IRB #2016897 MU

IRB Application #252905

Submission date: **08/24/2019**
Submitted by: **Duan, Sean Xiaohao**

1. Project Title/Investigators

1. **Project Title**

   If the study is externally funded or internally grant funded, this title should match the title on the grant/contract.

   Impact of an explicit health benefit plan on support for universal health care

2. *Key Personnel - List all investigators engaged in the research by clicking on the "Add an Investigator" button. This includes individuals interacting or intervening with subjects, collecting or accessing identifiable data, or consenting subjects. Please note, if individuals are performing services that are typically performed for non-research purposes, and they are only providing a service for this project, they do not need to be listed.*

   Principal Investigator Assurance: After you hit submit on this application, the PI will be sent an email from the system requesting the completion of the PI Assurance Form. This application will not officially be submitted to the IRB until this step is complete.

   Primary Contact(s): Whoever you would like to be copied on IRB correspondence, including reminders and approvals, please be sure to add them as primary contacts when prompted under the "Add an Investigator" button. There must be at least one primary contact on this application.

   Fellows and Residents: Must have a faculty member listed as a co-investigator.

   Student-Initiated Projects: Students must list themselves as Principal Investigator and also include an Advisor on the project. After you hit submit on this application, the Advisor will be sent an email from the system requesting the completion of the Advisor Approval Form. This application will not officially be submitted to the IRB until this step is complete.

   Medical Procedures and/or Treatment Studies: For activities that require consent to be obtained by a licensed physician outside the scope of research, only a physician, advanced practitioner, or appropriately licensed provider may have the consent role as "authorized to obtain consent". Review our Informed Consent Requirements SOP for additional information.

   Expedited and Full Board Studies: Please be sure the Principal Investigator has uploaded their Curriculum Vitae (CV) or resume to their personal document storage in eCompliance. When the PI logs into eCompliance, this will be uploaded under the "Prerequisites" column. This only needs to be uploaded once for all studies.

Role	Investigator	Department	CITI IRB Training	Primary contact	Consent personnel role	Veterans personnel
Principal	Duan, Sean	Psychological Sciences	08/22/2018	☑	Authorized	☐

Role	Investigator	Department	CITI IRB Training	Primary contact	Consent personnel role	Veterans personnel
Investigator	Xiaohao				to Obtain Consent	
Advisor/Co-Investigator	Shaffer, Victoria A	Psychological Sciences	07/09/2019	☐	Authorized to Obtain Consent	☐

3. Contact Information (Read-Only)

Principal investigator

Duan, Sean Xiaohao

Job title	GRAD RESRCH AST
Department	Psychological Sciences
Division	Arts & Science
Business unit	University of MO-Columbia

Primary contact

Duan, Sean Xiaohao

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Division	Arts & Science
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FORM INSTRUCTION: As you work through the form, you will be checking boxes that prompt additional questions. If you realize those additional questions do not pertain to your study, go back and uncheck the box that prompted those questions.

2. Determining What Rules Apply to Your Research

1. The answers to the following questions will determine what rules will apply to your study. It is very important these are marked correctly. If you are unsure how to answer any of these questions, please contact the IRB office at 573.882.3181 or email irb@missouri.edu.

   A. Is this federally funded or pending federal funding?

   Mark yes if you will not move forward with this project without federal funding. Do not mark yes if the funding is coming through Department of Justice or the Consumer Product Safety Commission. These two agencies have not yet adopted the revised rules.

   ○ Yes ● No

   B. Is this a clinical trial?

   A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on biomedical or behavioral health-related outcomes.

   ○ Yes ● No

   C. Does the study involve **MORE** than minimal risk?

   Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

   ○ Yes ● No

3. Exempt Determination

☐ If you already know that your project is NOT exempt, please check this box to skip this entire section and additional sections will populate. If you are unsure, do not check this box and continue with #1.

1. **Does the project fit under any of the following exempt categories? Check the box(es) applicable to your study. A project can fall under more than one category.**

   *Prisoners can only be involved if the research is aimed at involving a broader subject population that only incidentally includes prisoners. Research cannot be FDA regulated under #1-5.

   If needed, you may contact the IRB office for guidance (573.882.3181 or irb@missouri.edu).

