IRB #2095965 MU

IRB Application #390263

Submission date: **02/28/2023**
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.

   Social Memory and Recollection on Current and Past Issues

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. Expedited/Full board projects - do not add external investigators from another institution/organization who have their own IRB unless you are specifically asked by our office to add them to our application.

   Investigators serving as a Principal Investigators must have a current and active UM appointment. Individuals with a visiting scholar/faculty or courtesy appointment (including adjunct faculty without a significant time appointment as an UM employee) will be required to indicate support from their home/ sponsoring department and will be required to have an active UM faculty member with human subject research experience serving in a Co-Investigator (Co-I) role on human subject research studies.

   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 as PI: 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, and the student completes the PI Assurance received via email. See the MU IRB webpage for Student Researchers.

   Dissertations, Thesis projects, and other required student-led research projects: Students must have their own, separate IRB approval. Combination of projects are not accepted. For example, if a student wishes to use data from a faculty research project for their dissertation, the student must submit an IRB application to use the data. Also, MU graduate student-led projects must receive approval by the MU IRB even if activities are occurring at another site with an IRB. See MU IRB HRPP Policy here. See the MU IRB webpage for Student Researchers.

Classroom Projects: Projects conducted for purposes of a grade only and results are not disseminated outside the classroom do not meet the federal definition of research and do not require IRB review. However, the IRB has built into the exempt portion of the application the ability to practice submitting to the IRB when required by the instructor.

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.

Registered Nurses as PI or Co-I: If you are a Registered Nurse and Employee of MU Health Care, please contact Renae McIntosh, Coordinator of EBP and Nursing Research, for additional information regarding MU Health Care project tracking at mcintoshr@health.missouri.edu.

Role	Investigator	Department	CITI IRB Training	Consent personnel role	Primary contact	Truman VA Hospital personnel
Principal Investigator	Duan, Sean Xiaohao	Psychological Sciences	08/31/2021	Authorized to Obtain Consent	☑	☐
Advisor	Shaffer, Victoria A	Psychological Sciences	06/08/2022	Authorized to Obtain Consent	☐	☐

3. Contact Information (Read-Only)

Principal investigator

Duan, Sean Xiaohao

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

Primary contact

Duan, Sean Xiaohao

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

4. **Truman VA Research**

A. Is the research going to be conducted by investigators serving on Truman VA compensated, VA without compensation (WOC), or Intergovernmental Personnel Act appointments?

This includes paid as well as WOC criteria.

○ Yes ● No

VA EXEMPT PROJECTS: The MU IRB does not review VA exempt projects UNLESS the VA Research Office has informed you the study qualifies as exempt with a limited IRB review. First, you must contact the Truman VA Health System Specialist to obtain instructions for completing their VA exempt application since they utilize a separate online system, and they will inform you if you must submit the MU IRB form instead. Her contact information is: Elizabeth.Babb@va.gov or (573) 814 -6000 ext. 53761.

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. Exempt Determination

☑ **NOT EXEMPT: If you already know that your project is NOT exempt, please check this box and click Save & Continue. If you are unsure, do not check this box and continue below.**

3. Basic Project Information

1. **Select from the type of research this project would likely fall under:**

☐ **Biomedical** - Research that is conducted to increase fundamental knowledge and understanding of the physical, chemical and functional mechanisms of human life processes and diseases.

☑ **Social/Behavioral/Educational** - Research that encompasses a range of methodologies and seeks to answer questions to improve our understanding of human behavior, attitudes, beliefs, and interactions as well as social and economic systems, organizations, and institutions.

2. **Are there any conflicts of interests 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. Ensure you are aware of any specific restrictions for your department or college.

○ Yes ● No

3. **Investigator Qualifications**

☑ I attest that all members of the study team have appropriate training, qualifications, and credentials to perform study related procedures/activities.

A. Does the study involve any study related procedures that require specialized training or certification?

All personnel performing any procedures associated with a research study must have appropriate training and expertise. Individuals performing specific functions or procedures should have the necessary licensure and/or credentials to conduct the activity in accordance with the research study.

○ Yes ● No

B. Are you requesting an exception for the persons allowed to perform certain research only functions or procedures?

Exceptions and exemptions cannot be made under Federal or State Law, only to local institutional policies and procedures.

○ Yes ● No

4. **Does the study involve secondary research, limited to the analysis of materials** (data, documents, records, or specimens) collected for non-research purposes (such as medical treatment or diagnosis) or research purposes (such as data from another research project)?

