
Title : Behavioral studies of decision making and executive function
Approval Period: 03/13/2024 - 02/28/2025

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CITI Training current				Y
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CITI Training current				Y
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CITI Training current				Y

Participant Population(s) Checklist

Yes/No

- | | |
|---|---|
| • Children (under 18) | N |
| • Wards (e.g., foster children, incarcerated youth) | N |
| • Pregnant Women | N |
| • Impaired Decision Making Capacity | N |
| • Cancer Subjects | N |
| • Laboratory Personnel | N |
| • Healthy Volunteers | Y |
| • Students | Y |
| • Employees | N |

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- Prisoners N
 - Other (i.e., any population that is not specified above) N
 - International Participants N
- Please enter the countries separated by comma
-

Study Location(s) Checklist**Yes/No**

- Stanford University Y
- Other (Click ADD to specify details)

General Checklist**Collaborating Institution(s)****Yes/No**

- Are there any collaborating institutions? N

Payment or Reimbursement**Yes/No**

- Subjects will be paid/reimbursed for participation? See payment considerations. Y

Funding**Yes/No**

- Training Grant? N
- Federally Sponsored Project? Y

Funding**Funding - Grants/Contracts****Funding Administered By :** STANFORD**SPO # (if available) :**

134043

Grant # (if available) :**Funded By (include pending) :**

NIMH

Principal Investigator : Russ Poldrack**Grant/Contract Title if different from Protocol Title :**

Y For Federal projects, are contents of this protocol consistent with the Federal proposal?

Y Is this a Multiple Project Protocol (MPP)?

Y Is this protocol under a MPP?

Funding Administered By : STANFORD**SPO # (if available) :**

245169

Grant # (if available) : 1R01MH13089802**Funded By (include pending) :**National Institutes
of Health**Principal Investigator :** Russell Poldrack**Grant/Contract Title if different from Protocol Title :**

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Data-driven validation of cognitive RDoC dimensions using deep phenotyping	
--	--

- | | |
|---|---|
| Y | For Federal projects, are contents of this protocol consistent with the Federal proposal? |
| N | Is this a Multiple Project Protocol (MPP)? |
| N | Is this protocol under a MPP? |

Funding - Fellowships**Gift Funding****Dept. Funding****Department Name :** Psychology**Other Funding****Resources :****a) Qualified staff****State your and/or your study staff's qualifications to conduct this study.**

The protocol director and the post doctoral scholars both have a PhD in psychology and have previously conducted many behavioral studies. All other staff will be specifically trained on the procedures for this study and be overseen by the protocol director or post doctoral scholars.

b) Training**Describe the training you have received regarding the research-related duties and functions of this protocol. Also, describe the training received by study staff assisting you with the research.**

In addition to CITI Human Subjects Research training, all personnel will be trained in specifics related to this protocol and will attend regular meetings regarding the research-related duties of this protocol.

c) Facilities**Describe where the study will take place, including where data will be collected and where it will be analyzed.**

Data acquisition will take place in either Jordan Hall where there are specific lab rooms for behavioral testing or on Amazon Mechanical Turk or via Prolific.

d) Time**How much time will be needed to conduct and complete the research?**

This will be an ongoing study. There are sufficient staff, training, and access to participants to allow completion of this study in the allotted time. Should more time be necessary, we will file for a renewal at that point.

e) Participant access**Will you have access to a population that will allow recruitment of the required number of participants?**

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Subject recruitment will occur through a variety of means, including Stanford student subject pools, flyer, advertising in local media, and Amazon Mechanical Turk. Using a combination of these recruitment methods, we anticipate that we will be able to recruit a sufficient number of subjects.

f) Access to resources

Will you have access to psychological resources that participants might need as a consequence of participating in the research? If yes, describe these resources. Enter N/A if the need for psychological resources is not anticipated.

We do not anticipate any negative consequences resulting from our research. Should the participant feel uncomfortable, they can end the experiment at any point.

Expedited Form

Review your expedited paragraph selection(s) below. Make changes as applicable.