   ☐ **CATEGORY 1:**

   Research conducted in established or commonly accepted educational settings that specifically involve normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

   This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

   Clarification: The research can only be conducted in established or commonly accepted

educational settings. This includes, but is not limited to, schools and colleges. It may include other sites where educational activities regularly occur. Children may fall under this category.

☑ CATEGORY 2:

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) IF at least ONE of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; OR

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects. The study cannot involve children under this option.

Clarifications: Children can only be involved if their participation is limited to (1) educational tests or (2) observations of public behavior when the investigator(s) do not participate in the activities being observed. Children cannot fall under item (iii).

Educational Tests: These do not have to be administered in an educational setting like category 1.

Survey & Interview Procedures: This is not meant to include activities that will influence or change a participant's social, behavioral, or educational outcomes or abilities. This activity should be limited to completing a survey or an interview/focus group.

Observation of Public Behavior: To be considered public, the subjects would not have an expectation of privacy. It would reasonably be expected that observations or recordings could take place.

☑ CATEGORY 3:

Research involving *BENIGN behavioral interventions in conjunction with the collection of information from an ADULT subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection AND at least ONE of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; OR

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to subjects.

** Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples could include playing an online game, solving puzzles under noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.*

If the study involves deceiving the subjects regarding the nature or purposes of the research, this exemption does not apply UNLESS the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ **CATEGORY 4:**

Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens IF at least ONE of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, and the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis, that either:

(a) involves the investigator's use of identifiable health information when that use is regulated under HIPAA for the purposes of "health care operations," or "research," or "public health activities and purposes" as defined by HIPAA; (Note: HIPAA only covers protected health information associated with a biospecimen, not the biospecimen itself. See option i or ii in this category for biospecimens) OR

(b) involves research conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 or Privacy Act of 1974, 5 U.S.C 552a.

☐ **CATEGORY 5:**

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of federal department or agency heads (or the

approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects).

The research is designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

The research must be conducted pursuant to specific statutory authority of the US federal government. There is no statutory requirement that an IRB review the research. The research does not involve significant physical invasions or intrusions upon the privacy of participants.

☐ **CATEGORY 6:**

Taste and food quality evaluation and consumer acceptance studies:

(i) if wholesome foods without additives are consumed; or

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

2. **Please answer the following questions regarding your exempt project.**
   - **A.** Provide a description of your project.

     The purpose of this study is to determine how exposure to an explicit Health Benefits Plan affects support for Universal Health Care

     This study is in lab, it will be a two way mixed factorial design with a pre and post measure of support for Universal Health Care, and the varying condition being whether or not the participant is exposed to the control condition, the intervention with hands on exposure to creating a HBP, or the intervention where there is passive exposure to an HBP.

     In the control condition, subjects will be asked to budget and choose which ingredients a hypothetical favorite pizza store will sell.

     In the hands on intervention condition, subjects will be asked to budget and choose which components of health care coverage their Universal Health Care Package will provide.

     In the passive intervention condition, subjects will be asked to evaluate components of health care coverage provided by a government HBP.

   - **B.** Describe what subjects will be asked to do.

     If this is an observational study or review of existing data only, please state this.

     Subjects will be asked to complete a survey, pre and post intervention. Subjects will either fill out a form determining which ingredients a hypothetical pizza store will sell, or fill out a form determining which components of health care coverage their UHC will provide, or will evaluate a government provided HBP.

   - **C.** Explain how your project fits into the exempt category(ies) you selected above.

There is no PII, as the pre and post measures and survey questions do not ask for any distinguishing information.

Creating a menu, or choosing what items a healthcare plan could offer, or evaluating a hypothetical healthcare plan, all seem to be relatively benign.

D. Specify the option within the category your project falls under, and provide justification.

Categories 2, 3, 4, and 6 have options within the category where the study must fit. Identify the option (i, ii, or iii) and provide justification.

Category 2, option i

Category 3, option i

E. Recruitment

i. Describe your recruitment process.

Upload your recruitment materials (ads, scripts, emails, etc.)

Will obtain subjects from psych 1000 subject pool, and they will have the option to sign up for the experiment on the SONA webpage

ii. Select from the following recruitment avenues you intend to use:

☐ MU Info

☐ MU Listserves

☐ Social Media

☐ Other:

Upload your recruitment materials to the attached files section.

iii. Permission to conduct the study.