   Before selecting yes, refer to Exempt Category #4 (section 3 of the application) to ensure the project cannot be Exempt. Some activities fitting this limited analysis can be Exempt. Do not mark YES if you are interacting with subjects, including obtaining consent and/or prospective randomization. This should only be YES for studies with a proposed waiver of consent.

   ○ Yes ● No

5. Are you proposing to utilize or add information and/or biospecimens to an existing database/ biorepository ?

   MU Health Care Policy: It is important to familiarize yourself with the policy outlining exempt specimens from routine pathologic examination. You will want to check on the availability of specimens for research before proceeding with IRB approval: https://muhealth.policytech.com/docview/?docid=38100&public=true

   ○ Yes ● No

6. **Protocol Information**

   All expedited and full board applications must have a protocol unless there is no subject intervention or interaction. A protocol is considered a "living" document that provides the study team and IRB with a current status/snapshot of your project. It will need to be revised as changes to the study are made so it is always current. Please utilize the appropriate protocol template for your study, enter your study information in the appropriate fields, and upload to the attached files section. If you have a protocol drafted by a sponsor, please upload that protocol instead. Protocol templates can be found here. There is a biomedical template and a social/behavioral/educational template.

   A. What is the protocol version number?

   All protocols must have a version number (i.e. v1). The information pulls to the approval letter so it must match what is in the protocol uploaded.

   Version 1

   B. What is the protocol version date?

   All protocols must have a version date. The information pulls to the approval letter so it must match what is in the protocol uploaded.

   April 05, 2023

7. **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.
   Click here for guidance on making this determination, if unknown.

   ○ Yes ● No

8. **Is the research funded/supported?**

   Select "yes" for internal or external funding. If this proposal is associated with potential funding, please select "yes" and complete with the funding source you are seeking. When asked to submit the award information later in the application please indicate "pending". If funding is received, you will need to update your information in eCompliance.

○ Yes ● No

9. **Is this a multi-site collaborative study where UM is functioning as the lead site?**

This means the UM investigator is (1) a PI on a grant with another site(s) as a sub-contracted site(s), and/or (2) taking on the role as the lead investigator/site overseeing/coordinating the conduct of the study.

○ Yes ● No

10. **Select from the following to determine if HIPAA (Health Insurance Portability and Accountability Act) regulations apply to this study**: HIPAA Resource
TRUMAN VA: This section should not be completed for a Truman VA subject population. Truman VA reviews their own HIPAA components (i.e. waiver, stand-alone authorization, data use agreements).

☐ The study involves accessing/screening the medical record prior to contacting subjects and obtaining consent. A HIPAA waiver will be required (a subform will generate).

☐ The study involves medical record reviews with a waiver of consent. HIPAA Authorization is required unless a HIPAA waiver is approved or a Data Use Agreement is utilized for limited data sets.

☐ The research will be conducted within a covered entity and data are added to the medical record. HIPAA Authorization is required unless a HIPAA waiver is approved.

☐ The research will be conducted within a covered entity and the medical record will be accessed in conjunction with the research. HIPAA Authorization is required unless a HIPAA waiver is approved or a Data Use Agreement is utilized for limited data sets.

☑ None Apply - HIPAA may not apply.

Note: When applicable, the Privacy Review for MU Health occurs in conjunction with the review of this IRB submission. The Privacy Officer (or delegate) may be reaching out to you with questions/ revisions. For information about the MU Health policy, review its "HIPAA/Privacy - Protected Health Information and Research - Policy".

11. **Provide a description of your study, including the research objectives.**

The purpose of the study is to determine if perception of social consensus can impact an individual's choice to support or oppose universal health care. We would also like to determine if there is an interaction with between the effect of social consensus and moral/ethical beliefs, specifically that of utilitarianism and deontology. We have two main hypothesis. Hypothesis 1: We hypothesize that when participants perceive that a strong social consensus towards universal healthcare exists, they will be more likely to support universal healthcare, as opposed to when they perceive that there is a lack of social consensus. Hypothesis 2: Furthermore, we hypothesize that in conditions of high social consensus, there will be no effect on support towards Universal Health Care due to the individual moral and ethical differences of belief in utilitarianism and deontology.

There is significant scientific rationale for this study. In the existing literature, there is a great deal of research on the effects of deontological and utilitarian ethical beliefs on perceptions of moral and ethical issues. Previous literature focuses quite heavily on balancing both utilitarian and deontological moral beliefs in healthcare administration more generally, but has not examined closely whether or not those moral beliefs are predictive of support or opposition to Universal Health Care. Furthermore, existing literature on ethical and moral decision-making indicates that for issues where strong social consensus exists, this social consensus will tend to 'over-ride' how an individual would perceive a given issue, regardless of the 'normal' conclusion that their inherent moral leanings would generally trend towards. Interestingly enough however, there has been relatively little research on how to successfully manipulate this perception of social consensus with regards to Universal Health Care. This research will ideally add to existing knowledge by illustrating what the moral and ethical preferences tend to be for those that support or oppose Universal

Health Care, as well as provide insight as to whether or not social perception can be successfully manipulated with regards to Universal Health Care.

