COVER PAGE

HOPE Intervention for COVID-19
NCT04376515
6/8/2021

UCI Office of Research

Institutional Review Board
Human Research Protections

Exempt Self-Determination Tool

UPDATED! *Version June 2020*

UC Irvine IRB review is required for *most* activities that constitute engagement in human subjects research, as federally defined.

At UCI, researchers are permitted to self-determination their exempt research without confirmation from the IRB. This tool is intended to help you determine and document whether the human subject research qualifies for exempt self-determination or requires UCI IRB Review.

IMPORTANT! Should the study sponsor require evidence of IRB review for a self-determination of exempt research, please provide the sponsor this letter.

INSTRUCTIONS:

1. **To get started, review Parts A & B to determine if the research is eligible for exempt self-determination.**

2. **If the research is eligible for exempt self-determination, maintain a copy of the completed Exempt Self-Determination Tool and any supporting documentation in your records. IMPORTANT! Do NOT submit the Exempt Self-Determination Tool to the IRB.**

    a. **Sign the Lead Researcher (LR) Assurance statement at the end of the Exempt Self-Determination Tool. Obtain the Faculty Sponsor's signature as appropriate.**

3. **If UCI IRB Review *is* required, please submit a New IRB Application for exempt, expedited, or full committee review. For more information, please review: How To Submit Electronic IRB Applications for Review.**

If you have questions about completing the Exempt Self-Determination Tool or about the IRB process in general, contact the Human Research Protections staff.

IMPORTANT REMINDER! In accordance with the Vice Chancellor for Research's shutdown message, non-critical research has been halted. However, non-critical research that can be performed from home may continue. The research shutdown remains in effect consistent with California's Executive Order N-33-20.

Refer to the Office of Research webpage on Research Continuity for more details.

PART A: VERIFY SELF-DETERMINIATION ELIGIBILITY

The activity is eligible for exempt self-determination *IF* all of the statements below are true.

IMPORTANT! If one or more statement below are not true then the research is not eligible for exempt self-determination and IRB review is required.

☒ **A. The research IS human subject research.**
Please review the Non-Human Subject Research Determination form. If your activity is non-human subject research, please complete the form and maintain it for your records. If your activity does not qualify as non-human subject research, please check the box to the left and proceed to the next check box.
NOTE: Graduate students dissertation research involving humans is considered human subject research – please check the box to the left.

☒ **B. I am NOT a UCI undergraduate researcher.**
All UCI undergraduate research involving human subjects that meets the criteria for exempt review must submit for exempt confirmation through the Undergraduate Research Opportunities Program (UROP).

☒ **C. The research is NOT supported by the Department of Justice (DOJ).**
Research that is funded/supported by the Department of Justice (DOJ) is not eligible for exemption either by Self-Determination or through submission to the IRB. Submit a New IRB Application for expedited / full committee review. For more information, please review: How To Submit Electronic IRB Applications for Review.

☒ **D. The research does NOT include any of the following.**

1. The use or disclosure of UCI protected health information (PHI)[1]
   a. *Use* is any sharing, employment, application, utilization, examination, or analysis within the entity
   b. *Disclosure* is any release, transfer, provision of access to, or divulging outside of entity
2. A targeted recruitment of children targeted recruitment of children
3. A targeted recruitment of adults (age 18 or older) who may not be legally/mentally/cognitively competent to consent
4. A targeted recruitment of prisoners (*may* include parolees)
5. A targeted recruitment of American Indian/Alaska Native tribes
6. A targeted recruitment of undocumented people
7. International Research
8. A request for UCI to serve as IRB of Record for non-UCI individuals engaged in human subjects research.
   Note: To initiate a request for UCI to serve in this capacity, the LR must have a dual affiliation with the non-UCI entity and IRB review is required to formalize the reliance process.
9. A study team member has a Disclosable Financial Interest

IMPORTANT! IRB approval is required to enroll any of the above listed subject populations. Should the study team inadvertently encounter a potential subject that belongs to an excluded population above, this individual may NOT be enrolled in the study.

PART B: VERIFY EXEMPT CATEGORIES ELIGIBLE FOR SELF-DETERMINIATION

1. **Please review the following Exempt categories that are eligible for self-determination.**

2. **Check the category(ies) that apply to the research.**

IMPORTANT! If one or more category below are not applicable then the research is not eligible for exempt self-determination and IRB review is required.