☑ I attest that I already have permission to conduct the study, or am still needing permission, but permission will be secured prior to subject recruitment.

F. Describe the subject population.

Students who have enrolled in Psych 1000 and are over 18 years of age

G. Select if the population may include the following:

☐ Children

☐ Wards

☐ Adults unable to Consent

H. Select if your inclusion criteria (target population) includes the following populations:

Do not check if the research is aimed at involving a broader population that may only incidentally include one or more of the following:

☐ Students

☐ Employees

☐ Pregnant Women

☐ Community Veterans (do not check this if this study engages the Truman VA Hospital as a

research site)

☐ MU Student-Athletes

I. Are participants asked to answer questions and/or provide information that may be considered embarrassing, sensitive, or offensive?

○ Yes ● No ○ N/A

Upload your interview and/or survey questions, if applicable, to the attached files section.

J. Describe any potential risks for subjects associated with the research. The study must not involve more than minimal risk to be exempt.

Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

There are no potential risks for participants associated with the research. They will be asked to fill out a pre and post measure examining attitudes towards universal health care, and have the choice to fill out optional demographic information. The hypothetical exercise portion is not more strange or stressful than anything encountered in daily life.

K. Do you plan to recruit non-English speaking subjects?

Please note, there are resources available to you if you would like to include non-English speaking subjects. E-mail irb@missouri.edu for more information.

○ Yes ● No

L. Will you be processing (i.e. using, accessing, collecting, recording, storing, or transmitting) any personal data about individuals physically located in the European Union, or be involved with any transfer of personal information from the EU to an non-EU country?

If yes, the IRB SOP "Additional Protections for Vulnerable Populations, International, and Non-English Speaking Participants" must be reviewed to ensure all EU GDPR requirements have been met. Access the SOP here: https://research.missouri.edu/policies/by_department.php

○ Yes ● No

M. Are there any conflicts of interest with this study?

Example: Financial, personal, institutional, or other, for any study team member. If none, please indicate no conflict. We will verify your responses with existing data on file.

○ Yes ● No

N. Does this project involve Harry S Truman Memorial Veteran's Hospital participants, VA resources, and/or time of VA personnel?

A protocol is required to be uploaded to the "attached files" for VA exempt research. Also, if yes, an additional form will populate for your completion.
Harry S Truman Memorial Veterans' Hospital Research & Development Website

○ Yes ● No

O. Is the research funded/supported?

Select "yes" for internal or external funding.

○ Yes ● No

P. Are you offering subject compensation, including monetary payments or extra/course credit?

● Yes ○ No

Q. If you will offer subject compensation, describe what that will be.

If you are offering extra or course credit, also describe the alternative assignment since research is voluntary and they need another option to earn credit that does not involve active participation in research.

One credit towards the research requirement for PSYCH 1000 students will be fulfilled per half hour session of participation.

R. If you are offering subject payments, please list your departmental fiscal contact here:

For information about research participant payments, click here

S. Will you record identifiable information at any time during the course of the research?

○ Yes ● No

T. Answer the following questions. If you mark yes to any of them, you will need to confirm additional requirements will be met by checking the box(es) that will populate or answer questions. You will be attesting these requirements will be met when asked to check a box.

i. Will there be a subject interaction?

Interaction includes communication or interpersonal contact between investigator and subject.

● Yes ○ No

☑ You will inform the subject and/or their legal guardian of the following utilizing a written or oral script: 1) a statement that the activity involves research, 2) a description of what they will be doing, 3) a statement that participation is voluntary, and 4) inform subjects of your name and contact information. Upload the script to the attached files section for review.

ii. Describe the protections in place to protect privacy interests of participants.

A consent form will be provided before beginning the experiment. Participants will complete the experiment in a private location.

iii. Will the study involve accessing identifiable student records?

FERPA guidance can be found here: US Department of Education FAQ or MU Website.

○ Yes ● No

iv. Will the study release participant audio, video, or photographs outside of the research team?

○ Yes ● No ○ N/A

Supportive Documents: Be sure to upload recruitment materials, consent scripts, and/or surveys/interviews to the attached files section.