1. Clinical studies of drugs and medical devices (medical studies only)
2. Collection of blood samples (medical studies only)
3. N Prospective collection of biological specimens for research purposes by non invasive means.
Example: Collection of saliva or cheek swabs
4. N 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.
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 or an invasion of the subject's privacy;
 - b) Weighing or testing sensory acuity;
 - c) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. N Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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.)
6. Y Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Y 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 from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

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1. Purpose

a) **In 3-5 sentences, state the purpose of the study in lay language.**

The purpose of this study is to understand human decision making, executive control (the management and coordination of cognitive processes), learning, and memory and develop and advance related research methods. One specific aim of interest is developing methods to understand how behavioral change can be maintained over time.

b) **State what you hope to learn from the study and assess the importance of this new knowledge.**

Decision making, executive control, learning, and memory are four fundamental cognitive processes. Advancing the fundamental understanding of these processes is important to a number of fields, including but not limited to psychiatry and medicine. The specific aim to develop methods to encourage individual to make better choices has many potential applications, including but not limited to reducing obesity and drug abuse.

2. Study Procedures

a) **i) Describe ALL the procedures human participants will undergo. ii) Are the research procedures the least risky that can be performed consistent with sound research design? iii) For research involving collaborators, please specify the respective roles of Stanford and each collaborator on the protocol.**

We estimate that we will run 60 experiments in this line of research.

Subjects will participate in 1 to 20 experimental sessions. Multi-session studies may involve either more than one session in a day or a series of single sessions across multiple days. Participants can participate in more than one study as long as performing one would not influence their ability to perform the other (e.g., if stimuli were associated with one response in the first study and then the same stimuli were associated with a different response in the second study). Some subjects will participate in the lab at Jordan Hall, and others will run through the online platform of Amazon Mechanical Turk and Prolific. In both cases, the procedure is fundamentally the same. Each category of experiment (decision making, executive control, learning, and memory) could be done both online and in the lab.

Some subjects will be Mechanical Turk workers who have previously participated in other Mechanical Turk studies in our lab, who will be recontacted via Mechanical Turk or email. The subjects will first consent to participation in the study. They will then be instructed on how to complete a task on the computer, which requires making choices about various kinds of stimuli, including pictures, words, or numbers. Pictures will not include any offensive or potentially disturbing items.

Once the instructions are done, subjects will complete the task, which will involve making responses (manual or eye movement) to visual (e.g., pictures or words) or auditory stimuli (e.g., a tone) presented from the computer. They will then be debriefed.

During studies of decision making, subjects will be asked to decide between different stimuli (e.g., they may be asked whether they would choose to eat a candy bar or a bag of chips). In some studies we will introduce manipulations that attempt to adjust their decisions (e.g., have subjects withhold a response to a certain stimulus and test whether this reduces the frequency that they

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choose that stimulus).

During studies of executive control, subjects will be presented with stimuli and will be asked to perform cognitive task that require them to coordinate, inhibit, or change their behavior based upon the stimulus that appears (e.g., they may be asked to make one response when a circle appears but withhold that one response and make an alternative response when an infrequent square appears). We will measure the influence of the control process in the reaction time and accuracy of their responses.

During studies of learning and memory, subjects may be asked to learn a set of stimuli (e.g., names assigned to a set of abstract shapes), and then they will be later probed on their memory (e.g., presented with an abstract shape and asked to give the assigned name). Additionally, subjects may be presented with a stream of stimuli that require responses (e.g., respond with one keypress to a right facing arrow and respond with another keypress to a left facing arrow), and an implicit contingency may be embedded in the trial sequence (e.g., arrow direction is much more likely to alternate than repeat), and we will test their learning of this implicit contingency (e.g., see whether responses are faster when arrows alternate than when they repeat).

With MTurk and Prolific, response will be made with keypresses or via movements on the touchpad or touchscreen (depending on the given participant's device). In the lab, some experiments will use keypresses, and others will be made with eye movements (e.g., saccade to the location of the target).