12. Is there any part of this study attempting or intending to treat, diagnose, cure, mitigate, or prevent a disease or other condition?

○ Yes ● No

13. Check all that apply regarding questionnaires, tests, and/or procedures:

Both may be applicable to your study. Additional questions will populate based on your selection(s).

☑ **Research-only** questionnaires, tests, and/or procedures will be included in the study (occurring only because they are a participant in the research)

☐ **Routine Activities/Care** questionnaires, tests, and/or procedures will be included in this study (occurring regardless of the research, but will use the information in the research)

14. Specify what questionnaires, tests, and/or procedures included in your study are research-only (occurring only because they are a participant in the research).

Include a brief description of each questionnaire, test, and/or procedure. If this information is detailed in your protocol, you may refer to a specific page/section in your protocol.

Our participants will be asked to predict what the American public sentiment was towards the issues of human caused climate change, human trafficking, the necessity of universal health care, and the necessity of capital punishment. Please see pages 2 and 3 of our protocol.

15. Describe any special equipment/technology brought in from an outside source or sponsor to use in this study.

N/A

16. Does the study involve any research-only biomedical tests or procedures?

○ Yes ● No

17. What type of facility will be utilized for research activities?

Check all that apply:

☐ MU Health Care - Hospital and Clinic

☐ Other Missouri Hospital or Clinic

☐ Out of State Hospital or Clinic

☐ UM Campus Location

☐ Other Missouri College or University

☐ Out of State College or University

☐ Missouri K-12 Education Setting

☐ Out of State K-12 Education Setting

☑ Other

A. Describe Other:

This study will be completed entirely online.

18. Where will the research take place?

Indicate the location(s) of the study visits/sessions.

Qualtrics Survey provided online

19. Permission to Conduct the Study

Be sure to keep documentation of permission, if required, in your research records.

● I attest that I already have permission to conduct the study at these locations.

○ I am still needing some or all permission to conduct the study, but permission will be secured prior to subject recruitment.

20. How long will the subject actively participate in the research?

Actively participate includes the protocol-specific visits/sessions that require their attendance and/or participation. Specify minutes, hours, months, or years.

Less than 30 minutes

21. How long will the subject be in long-term follow-up?

This means subjects that have completed all study-related treatment/interventions, but are being followed per study protocol to monitor study-related outcomes. This includes interactions that involve no more than minimal risk (i.e. quality of life surveys/follow-up surveys), and collection of follow-up data from procedures or interventions that would have been done regardless of the research (i.e routine clinical or non-clinical activities to further monitor a subject). Specify minutes, hours, months, or years.

If follow-up is not applicable, please state “no follow-up”.

no follow-up

22. Does the study involve a sub-study?

This means subjects enrolled in the main study may be eligible to participate in sub-study. This is not for new enrollees (you cannot have multiple studies with different populations under one IRB project)

○ Yes ● No

23. Does the study involve subject compensation?

Compensation includes reimbursement, covering expenses (hotel/car), course/extra credit, monetary payments (check, gift card, cash), non-monetary items (gifts, food/drinks, supplies), etc.

● Yes ○ No

24. Describe the amount of subject compensation.

1 Research Credit that will fulfill in part the research credit requirement for students of Psychology 1000 courses.

25. What is the proposed payment type?

☐ Check

☐ Gift Card

☐ Cash

Other:

1 Unit of research credit.

26. Describe the timing of disbursement.

The payment cannot be contingent upon completing the entire study. If there are multiple visits/sessions, this should be pro-rated. Describe that plan here.

The singular unit of research credit will be automatically granted upon submission of the survey.

27. In your opinion, will the subject be influenced by the compensation offered?

○ Yes ● No

28. If you are offering extra credit or course credit for student participation, describe the alternative assignment for students who may decline.

The alternative assignment must be comparable in effort and time commitment.

From my understanding, psychology 1000 students can choose to write one essay in exchange for each required unit of research credit needed for their course.

29. Are you using an institutionally approved method/system of payment?

You will need to work with your department to ensure all institutional processes are followed for subject payment.

