hispanic adult women enrolled in their last year of the EHD-ELPS program"

members of the UTSA community

*required

Exclusion Criteria

Describe the exclusion criteria that will be used to exclude participants described above from your sample.

-Unable to read and understand English instructions; -Unable to hear an auditory prompt played over computer speakers; -Unable to access the internet on a personal device that can play sound AND unable to come to UTSA Main Building to access a lab computer

*required

Number of Participants

Please enter the maximum number of participants to be enrolled at all study sites.

60 participants

*required

Ages of Participants

Select the age range of participants that will be enrolled in this study. Check all that apply.

fetus

✓ birth to less than 18 years old

*required

Number of participants less than 18 years old

Complete and upload Children's Checklist

up to 60 , if no participants above 18 years of age elect to participate

✓ 18 years and older

*required

Number of participants 18 years and older

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up to 60

*required

Vulnerable Populations

Please check the population(s) that will be enrolled. Check all that apply.

Fetuses

Minors with Parental Consent

Minors Who can Consent Themselves *(e.g., emancipated minors)*

Pregnant Women (only if they are a target population)

Prisoners

Decision Impaired Adults

Other

✓ Not Applicable

*required

Special Considerations

Check the box if any of the considerations apply to your population.

- [ ] Non-English speaking *(A translated consent form will be needed for the subject's native language in a different section of this form.)*
- [ ] Students in PI's class *(specifically for faculty PI)*
- [ ] Employees under the direct supervision of the PI
- [x] None

*required

Necessity of Inclusion

Provide justification for the inclusion of children.

This study provides an opportunity for students enrolled in the Introduction to Psychology course to receive research participation credit. If we were to only allow students above 18 years of age to participate, students younger than 18 would not receive the same opportunities as their classmates.

*required

Special Arrangements

Describe any special arrangements to protect the participant's safety. Examples: equipment to support autistic children with specific sensitivities

No special arrangements will be included; If participants feel uncomfortable, they can withdraw at any time.

*required

Assent

How will you obtain assent? Assent means the ability of children to state whether or not they wish to participate in the research.

After reading a screen describing the study, participants will be able to select a button to either continue to the experiment or end the study. In addition, the participants will be able to end the study at any time by pressing the 'esc' button on their keyboards or closing the internet tab (as explained in the informed consent).

*required

Foreign Country

Will any data collection occur in a foreign country?

- Yes
- ✓ No

Study Procedures

*required

Study Design

- [x] Quantitative
- [ ] Qualitative
- [ ] Mixed Methods

*required

Recruitment Methods

Check all that apply and submit related documents.

- [ ] Recruitment via flyers, handouts, or web announcements.
- [ ] Recruitment via verbal methods.
- [x] Established Participant Pools (Business/Marketing Pool or Psychology - ***Approval is required by department***).

  *required

  Attach the approval document from the Department of Psychology or Marketing, if using the subject pool.

  RTCog_Signed SONA Form.pdf

- [ ] Recruitment via email
- [ ] Not Applicable

Compensation and Incentives

Will you provide any compensation, incentives, or giveaways for participation?

✓ Yes

*required

Describe the type of compensation (e.g., cash, class credit, raffle, gift card, etc.) Include type of gift card (e.g. Amazon, Starbucks, etc.)

Credit towards course requirement

*required

Provide the amount of compensation. Include pro-rating when applicable.

0.5 credits for 30 minutes of participation

*required

Describe when the participant will be compensated. (e.g., when the participant has completed his/her participation, after study has ended, etc.)

Explain time spent per session, multiple data points/interviews, study phases, etc. for participants.

After completion of session.

No

*required

Recruitment Methods

Briefly describe when, where, how, and by whom participants will be recruited.

This experiment will be posted on the online research enrollment platform called SONA, which is commonly used for student research participation.

*required

Total Participant's Time

How much total time will the participant be expected to participate?

30 minutes

*required

Participant Activities Timeline

Briefly describe, in timeline sequence, all the activities participants will be asked to perform specifically for the research, and how much time each activity will take. Specific dates are not necessary.