[1] When PHI is communicated inside of a covered entity, this is called a ***use*** of the information. When PHI is communicated to another person or organization that is not part of the covered entity, this is called a ***disclosure***. HIPAA allows both use and disclosure of PHI for research purposes, but such uses and disclosures have to follow HIPAA guidance and have to be part of a research plan that is reviewed and approved by an Institutional Review Board (IRB).

Category 1: Education (the following criteria must be met)	
☐	Research, conducted in established or commonly accepted educational settings and specifically involves 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.
Category 2: Interactions (the following criteria must be met)	
☐	Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) [2] ***One of the following criteria must be met:*** ☐ 2i) 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*** ☐ 2ii) 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 **Reasonably defined as with fair and sound judgment; a standard used by an ordinary, rational person under similar circumstances.*
Category 3i: Behavioral Interventions ***(All of the following criteria must be met)***	
☒	The research involves 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
☒	The 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

[2] Subpart D applicable only when involving educational tests or the observation of public behavior when the investigator(s) do NOT participate in the activities being observed.

☒

One of the following criteria must be met:

☐ 3iA)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

☒ 3iB) 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

**Reasonably defined as with fair and sound judgment; a standard used by an ordinary, rational person under similar circumstances.*

SECTION 1: STUDY INFORMATION

1. Study Title:

HOPE COVID-19 Vaccine Opinion Study

2. Identify the funding source. *Check all that apply:*

☒ Grant/Subaward ***OR*** ☐ Contract/Subcontract

(provide details below)

Prime Awardee(s): Sean Young

Sponsor Name(s): NIAID

SPA Proposal or Award #(s): 5R01AI132030-05

☒ ***Check here to confirm a copy of the human subjects portion of the grant is available and kept on file***

☐ Department or campus funds (includes department support, unrestricted funds, start-up funds, personal funds, campus program awards, etc.)

☐ Non-cash support from manufacturer/sponsor (e.g., free drug, device, research materials)

☐ Subject/subject's insurance/third party payer

☐ Student project that will incur no costs.

SECTION 2: STUDY TEAM

1. **Complete the table below.**

2. **List the Lead Researcher (LR), Co-Researchers (CR), and Research Personnel (RP) who will be engaged in human subject research.**
   - **Co-Researchers are faculty, staff, students and other academic appointees who the LR considers to be key personnel for conducting the research study. These individuals work closely with the LR to design, conduct, and/or report on the research.**
   - **Personnel who are not interacting with participants for research purposes and/or who do not have access to identifiable private information (e.g., statisticians) are not engaged in human-subjects research and therefore should not be listed below.**
   - **IMPORTANT! Do not list non-UCI researchers below. To initiate a request for UCI to serve as the IRB of Record for non-UCI researchers, the LR must have a dual affiliation with the non-UCI entity and IRB review is required to formalize the reliance process.**

3. **If there is a Faculty Sponsor (FS), they must be listed below, as they must be identified to provide oversight and guidance to the LR. If there is collection of identifiable information, the Faculty Sponsor should be designated as having access to the identifiable information.**

Role	Name, Title & Degrees	Department & UCI Affiliation - Faculty, Staff, Graduate or Undergraduate Student	Recruit	Informed Consent Process	Interact with Participant	Access Participant Identifiable Information	Analyze Participant Identifiable Information
LR	Sean Young, PhD, MS	☒ Faculty ☐ Staff ☐ Grad Student ☐ Undergrad ☐ Other UCI: Type Here	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No
FS	Type Here	☐ Faculty ☐ Other UCI: ☐ Other UCI: Type Here	☐ N/A ☐ Yes ☐ No	☐ N/A ☐ Yes ☐ No	☐ N/A ☐ Yes ☐ No	☐ N/A ☐ Yes ☐ No	☐ N/A ☐ Yes ☐ No
☐ CR ☒ RP	Dominic Arjuna Ugarte, MD, MBA	☐ Faculty ☒ Staff ☐ Grad Student ☐ Undergrad ☐ Other UCI: Type Here	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No
☐ CR ☒ RP	Lidia Flores, BA	☐ Faculty ☒ Staff ☐ Grad Student ☐ Undergrad ☐ Other UCI: Type Here	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No