● Yes ○ No

30. If you are using University funds for subject payments, describe your secure plan to collect identifying information necessary to comply with the University policy linked below. Only the use of personal funds are excluded from this policy.

https://www.umsystem.edu/ums/policies/finance/payments_to_research_study_participants

The identifiers necessary for payment and the process to collect them must be disclosed in the consent. If you are seeking a waiver for obtaining a social security number for payments, email the request to muacctgpaymethodapp@missouri.edu.

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

For information about research participant payments, click here.

32. Does the study involve audio recording, video recording, or photographing?

○ Yes ● No

33. Does your study include presenting photographs or other potentially identifiable media to the participants in your study?

As a reminder, just because pictures and other items are available on the internet does not mean they are approved to use in your research.

○ Yes ● No

4. Subject Recruitment

1. List your inclusion criteria.

This would be a description of your subject population, who you will be targeting for recruitment. If all of this information is clearly stated in your protocol, you may refer to a specific page/section in your protocol.

Psychology 1000 Students who are needing research credit units.

2. List your exclusion criteria.

This would be a description of who cannot participate in your research, who you are not targeting for recruitment. If all of this information is clearly stated in your protocol, you may refer to a specific page/ section in your protocol.

No exclusion criteria in particular

3. Select who is allowed to determine eligibility for this study based on inclusion/exclusion criteria:

- ☐ Subject (or their legally authorized representative)
- ☑ Research personnel authorized to obtain consent
- ☑ PI and/or Co-Investigators Only
- ☐ PI Only

4. 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
- ☐ Community Veterans (do not check this if this study engages the Truman VA Hospital as a research site)
- ☐ MU Student-Athletes

5. You selected students above. Are you (or any other research member) recruiting your/their own students?

○ Yes ● No

6. Will you be processing (i.e. using, accessing, collecting, recording, storing, or transmitting) any 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?

○ Yes ● No

7. Explain how you will have access to this population and what method will be used to identify and recruit subjects.

If you are using medical records to identify potential subjects, you must describe the providers or group of providers that have treating relationships with the patients, and describe your plan to consult the providers before contacting patients.

Student subjects will self-select our experiment, as one of a variety of choices that they can participate in, in order to obtain research credit.

8. Do you plan to use social media for subject recruitment purposes?

○ Yes ○ No ● N/A

9. Do you plan to use an online recruitment/research panel to recruit subjects?

An online recruitment panel allows you to send your survey to a targeted population of respondents.

○ Yes ○ No ● N/A

You must upload all recruitment materials for review, including but not limited to, letters, emails, verbal scripts, advertisements, etc. All recruitment materials must receive IRB approval before use.

10. If there is a plan to screen potential participants to determine eligibility in this study, select if any of the following apply:

☐ You plan to obtain information through oral or written communication with the prospective subject or legally authorized representative (LAR).

☐ You plan to obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

☑ Neither Apply - There is no need to screen to determine eligibility in this study.

11. What methods will be used to avoid inadvertent coercion or undue influence in the recruitment process?

The Belmont Report defines coercion and undue influence: Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.

We will offer only a reward (research credit) that is commensurate with the exact type of reward (research credit) that is offered by similar studies that can be taken by Psychology 1000 students to fulfill course requirements. I believe that there will be absolutely no possibility of coercion for our research subjects, as they will consent to participate themselves with no outside pressure provided.

12. Do you plan to retain any information on recruitees not ultimately enrolled in the study?

○ Yes ● No

13. Would you like to request for this study to be advertised on an MU Division of Research, Innovation, and Impact (RII) website created for recruitment purposes?

If yes, you will be asked additional questions creating information to pull to the website about your study as soon as this application is approved. If you wish to remove the listing from the website later, you can submit an amendment with the answer to this question changed to "no" and it will be removed after approval. The listing will also be removed from the website if the project is closed to enrollment or has expired. Click here to view the website: https://research.missouri.edu/human-subjects-research/participant-outreach

○ Yes ● No

14. Are you requesting to add this study to researchmatch.org to advertise? If yes, you must upload the ResearchMatch Contact Message for IRB review and approval.

MU is a participating site of researchmatch.org. The advertisement is free. View the Researcher FAQ for additional information: https://www.researchmatch.org/researchers/faq

○ Yes ● No

Enrollment

15. How many people do you expect to complete the study?

An Amendment Form is required if your enrollment is going to exceed your target enrollment by more than 20%.

176 people enrolled.

16. How many people will be enrolled (sign a written consent or consent with a waiver of documentation) to reach the number listed in the previous question?

For some studies, this number may be the same, for other studies there may be a high rate of screen failures, so you will want to account for those screen failures.

I believe that this number will be roughly the same, perhaps a small amount higher to account for incomplete surveys, so roughly 180 people.