Upon either following the link to the Pavlovia experiment on a personal computer or sitting at a lab computer containing the Pavlovia experiment:
-Read the informed consent screen, then select to accept or decline [approximately 2 minutes]
>If declined: Experiment ends
>If accepted:
-Participants select their age group, gender, ethnicity/ race, and device type [approximately 2 minutes]
-Cognitive task begins, with instructions informing the participant which keystrokes to use for each type of response time task (e.g., hold down the green button until the bar has filled to the target line, or hold down the green button until the arrows turn green) [approximately 20 minutes]
-Participants provided with a Likert scale to answer if they felt mentally fatigued after completing the study [approximately 1 minute]
At this point, the Pavlovia experiment will provide a "Thank you for participating" message with the contact information of the primary investigator listed

Study Procedures

Check all that apply and submit related documents.

- Survey/Questionnaires
- Interviews
- Audio Recording
- Video Recording
- Diaries or Journals that will be kept by participants

Still Photography

Focus Group

Observation *(specifically for the research project)*

Deception

✓ Other

*required

Describe.

Participants will complete a series of trials on cognitive tasks that collect response time and accuracy for each trial

*required

List and describe all study procedures that everyone is required to do regardless of whether or not they participate in the research *(e.g., required class assignments, data collected during required student activities, etc.)*.

Answer "NA" if not applicable

N/A

Records and/or information sources that will be specifically accessed to collect data about participants for this research study.

Check all that apply.

✓ Not applicable

Existing data

Publicly available dataset

Restricted datasets

Coded *(already coded data that can be linked to a participant by use of a "code key"*

Future information *(e.g., data does not currently exist)*

Anonymous *Dataset (No identifiers are available in/from the sources)*

*required

Genetic Testing

Will this study involve genetic testing?

Yes

✓ No

*required

Drugs, Devices, Biologics, or Nutritional Supplements Also see: Investigational Device Worksheet

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Will the study involve administering any of the following? Check all that apply.

Drug

Biologic

Device

Nutritional Supplement

✓ None of the above

*required

Participant Data, Specimens, and Records

Does this project involve the collection or use of materials (data or specimens) recorded in a manner that could identify the individuals who provided the materials, either directly or through identifiers linked to these individuals? This includes interviews, audio/video recordings, and other forms of data obtained from participants.

Yes

✓ No

*required

Community-Based Participatory Research (CBPR)

Is this research CBPR?

Yes

✓ No

Data Management

*required

Data Analysis

Briefly describe your data analysis plan.

-Response time distributions will be generated for each participant
-Response time models will be fit to these distributions to obtain model parameters (e.g., drift rate, response threshold, non-decision time)
-T-tests will be used to assess potential differences in parameters based on device type or demographic information
-A power analysis will be computed with the trials to assess what is the minimum number of trials necessary to provide accurate model parameters

*required

Data Location

Where will your data be stored, short-term and long-term? Check all that apply.

- ✓ UTSA owned computer
- ✓ Study personnel's computer
  *required
  - Encrypted
  - ✓ Password protected computer
  - Password protected file
- External storage device/hard drive
- Other

*required

Data Storage

How long will the data be kept?

- ✓ Per UTSA policy *(see Help using the question bubble to the right)*
- Other

*required

Who will have access to the data?

Check all that apply.

- ✓ Study personnel listed on approved IRB documents
- Registries *(Data Repositories, Data Banks, Health Information Data Registries)*
- Funding agency for grant project
- Other

*required

Will data be stored for future use (*as yet unknown)?*

- ✓ Yes

*required

Describe your data sharing procedures

- Data will NOT be shared with others
- ✓ Data will be de-identified prior to sharing
- Other

No

*required

Encryption

Check all encryption methods that apply.

- ✓ Computer
- Study and data files
- External storage device/hard drive
- None

*required

Password Protection

Check the methods of password protection that study personnel will use.

- ✓ Computer
- Files
- External storage device/hard drive
- Other
- None

*required

Data Security During Use and Transmission

Check all that apply.