Performance bonuses may be given, especially in decision making studies. For example, in some studies subjects may need to decide between making a small amount of money with certainty or having the small possibility of making a larger amount of money. We may pay subjects based upon their choices on all or a subset of their trials. Any bonus payments will be explained to the subjects during instructions.

Subjects may also be asked to complete one or more questionnaires, including those attached in section 11 (Beck Depression Inventory (BDI.pdf), Behavioral Inhibition System questionnaire (BIS.pdf), Behavioral Inhibition System/Behavioral Approach System questionnaire (BISBAS.pdf), Demographic Self Report Questionnaire (DemogSelfReport.pdf), Food Habits questionnaire (Food Habits.pdf), Habit Strength questionnaire (Habit_strength.pdf), Self-Reported Habit Index (Self-Reported Habit Index.pdf), UPPS Impulsivity Survey, DASS-21 Survey, DOSPERT RT survey, Childhood Trauma Survey, RISQ survey, PSQI survey, Demographics survey, DOSPERT EB survey, DOSPERT RP survey, K6 survey, DSM-5 cross-cutting stanford baseline, PANAS last two weeks survey, Race Ethnicity RMR survey, Brief self-control survey, Three factor eating questionnaire, L-CAT survey, Fagerstrom test survey, McArthur social status survey (Survey Questions.xlsx)).

- b) **State if audio or video recording will occur. Describe how the recordings will be used, e.g., shown at scientific meetings, used for transcription. Describe the final disposition of the recordings, e.g., erased, stored.**

No audio or video recording will occur. The eye tracking system uses video to measure eye movements, but no recording is saved.

- c) **Does the study involve deception? Deception occurs when information about the study is deliberately withheld from subjects, or when subjects are intentionally misled about the study. If this study includes deception:(i) Explain and justify the deception (ii) Explain the debriefing procedure (ensure a debriefing document is attached to the protocol) OR explain why debriefing would not be appropriate**

Some recent work suggests that implicit knowledge (i.e., without awareness) may influence choices differently or more potently than explicit knowledge (i.e., with awareness). Additionally, implicit knowledge may be more malleable than explicit knowledge, so may be a better target for our proposed

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manipulations of behavioral choices (see specific example below). A common procedure to encourage implicit (instead of explicit) learning is to embed contingencies in the task design but provide instructions that deceive subjects into thinking that the contingencies do not exist. For example, if responses to certain stimuli are going to be rewarded more than others, and the intention is for subjects to gain implicit and not explicit knowledge of this contingency, the subjects may be instructed that their rewards are not based upon the identify of the stimuli but instead are based upon some other aspect of performance (e.g., reaction time). Therefore, we may need to provide deceptive instructions or feedback in order to understand and evaluate specific hypotheses for the mechanisms underlying decision making and behavioral change.

More generally, in order to distinguish real behavioral change from change resulting from demand characteristics (i.e., the subject inferring the purpose of the study and changing their behavior to align with the purpose) we may need to use deceptive instructions or feedback to try to conceal the purpose of the study. In all cases, we will debrief the subjects on any deception at the end of the experiment.

In our protocol, a specific example of how we propose to include deception in instructions and feedback is as follows: subjects will make speeded responses to a set of stimuli (e.g., a square, circle, triangle, and diamond), and they will be given feedback in the form of a monetary reward after making their response. Unbeknownst to the subjects, certain stimuli are associated with high reward feedback (e.g., square and circle = \$4) and other stimuli are associated with low reward feedback (e.g., triangle and diamond = \$1). In order to discourage explicit knowledge and instead encourage the development of implicit knowledge of this stimulus-reward association, we will deceive the subjects by instructing them that the amount of reward feedback after each response is based upon the speed of their responses, not the assignment of specific stimuli to specific reward values. This

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manipulation involves both deceptive instructions and deceptive feedback, because the reward feedback is being based upon something different than what we told them it would be based upon.

Once we have established an implicit stimulus-reward association, we will introduce manipulations to see whether we can successfully influence this implicit association. If subjects only have an implicit association between the stimulus and the reward, and not explicit knowledge of which stimuli are associated with which rewards, we may be able to more successfully adjust their stimulus-reward association.