Policy Regarding Recruitment Materials:

The recruitment should be limited to:

- The name and address of the investigator or research facility
- The condition under study or the purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the study
- A brief list of participation benefits, if any
- The time or other commitment required of the subjects
- The location of the research and the person or office to contact for further information

The recruitment cannot:

- State or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol
- Make claims, either explicitly or implicitly, that the drug, biologic or device was safe or effective for the purposes under investigation
- Make claims, either explicitly or implicitly, that the test article was known to be equivalent or superior to any other drug, biologic or device
- Use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article was investigational
- Promise “free medical treatment,” when the intent was only to say participants will not be charged for taking part in the investigation
- Include exculpatory language
- Emphasize the payment or the amount to be paid, by such means as larger or bold type

5. Subject Consent

1. **Select what type(s) of consent will be obtained (there may be more than one):**

☐ **Written (or the electronic equivalent)** - Templates can be found here

☐ **Waiver of Documentation (no signature requirement) -** Templates can be found here.
Example:
Telephone or online survey/interview
Note: A waiver of documentation of consent is no longer required for screening, recruiting, or determining eligibility, if you are obtaining information through oral or written communication with the subject or legally authorized representative UNLESS you are asking subjects to do something required by the protocol (i.e. fast, withhold medications, etc.). HIPAA regulations still apply to protected health information, and an authorization or waiver/alteration may still be required.

☑ **Waiver or Alteration of Consent**
Examples:
1. No consent will be obtained for the entire study (i.e. record review or observational only study)
2. The study involves deception (this would be an alteration of consent since certain elements of consent are being altered)
Note: A waiver of consent is no longer required for screening, recruiting, or determining eligibility, if you are (i) obtaining information through oral or written communication with the subject or legally authorized representative; or (ii) obtaining identifiable private information or identifiable biospecimens

by accessing record or stored identifiable biospecimens. A HIPAA waiver is still required for access and use of protected health information.

2. Will the study involve accessing identifiable student educational records?

Written consent must be obtained from the subject or their legal guardian to allow the release of identifiable student educational records UNLESS the study meets an exception to written permission. Additional information can be found here: US Department of Education FAQ or MU Website

○ Yes ● No

3. Please select the option that you are requesting:

☐ A full waiver of consent

☑ An alteration of consent (example: deception studies)

A. Describe how the research involves no more than minimal risk to participants.

Providing false information regarding American public opinion circa 2018 on several social issues does not seem like a particularly dangerous thing. It shouldn't change a person's own family or friends relationship with this information, and we provide the accurate information in the debrief, so this false information does not carry on past the study itself.

B. Describe how the waiver or alteration will not adversely affect the rights and welfare of the participants.

Holding somewhat inaccurate information on these topics for the brief duration of the study (less than 30 minutes) should not affect the welfare and rights of the participants, as it is such a short span of time and would generally be considered uncontroversial or unimportant information.

C. Describe how the research could not practicably be carried out without the requested waiver or alteration.

The direct purpose of the study is to manipulate perception of social consensus, which definitionally for this protocol/procedure to provide inaccurate information.

D. If the research involves identifiable private information or identifiable biospecimens, describe how the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

E. Whenever appropriate, describe how the subjects or legally authorized representatives will be provided with additional pertinent information after participation (debriefing).

Accurate information on what the survey values themselves consist of will be provided in the debrief.

F. Describe what it is you are altering or omitting.

Please click here to view the general requirements of informed consent to help explain what it is you are altering or omitting.

We are changing the percentage of Americans that agree or disagree with several contemporary issues either up by 20%, or down by 20%. E.g., if 50% of Americans (circa 2018) actually support capital punishment, then we would either tell participants that the 'real value (lying)' was 30% or 70%, in the low or high consensus conditions respectively.

G. Are you requesting an alteration of consent because the study involves deception?

Deception is defined as deliberately giving false information about some aspect of the research to the subject.

● Yes ○ No

H. Justify the use of deception in your research and describe how it is a necessary and unavoidable component to your research design.

Further explain how it provides value to the body of knowledge. Your response might also describe how the absence of deception would significantly compromise the study's ability to provide value to the body of knowledge.

We are trying to determine how perception of social consensus can affect individual differences in ethical and moral perception, especially as it relates to individual support or opposition of these assorted issues. Without deception, there are no contemporary methods that can be leveraged to manipulate perceived social consensus on general public opinion.

I. How will the participants be debriefed?

The debriefing is an essential part of the informed consent process and is required when the research involves deception. The debriefing provides the participants with an explanation of the study's goals (or hypotheses) in a manner that they can understand, procedures to deceive participants and the reasons why it was necessary. Upload the debriefing script for IRB review.