☐ CR ☒ RP	Romina Romero, PhD, MPH	☐ Faculty ☒ Staff ☐ Grad Student ☐ Undergrad ☐ Other UCI: Type Here	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No
☐ CR ☒ RP	Desirée Fehmie, MPH, MSc	☐ Faculty ☒ Staff ☐ Grad Student ☐ Undergrad ☐ Other UCI: Type Here	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No
☐ CR ☒ RP	Parvati Singh, PhD	☐ Faculty ☒ Staff ☐ Grad Student ☐ Undergrad ☐ Other UCI: Postdoc	☐ N/A ☐ Yes ☒ No	☐ N/A ☐ Yes ☒ No	☐ N/A ☐ Yes ☒ No	☐ N/A ☒ Yes ☐ No	☐ N/A ☒ Yes ☐ No

To add more study team members, click into this space, then click the new + button on the right ➡

5. If applicable, specify which members of the above study team will be responsible for interacting with non-English speaking participants.

NA: English speaking participants only

SECTION 3: WHAT IS YOUR RESEARCH QUESTION?

1. State the hypothesis or primary objective of the research. Include a rationale for conducting the study. *[Maximum length = 250 WORDS]*

This study seeks to utilize our previously tested Harnessing Online Peer Education (HOPE) online community intervention to connect peer leaders with healthcare personnel and frontline essential workers choosing not to receive the COVID-19 vaccine. Over the 4-week intervention we aim to teach participants about the risks of COVID-19 and the benefits of the COVID-19 vaccine.

The peer community leader model, which teaches community popular opinion leaders about how to disseminate behavior change messages throughout the community, has been proven to increase prevention behaviors in things like HIV prevention. Social networks, such as Facebook.com may be a cost-effective platform for scaling these models. Our research team has employed our HOPE intervention previously, for example, in populations who are high risk for HIV/AIDS and in populations suffering from anxiety due to COVID-19. Following that same model, we will modify it to help combat the current low rates of COVID-19 vaccination, with some places experiencing as high as 50% of healthcare personnel refusing to receive the COVID-19 vaccine. If we are able to increase the rates of COVID-19 vaccination, it will show potential as a useful tool to aid in future public health crises and vaccination campaigns.

2. COVID-19: Does this research include a focus on SARS-CoV-2/COVID-19 (Coronavirus)?

☐ **NO**

☒ **YES: Please consider whether Ancillary Committees for COVID-19 Research apply.**

SECTION 4: SUBJECT POPULATION

Complete the table below. Specify the maximum number of individual-level information to be accessed/analyzed within each cohort and in total across all cohorts.

Category/Group (e.g., students in School or Course, consumers on website, people being observed at location)	**Age Range** (e.g., adults 18 and over)	**Maximum Number of Subjects**
American Adult in phase 1a or 1b of COVID-19 vaccine rollout who have refused to receive the COVID-19 vaccine	18+ years old	120
Type Here	Type Here	Type Here
To add more categories/groups, click into this space, then click the new + button on the right →		
		Total:120

SECTION 5: RECRUITMENT METHODS

1. Indicate which recruitment methods will be utilized. Check all that apply:

IMPORTANT! Advertisements must adhere to UCI Recruitment Guidelines. Various templates are available on the HRP webpage Application and Forms (see sub-section HRP and then Recruitment Templates).

☐ This study involves no direct contact with participants (i.e., passive observation of public behavior or secondary use of information). ***Skip to SECTION 6.***

☒ Online Advertisements – Including Social Media
☐ Radio / Television Advertisement
☐ Newspaper Advertisement
☐ Flyers
☒ Letters or Emails
☒ Phone Call
☐ Other (specify): Type Here

2. Describe when, where, by whom and how potential participants will be approached.
3. If posting on your Facebook page or other social media sites, please explain.
4. If you will recruit by e-mail, phone, etc., explain how the researcher will obtain the participants' contact information.