3. Background

a) Describe what led to the formulation of the study.

This work aims to gain a deeper understanding of key cognitive processes, including response inhibition, cognitive control, working memory, task switching, attention, learning and decision making. One specific focus is encouraging positive behavioral change. A broad range of challenges to public health stem from unhealthy behavior like overeating or abuse of both legal and illegal drugs. A number of interventions have been developed to help individuals overcome such habitual behaviors. However, most of these interventions rely on willpower, which has been found to be fragile and prone to failing under a number of conditions such as stress or distraction.

The ultimate goal of the proposed work is to inspire new approaches to the development of programs for behavioral change through a better understanding of the underlying neural and cognitive mechanisms of successful behavioral maintenance. We propose to enhance the retention of a learned response by strengthening its memory trace. Strengthening the learning of behavior can be accomplished through spacing or distributed practice where training trials are presented in a temporally spaced rather than massed fashion. Finally, training of the later-learned behavior across a broad range of contexts could also serve to decrease the default nature of the first-learned response and increase generalization of the later-learned behavior.

4. Participant Population

a) (i) How many participants do you expect to enroll at Stanford? (ii) How many participants do you expect to enroll outside Stanford? (iii) What type of participants will you enroll (e.g., high school students, teachers, government officials)?

Because online recruitment sources such as Mechanical Turk or Prolific allows such rapid recruitment of participants, we will be able to recruit a very high number of participants. Hence, we expect to recruit 50,000 participants for this protocol over the life of the study. Of those 50,000, we expect 2,500 to be ran in

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the lab and 47,500 to be ran online. All participants will be run at Stanford or online. Healthy young adults (18-50 years old) will be used.

b) What are the age range, gender, and racial or ethnic background of the participant population being targeted?

Our experiments will not restrict participants based upon gender, racial, or ethnic background. We will restrict participants to an age range of 18-50 years, as we are interested in the cognition and decision making of healthy adults. During the consenting process, subjects will be asked to verify that they are in this age range.

c) If applicable, explain why potential vulnerable participants are needed (e.g., children, pregnant women, students, economically or educationally disadvantaged, homeless, or people with impaired decision making capacity).

This study will not include potentially vulnerable subjects.

d) Will the research include women, minorities, or minors? Provide a rationale for not including these populations if the research might benefit these groups (e.g., results of a survey study about salaries might benefit women, but if you choose not to include them, explain why).

The present research will include women and minorities, though the research is not specifically targeting these groups.

e) Will any participants be your students, laboratory personnel and/or employees? See Stanford University policy at

<http://doresearch.stanford.edu/policies/research-policy-handbook/human-subjects-and-stem-cells-research/use-employees-o>

No

f) How will you recruit participants (E.g., by: Honest Broker or other <https://researchcompliance.stanford.edu/participantengagement> Research Participation services; ads, classroom recruitment, word of mouth, letters mailed home, email)? Attach recruitment materials in the Attachments section. YOU MAY NOT CONTACT POTENTIAL PARTICIPANTS PRIOR TO IRB APPROVAL. ALL FINAL OR REVISED RECRUITMENT MATERIALS, FLYERS, ETC. MUST BE SUBMITTED TO THE IRB FOR REVIEW AND APPROVAL BEFORE USE.

We will recruit through flyering, Stanford University subject pool, the lab website, and advertising in local media. We will also recruit through Mechanical Turk or Prolific, either via participants who have previously participated in Mechanical Turk studies in our lab, or the broader participant pool on Mechanical Turk or Prolific.

g) PAYMENT or REIMBURSEMENT. Will participants be paid or reimbursed for participation? If yes, how much, and explain why proposed payments/reimbursements are reasonable. Explain how payment will be prorated, if there is more than one study session. See payment considerations.

Payment for studies at Jordan Hall will be \$12 per hour, paid at the end of the testing session. Payment will be rounded to the next half hour (e.g., a 70 minute study will pay \$15).