Participants will be lead to a debriefing screen as the final element in our qualtrics survey. We will include accurate information as to the original goals and intent of the study, as well as why deception was necessary. We will clearly indicate to our participants what the 'true values' were for our four survey issues that were used to assess social consensus cognition.

J. Who is responsible for debriefing the participants?

The online qualtrics survey will be responsible, it is automatically set to display the debrief at the end of the survey.

K. Describe the timing of debriefing.

Will the debriefing occur immediately following the experiment or will it be delayed? Justify a delayed debriefing.

At the end of the survey, a debrief will be provided

L. Describe whether participants are given the opportunity to ask questions about the debriefing.

Yes, participants are given contact information of both the researcher and the MU IRB, and are able to contact either or both to get more information.

M. Is the participant free to withdraw his/her data after being fully debriefed?

This answer must be YES.

● Yes ○ No

N. Could the deception influence the participants' willingness to participate?

No

O. Does the presence of deception increase the risk to participants? Explain.

Studies involving greater than minimal risk will not be approved with deception.

No, because holding somewhat inaccurate information on these topics for the brief duration of the study (less than 30 minutes) is not an inherently risky situation to put oneself in. It is such a short span of time and would generally be considered uncontroversial or unimportant information, additionally, we will give them accurate information as soon as the survey is complete.

P. **Research or demonstration projects that are conducted by or subject to the approval of state or local government officials**

*This is another waiver/alteration option infrequently used here, but available if needed.

☐ The research or demonstration project is designed to study, evaluate, or otherwise examine: (A) public benefit or service programs; (B) procedures for obtaining benefits or services under those programs; (C) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration.

4. Do you plan to use the information (and/or biospecimens) collected in this study for **future research studies** or distribute to another investigator for future research studies?

   A statement whether information/biospecimens will be used or distributed for future research must be disclosed in the consent, or a waiver of consent was requested.

   ○ Yes ● No

5. Do you plan to use the information (and/or biospecimens) collected in this study for **future non-research uses** such as educational uses, quality improvement activities, and/or marketing purposes?

   If yes, details must be included in the consent(s), or a waiver of consent is requested.

   ○ Yes ● No

6. Risks and Benefits

1. Describe the potential risks associated with the research and identify the procedures that will be used to prevent and/or minimize any potential risks and discomforts.

   For drug studies, please do not list all drug side effects (these will go on the drug sub-form). Some examples of potential risks may include, breach of confidentiality, invasion of privacy, psychological, physical, social, economic, legal, or other.

   There are three reasonable foreseeable risks or potential discomforts for our subjects. The first risk is that our participant will take the information we provide to them about social consensus extremely seriously, and that it could perhaps lead to an unintentional warping of their worldview. The second risk is that our participants will be emotionally distressed once they realize that they have been deceived. The last potential risk will be participants disclosing their personal opinions on a small number of social/political issues. Participants could experience embarrassment or distress if a breach of confidentiality occurred, and their responses were revealed to family, friends, or colleagues.

   Our main step to minimize these risks is to provide a thorough debrief at the end of the study, where we inform our participants of the actual social consensus results, as well as give them an explanation of how and why we felt that deception was necessary for our study. For risk #3 (personal opinions being revealed) this is mitigated by the nature of our survey itself being anonymous with no identifying information.

2. Does the study involve drugs or any procedure that may affect (known/unknown) an unborn child?

   ○ Yes ● No

3. What are the potential direct benefits to the subjects?

   It is possible the study has no potential for direct benefit. If this is the case, please state this.

   The main direct benefit for our subject would be to gain a deeper understanding of how social perception affects issues where there is still significant mixed support on. This is especially pertinent for issues where there is already a strong scientific consensus, but no social consensus (for example, climate change).

4. What are the potential benefits to the community and society?

Thee main indirect eventual benefit from this study is the improved likelihood of the U.S adopting Universal Health Care, which generally leads to significant improvements in health outcomes both for individuals and society.

5. Does the study require a data and safety monitoring plan?

A plan is required if this is a clinical trial, treatment and/or intervention study, sensitive data are being collected, there is a potential for subjects to experience adverse events, etc.

○ Yes ● No

6. Will subjects be asked questions about suicidality?

For example, the administration of the PHQ-9 instrument.

○ Yes ● No

7. Do you have or plan to obtain a Certificate of Confidentiality? For more information on Certificates of Confidentiality, please go here.