✓ Data will be collected without identifiers

Data review and analysis will be done in a secure/private space/office

Review and analysis of **identifiable data** will be done in a secure/private space/office

A certificate of confidentiality will be obtained (for NIH studies)

Data will be de-identified prior to sharing/transmitting

✓ All research staff will be trained on the proper handling of confidential data or information

No data will be shared or transmitted for this research study

Other

Important Note Regarding Data Ownership: UTSA owns intellectual property (IP) including research data created by UTSA employees, as explained in the IP policy, HOP 10.15. Students own the IP and data they create unless one or more of the following conditions are met:

1. they are working with a faculty member or mentor on a project,
2. they are employees and the IP is developed within the scope of employment,
3. they develop the data/IP as part of a sponsored program, OR
4. they use UTSA owned equipment.

Students are responsible for safeguarding all data and IP whether owned by UTSA or the student; this includes proper storage, access, and destruction. Students are responsible for immediately notifying the faculty member, researcher, mentor, or appropriate university personnel they are working with as soon as the student is aware of a breach or release of data/IP. Students leaving the university with any student-owned IP or data are still responsible for safeguarding the data/IP.

For more information check the HOP policy or contact the Office of Commercialization and Innovation at (210) 458-6963.

Participant Protection

NOTE: Privacy refers to a person's desire to place limits on with whom they interact or to whom they provide personal information.

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*required

Location of Interactions

Where will interactions with participants occur? Check all that apply.

- [ ] Public spaces
- [x] On-line
- [x] Private office/space
- [ ] A location the participant selects
- [ ] Other

*required

Research Interactions

Who will be involved in the research interactions with participants? Check all that apply.

- [ ] PI only
- [x] Research staff listed on this protocol
- [ ] Other participants
- [ ] Other

*required

Confidential Records Collection

Do you intend to request confidential records about your research subjects from the participants or from parties with access to those records?

- Yes
- ✓ No

*required

Informed Consent

How will you obtain consent from the participants?

- Written, with participant signatures. I agree to follow the Investigator Guidance: Informed Consent (HRP-802) and Investigator Guidance: Documentation of Informed Consent (HRP-803).
- ✓ Written, online. Participants will indicate their consent via online methods.
- Verbal. Consent will be noted in each participant's research record and information for consent will be contained in the Information Sheet.
- Consent will not be obtained.

*required

Describe your consent process.

At the beginning of the computerized experiment, the participants will read a statement explaining that after reading the instructions, they will complete a series of trials where they are asked to press a button on their device based on verbal and/or audio cues. This informed consent will explain that they will not be penalized if they elect not to continue the study, and that they can exit the study at any time by pressing the escape key. If they decline, the experiment will present a "Thank you for your time" screen before automatically closing. If they accept, the experiment will continue with the demographic information and cognitive tasks.

Personal Identifiers

Will identifying information be collected or maintained?

- ✓ No, the participants will be anonymous.
- Yes, personal identifiers will be collected.

Data Coding for Confidentiality

Please indicate how identifiers will be separated from data

- PI will create a coding system *(e.g., letter/number combination)*
- Pseudonyms
- Other
- ✓ Not applicable

Attachments

Outside IRB of Record

Study Protocol

Attach the protocol for this study that was reviewed by the Outside IRB.

Outside IRB Approval

Attach the IRB Approval from the Outside IRB.

Outside IRB Review Meeting Minutes

Attach the minutes from the outside IRB meeting(s) for the review of this study.

Outside IRB Correspondence

Attach all correspondence concerning the review of this study by the Outside IRB.

Study Procedures

Recruitment Materials

If applicable, this includes flyers and scripts used for recruitment. This should include any written/visual materials meant to be seen or heard by subjects.

Data Collection Instruments

Attach all instruments (i.e. surveys, interview questions) to be used in the study.
RTCog_Assessments.docx

Advertisements

Any printed, audio, or video advertisements used for recruitment.

FDA Letter

Miscellaneous Attachments

RTCog_Children-Checklist.pdf

Informed Consent Documents

Attach consent document(s) **in .pdf format**, even if consent will not be documented in writing. (Note: Non-English versions should be submitted after English versions are approved.)

Informed Consent Form (See consent form template and consent information form.)

Upload only in .pdf format.
RTCog_SONA_Informed Consent.pdf