Payment for studies on Mechanical Turk will be paid at a rate of approximately \$4/hour. Payment will be prorated to the nearest 10 minutes. A bonus of an additional \$4/hr will be paid upon completion of entire battery of tasks. After the bonus, this is at or above the standard rate for Mechanical Turk payments for psychology experiments, and our lab has had success with a similar payment structure in the past.

Payment for studies on Prolific will be paid at a rate of at least \$8/hour, in line with Prolific payment requirements, with the possibility of a bonus up to \$5/hour. These rates are on par with the minimum rate recommended by Prolific.

Some studies will be more than an hour and therefore the total bonus could be more than \$5. The reason for this new bonus structure is that we are attempting incentivize complete, good performance with a larger bonus.

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- h) **Explain what costs will be incurred by the participant. If none, enter none.**

None

- i) **What is the total time that each participant will spend in the entire study (e.g., 20 minutes, 2 hours, 3 days)?**

Participation will take between 15 minutes and 20 hours (longer studies will likely be split between multiple days), depending on the particular experiment that subjects are completing.

5. Risks

- a) **In order to qualify for expedited review, the protocol must present no more than minimal risk to participants. Describe any reasonably anticipated potential risks(s), including risk(s) to physical, psychological, political, economic or social well-being, or participant confidentiality (such as a confidentiality breach). Please ensure that your response to this question is consistent with the risks you have indicated in your consent form.**

We do not anticipate any potential risks to physical, psychological, political, economic, or social well-being.

- b) **If you are conducting international research, describe qualifications/ preparations that enable you to both estimate and minimize risks to participants. ?Please review the Listing of <https://www.hhs.gov/ohrp/international/social-behavioral-research-standards> Social-Behavioral Research Standards, to ensure that your research complies with all applicable standards and complete the [LINKFORINTERNATIONALRESEARCHFORM] International Research Form. If not applicable, enter N/A.**

- c) **Will you be working with any Political Action Committees or other political organizations that are involved in partisan activities? If yes, describe below. See Admin Guide 1.5.1 for restrictions on doing research involving partisan organizations.**

- d) **Children's Findings (OHRP)**

Confirm that your study meets the criteria for 46.404 below:

Provide the rationale that this study presents no greater than minimal risk to children, and indicate whether parental permission will be obtained. If parental permission is to be obtained, indicate whether one or both parental signatures will be sought.

Rationale:

6. Benefits

- a) **Describe the potential benefit(s) to be gained by the participants and/or by society as a result of this study. Please ensure that your response to this question is consistent with the potential benefits you have indicated in your consent form**

This work involves exploring ways to enact behavioral change. We hope that this work can be used to help people make better choices that will improve public health.

7. Privacy and Confidentiality

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Privacy

Privacy refers to the environment in which data are collected from participants (e.g., interviewing participants individually in a place where personal responses will not be seen or overheard).

- a) Explain where the research takes place (e.g., in a lab, online, at school). Describe how you will maintain privacy in this setting.**

When the experimental session occurs in Jordan Hall, the interactions will occur in a private setting of the behavioral testing rooms. Only the subject and the members of the research team will be present during the interaction.

When the experimental session occurs in Amazon Mechanical Turk or Prolific, the participants are able to do the research wherever they feel comfortable. Their privacy is protected by associating their work only with a Worker ID and not their name or any other identifying information.

Confidentiality

Confidentiality refers to your agreement with the participant about how the participant's identifiable personal information (i.e., identifiable data) will be handled, managed, stored, and disseminated.

- b) What identifiable data will you obtain from participants? Enter 'none' if identifiable data will not be obtained.**

none

- c) Describe if applicable:**

- (i) how you will manage the identifiable data (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device)
- (ii) how you will ensure the security of identifiable data (e.g., password protected computer, encrypted files, locked cabinet, locked office);
- (iii) who will have access to the identifiable data (e.g., research team, sponsors, consultants)
- (iv) confirm that all devices on which data will be stored will also be encrypted
- (v) describe an adequate plan to remove and destroy the identifiers from the data at the earliest opportunity

NA

- d) 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. See the Stanford Information Security Office website. If not applicable, enter N/A.**

N/A

- e) If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.**

N/A

8. Potential Conflict of Interest

Investigators are required to disclose any outside interests that "<https://researchcompliance.stanford.edu/protocol-coi>" target="_blank" reasonably appear to be related/li to this protocol.