Certificates of Confidentiality are issued to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. NIH funded researchers are automatically issued a CoC through their award. Other Department of Health and Human Services (HHS) agencies issue CoCs to researchers they fund. Researchers not funded by HHS can continue to apply to NIH or the FDA as appropriate to request a CoC for HHS-mission relevant research.

○ Yes ● No

8. Select from the following to describe the protections in place to protect privacy interests of participants.

Check all that apply.

- ☑ Subjects decide the time and place where they give study information and who can be present.
- ☑ Subjects have the ability to decide who receives and can use the study information.
- ☑ Subjects can skip questions and control the nature of the information they give without penalty.

If there are additional privacy protections in place, please describe.

9. What are the consequences to subjects if a loss of privacy were to occur (e.g. risks to reputation, insurability, embarrassment, other social risks)?

participants are disclosing their personal opinions on a small number of social/political issues. Participants could experience embarrassment or distress if a breach of confidentiality occurred, and their responses were revealed to family, friends, or colleagues. This is mitigated with the lack of identifying information in our study.

10. Mandated Reporting

If you anticipate obtaining information during the research study which might fall under mandated reporting guidelines, select the guidelines that will be followed:

- ☐ Missouri Department of Social Services (i.e. child abuse)
- ☐ Missouri Department of Health and Senior Services (i.e. elderly abuse)
- ☐ Title IX
- ☐ Other

☑ None apply

7. Confidentiality and Security

1. Select all identifiers that may be accessed and/or included in the research records for the study, check all that apply:

☐ Names

☐ Address - All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent codes

☐ Dates - All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

☐ Telephone Numbers

☐ Fax Numbers

☐ E-Mail Addresses

☐ Social Security Number

☐ Medical Record Number

☐ Health Plan Beneficiary Number

☐ Account Numbers

☐ Certificate/License Numbers

☐ Vehicle Identifiers and Serial Numbers, including License Plate Numbers

☐ Device Identifiers and Serial Numbers

☐ Web Universal Resource Locators (URLs)

☐ Internet Protocol (IP) Address Numbers

☐ Biometric Identifiers, Including Fingerprints and Voiceprints

☐ Full-Face Photographic Images and any Comparable Images

☐ Any Other Unique Identifier, Characteristic, or Code

2. If you plan to disclose any subject identifiers listed above as part of the study process with anyone outside of the research team, identify the individuals or entities that will have access.

This must be disclosed in the consent document and HIPAA Authorization, if applicable.

3. Will any web/electronic software/applications be utilized for such purposes as recruiting subjects, completing questionnaires/surveys, conducting interviews/focus groups, or processing/storing data?

● Yes ○ No

4. List all web/electronic applications that will be used in the study.

DCL means Data Classification Levels.
Click here to determine the data classification levels associated with your project: https://www.umsystem.edu/ums/is/infosec/classification-definitions
DCL in a Nutshell: https://www.umsystem.edu/media/is/infosec/DCL_In_A_Nutshell.pdf

A. **Approved for DCL4 and below (this includes protected health information - HIPAA, social security numbers, and other highly restricted data)**

- ☐ Microsoft Teams
- ☐ Microsoft OneDrive
- ☐ REDCap
- ☐ Protected Zoom (Protected Version: https://umsystemprotected.zoom.us)

B. **Not Approved for DCL4 (highly restricted) but Approved for DCL3 (restricted) and below (sensitive & public)**

- ☑ Qualtrics
- ☐ Google Survey
- ☐ Microsoft Forms/Survey
- ☐ Zoom (https://umsystem.zoom.us)

C. **Other**

- ☐ Other
  - **i.** Name of Application(s):
  - **ii.** Describe its security features and identify the DCL associated with the data collected.

5. Are you proposing to administer an anonymous survey/questionnaire in this study?

This means no identifiers collected.

● Yes ○ No

6. Anonymous Survey/Questionnaire

A. If administering an online survey/questionnaire, have you checked the appropriate boxes/places on the survey tool to ensure the data collected will not record identifiers, for example IP address, that you would have access to?

● Yes ○ No ○ N/A

B. Could it be possible to identify an individual in your study based upon using a smaller sample size, and you are asking about a particular disease/condition, geographical location, or other unique, identifying characteristic?

○ Yes ● No

7. Will this research need a Material Transfer Agreement (MTA) governing the transfer of human material/ biospecimens between institutions for use in research?

If yes, you will need to work with the MU Office of Sponsored Programs to execute the agreement. A fully executed, signed copy of the MTA must be uploaded upon receipt using the "Support Letters, Agreements, and Documentation Form" in eCompliance.