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Outside Interest Tasks

Investigators	Role	Potential COI?	Date Outside Interest Answered	Date OPACS Disclosure Submitted	COI Review Determination
Russell Alan Poldrack	PD	N	02/28/2024		N/A

9. Consent Information

A protocol should include at least one of the following consent options. More than one may be included. See more information on <https://rco.sites.stanford.edu/panels/hs/forms/definitions> Informed Consent, Waiver of Consent, Waiver of Documentation and Alteration of Consent.

- Waiver of Consent**

Applicable for research involving identifiable data or records, when asking to waive parental permission, or other situations where consent is not possible

- Consent**

Applicable for research involving signed consent or parental permission forms

- Waiver of Documentation**

Applicable for internet research or oral consent when a signature is not obtained

- Alteration of Consent**

Applicable when some required elements of consent are eliminated, such as incomplete disclosure of the purpose of the research (deception)

For IRB consent form templates, please click [here](#)

- a) **Describe the informed consent process. Include the following: Who will obtain consent? When and how will this be done? If you are requesting to completely waive consent, enter "Waiver of Consent" in the text boxes a, b and c below.**

For participants who complete the study at Jordan Hall, they will be provided with a copy of the consent document by email prior to their participation, and will be asked to read the document before coming for their study session. The investigator will first confirm that they have read the document, and ask whether they have any questions. The investigator will then ask the subject to verbally agree to the consent form, and will record the date and time of consent. For participants who complete the study on Mechanical Turk and Prolific, a similar consent document will be presented (see MTurk consent). If they consent, they will proceed to the experiment. If they have any questions about the study, they can email the experimenter. The contact information for the experimenter in charge of that particular study will be included on the consent form.

Note: The person obtaining consent must be knowledgeable about the study. Sufficient time must be devoted to allow the participant to consider whether or not to participate. Steps must be taken to minimize the possibility of coercion or undue influence.

Note: If consent relates to children, the IRB will determine whether one or two parents' signatures are sufficient.

- b) **What procedure will you use to assess if the participant understands the information contained in the consent? How will the information be provided to participants if they do not understand English? See HRPP Chapter 14.6 for guidance.**

If the participant has any questions, they can ask the experimenter in person (if at Jordan Hall) or email the experimenter (if on Mechanical Turk or Prolific). Subjects must be able to understand English to partake in the study.

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c) Are you planning to enroll participants who do not have the capacity to consent?

No

Any consent form document (including information sheets used for consenting) should be attached by clicking the ADD button below, and then selecting the appropriate option in the drop-down menu.

9.1 Waiver of Documentation MTurk Waiver of Doc 2/12/24

Select ALL applicable regulatory criteria for a Waiver of Documentation and provide a protocol-specific justification:

- 1) 45 CFR 46.117(c)(1)(i), that the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each participant (or legally authorized representative) will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.
- 2) Y 45 CFR 46.117(c)(1)(ii), that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.
- 3) 45 CFR 46.117(c)(1)(iii), if participants or legally authorized representatives (LAR) are members of a distinct cultural group in which signing forms is not the norm, the research presents no more than minimal risk and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Rationale for above selection:

This research presents no more than minimal risk to subjects, as they are completing behavioral tasks.

9.2 Waiver of Documentation In Lab Consent 2/12/24

Select ALL applicable regulatory criteria for a Waiver of Documentation and provide a protocol-specific justification:

- 1) 45 CFR 46.117(c)(1)(i), that the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each participant (or legally authorized representative) will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.
- 2) Y 45 CFR 46.117(c)(1)(ii), that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.
- 3) 45 CFR 46.117(c)(1)(iii), if participants or legally authorized representatives (LAR) are members of a distinct cultural group in which signing forms is not the norm, the research presents no more than minimal risk and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Rationale for above selection:

There is no more than minimal risk for this research

9.3 Waiver of Documentation Prolific Waiver of Doc 2/12/24

Select ALL applicable regulatory criteria for a Waiver of Documentation and provide a protocol-specific justification:

- 1) 45 CFR 46.117(c)(1)(i), that the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each participant (or legally authorized representative) will be asked whether

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he/she wants documentation linking the participant with the research, and the participant's wishes govern.

- 2) Y **45 CFR 46.117(c)(1)(ii)., that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.**
- 3) **45 CFR 46.117(c)(1)(iii)., if participants or legally authorized representatives (LAR) are members of a distinct cultural group in which signing forms is not the norm, the research presents no more than minimal risk and there is an appropriate alternative mechanism for documenting that informed consent was obtained.**

Rationale for above selection:

There is no more than minimal risk for this research.

10. Assent Background (less than 18 years of age)

Children must assent to participating in research unless the children are not capable of assenting because of age, maturity, psychological state, or other factors. See more information on /assent-process Assent. A protocol that involves children should include at least one of the following. Depending on the nature of the research and the subject population, more than one may be included by clicking the ADD button below and then selecting the appropriate option from the drop-down menu.

- a) **Describe the assent process. Include the following: Who will obtain assent? When and how will this be done?**

N/A

Note: The person obtaining assent must be knowledgeable about the study. Sufficient time must be devoted to allow the child to consider whether or not to participate. Steps must be taken to minimize the possibility of coercion or undue influence.

- b) **What procedure will you use to assess if the child understands the information contained in the assent? How will the information be provided to children if they do not understand English? See Guidance.**

N/A

- Assent
- Waiver of Assent (used when assent will not be sought for some or all children who are capable of assenting)
- Assent Not Applicable (used when all children are not capable of assenting)

11. Attachments

Attachment Name	Attached Date	Attached By	Submitted Date
BISBAS	12/09/2014	pbissett	
Food Habits	12/09/2014	pbissett	
DemogSelfReport	12/09/2014	pbissett	
BDI	12/09/2014	pbissett	
BIS	12/09/2014	pbissett	
Habit_strength	12/09/2014	pbissett	
Self-Reported Habit Index	12/09/2014	pbissett	

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Flyer	12/10/2014	pbissett	
NIH grant e-application_submitted	12/10/2014	kanerva	
MTurk Recruitment	04/03/2015	pbissett	
Deception Debriefing	04/03/2015	pbissett	
MTurk Recontact Message	10/19/2018	mphagen	
Lynde-CitiCertification_2	08/26/2022	jahrios	
Lynde-CitiCertification_1	08/26/2022	jahrios	
RDoC grant proposal	02/09/2024	sjshim	
Survey Questions	02/12/2024	pbissett	

Obligations

The Protocol Director agrees to:

- Adhere to principles of sound scientific research designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection ethical principles, regulations, policies and procedures
- Ensure all research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected, including privacy and confidentiality of data
- Ensure that, when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.
- Disclose to the appropriate entities any potential conflict of interest
- Report promptly any new information, modification, or unanticipated problems that raise risks to participants or others
- Apply relevant professional standards.

Any change or modification in the research protocol must be submitted to and approved by the IRB prior to the implementation of such change, except when necessary to eliminate apparent immediate hazards to the participant.

For studies with expiration dates, submit a Continuing Review prior to the end of the approval period. An IRB Continuing Review (Renewal) Notice is sent to the Protocol Director prior to the expiration date of the protocol.

Report promptly any new information, complaints, possibly serious and/or continuing noncompliance, or unanticipated problems involving risks to participants or others. Report promptly any new information, complaints, possibly serious and/or continuing noncompliance, or unanticipated problems involving risks to participants or others.

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All data, including signed consent forms when applicable, must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. (See also Research Policy Handbook <https://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/retention-and-access-research-data> Retention of and Access to Research Data)

Y By checking this box, I verify that I, as the Protocol Director (PD) responsible for this research protocol, have read and agree to abide by the above obligations, or that I have been delegated authority by the PD to certify that the PD has read and agrees to abide by the above obligations.