○ Yes ● No

8. Data Storage and Retention

Select only one option per question based on these definitions -

Identified: Identifying information (such as name) enables the investigator to readily ascertain the identity of the individual to whom the private information pertain.

Coded: Identifying information (such as name) that would enable the investigator to readily ascertain the identity of the individual to whom the private information pertain has been replaced with a code (number, letter, symbol, or any combination) and a key to decipher the code exists, enabling linkage of the identifying information to the private information.

De-Identified: Data that are stripped of all identifying information, and there is no way the data could be linked back to an individual through a key or other coding method. Best practice when de-identifying data is to use the safe harbor method where all HIPAA identifiers are removed.

A. **How will information be kept during active data collection?** Select one.

- ☐ Identified
- ☐ Coded
- ☑ De-Identified

B. **How will information be kept during data analysis (after data collection is complete)?** Select one.

- ☐ Identified
- ☐ Coded
- ☑ De-Identified

C. **How will information be kept when the study is complete (after data analysis is complete)?** Select one.

- ☐ Identified
- ☐ Coded
- ☑ De-Identified

9. Where will data be stored after the study is complete?

Records must be retained for seven years after the completion of the study. If the research is being done under a contract that requires a specific retention time (shorter or longer), the contract retention time will apply.

Data will be stored online through the MU Qualtrics shared server.

8. Costs Associated with the Research

1. Are you conducting the study with patients/subjects in a MU Health Care location?

○ Yes ● No

2. If there may be costs incurred in the research for ancillary resources, such as medical treatment, psychological counseling, emergency services, or concomitant medications, how will the cost be covered?

Place NA if none are expected.

NA

3. Do you have adequate resources to conduct the study?

Consider adequate time for the researchers to conduct and complete the research; adequate qualified number of staff; adequate facilities and equipment; access to a population that will allow recruitment of the necessary number of participants; and availability of medical or psychological resources that participants may need as a consequence of the research.

● Yes ○ No

9. Completion of Required Sub-Forms

1. **Select the items that are included as part of your study. For items marked, an additional form will be generated for your completion at the end of this application and is labeled "Additional Forms".**

   FORM INSTRUCTION: As you work through the list and you check a box that generates a sub-form, then you realize those additional questions in the sub-form do not pertain to your study, go back to this page and uncheck the box that generated the sub-form to make it go away.

BIOMEDICAL SPECIFIC SUB-FORMS

☐ Collection of **biospecimens (i.e solid tissue, blood, saliva, urine, and other biospecimens)**

☐ Administration of a **drug or biologic** (investigational - new drug/biologic or FDA marketed drug/biologic administered for research-only (protocol-driven)). This includes placebos if applicable. Do not complete this subform if using a marketed drug in the course of medical practice (i.e. standard of care administration/use) where the use is for an individual patient and the primary intent is to treat the patient.

☐ **Compassionate Use (Expanded Access)** Request

☐ Administration of a **supplement, food, cosmetic, or other substance/product** (this includes placebos)

☐ **Radioactive or Cold Isotopes**

☐ **Medical Devices** (including HUDs) in a clinical investigation (new devices, off-label uses, and/or FDA approved devices when collecting information on its safety and effectiveness) - this includes invitro diagnostics as well. Unsure if you are collecting information on its safety and/or effectiveness? Click HERE

☐ **Radiological Procedures** (may or may not involve radiation - MRI, xray, ultrasound, DXA Scan, etc.) - only complete for research-only procedures, not procedures subjects will normally receive as part of standard of care

☐ **Radiation Therapy**

☐ Involves an **Exception from Informed Consent for Planned Emergency Research**

SUBJECT POPULATION SUB-FORMS

☐ **Children** (under 18 in Missouri, also dependent on State law)

☐ **Pregnant women or fetuses** (This item is for studies that will target pregnant women, or is a treatment-intervention study (i.e. drug/device) that will not exclude pregnant women/fetus)

☐ **Non-viable neonates or neonates of uncertain viability** (neonates=newborns)

☐ **Non-English speaking subjects** (Select if it is known at this time that you will enroll non-English speaking subjects, and the study documents will need to be translated. You can always amend your study to add non-English speaking at any time)

☐ **Prisoners**

☐ **International Study** involving an international population, international investigators, or the sharing of information/biospecimens with international collaborators/sponsors/agencies where "international" indicates outside the United States

☐ **Short Form Consent** (Enrollment of potential non-English speaking) - Do not check if the entire consent form will be translated.

OTHER SUB-FORMS

☐ Establishing a **Biorepository and/or Database for Future Unspecified Research Uses** (do not complete if established by external sponsor)

Generated at: **04/11/2023 11:13 AM**