Participants in both the control and intervention group will be recruited through online advertisements on Facebook, Google ads, our Facebook page, and online forums like Reddit. We may also contact healthcare organizations, hospital departments, and academic institutions by phone or email asking them to send emails with information about the study to any frontline essential workers through a mailing list. Advertisements will be designed to recruit healthcare personnel and frontline essential workers who have refused to receive the COVID-19 vaccine. Participants who click on the ads or links on the forums will be routed to a website/survey (such as Qualtrics) where they are screened online for eligibility with our questionnaire. Those who visit our Facebook page may have the option to interact with a chat box that will eventually route potential participants to the website/survey as above.

Inclusion criteria:
1. Adults, 18+ years old, who are competent to give informed consent
2. English speakers only
3. U.S. Resident
4. Part of phase 1a or 1b of COVID-19 vaccine rollout – healthcare personnel and frontline essential workers (employment verified through LinkedIn profile or similar)
5. Uses social media and/or online communities greater than twice per week
6. Has, or is willing to accept a friend request and group invite from our Facebook social media page
7. Has not received a COVID-19 vaccine and does not have medical conditions or other circumstances preventing them from receiving one

Phase 1a includes **healthcare personnel** such as physicians, nurses, technicians, therapists, pharmacists, administrative staff, environmental services staff, students, and other trainees.
Phase 1b includes **frontline essential workers** such as fire fighters, police officers, corrections officers, food and agricultural workers, United States Postal Service workers, manufacturing workers, grocery store workers, public transit workers, and those who work in the educational sector (teachers, support staff, and daycare workers.)
See CDC recommendations for further details: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations.html

Those who do not qualify to participate in the study will see a web page that thanks them for their interest and tells them that they are not qualified to participate at this time and that their data will not be used and will be destroyed to protect their confidentiality. Those who are unqualified will not be able to access the Informed Consent Information Sheet. If eligible, potential participants will be sent a brief description of the study and the Informed Consent Information Sheet. If they would like to participate in the study they will be asked to continue with the consent process. By clicking continue, they will have implied consent to the study and be routed to a webpage where they can provide an email address and phone number for future contact, as well as begin the baseline survey. After survey completion, they will be instructed to friend request our HOPE Study Facebook profile or be provided a link to join the group.

After 1) consenting to the study (by clicking continue), 2) friending us on Facebook, 3) completing a baseline survey, and 4) joining our private Facebook group (they will be randomly assigned to a group and group request will be sent to them), participants will be officially enrolled in the study.

If participants have yet to friend us or join our private group, we will email them a reminder and/or call them every 24 hours until the invitation is accepted.
In the event that a participant has trouble friending us on Facebook, participants may alternatively be sent a link to join the Facebook group.
If the baseline survey is not completed after 48 hours, we will attempt to reach the participant by phone every day until we successfully make contact. We may call them multiple times per day up to a maximum of 3 attempts.

Peer Leader Recruitment:
Up to 30 peer leaders will be recruited using online advertisements as above, as well as by direct message of healthcare personnel or frontline essential worker that has shared a picture of their vaccine card or vaccination sticker online, for example on Reddit. Advertisements will be designed to recruit people who are social online (e.g., chat frequently online, create TikTok videos, etc.) and report having received the COVID-19 vaccine. Potential peer leaders who click on the ads will be routed to a website/survey (such as Qualtrics) where they are screened online for eligibility with our questionnaire.

Inclusion criteria:
1. Adults, 18+ years old, who are competent to give informed consent
2. English speakers only
3. U.S. Resident
4. Part of phase 1a or 1b of COVID-19 vaccine rollout - healthcare personnel and frontline essential workers (employment verified through LinkedIn profile or similar)
5. Uses social media and/or online communities greater than twice per week and is active on TikTok or Instagram (ideally with at least 10,000 followers)
6. Has, or is willing to accept a friend request and group invite from our Facebook social media page
7. Has received a COVID-19 vaccine

Phase 1a includes **healthcare personnel** such as physicians, nurses, technicians, therapists, pharmacists, administrative staff, environmental services staff, students, and other trainees.
Phase 1b includes **frontline essential workers** such as fire fighters, police officers, corrections officers, food and agricultural workers, United States Postal Service workers, manufacturing workers, grocery store workers, public transit workers, and those who work in the educational sector (teachers, support staff, and daycare workers.)

See CDC recommendations for further details: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations.html

As this is a time-sensitive study, peer leaders might be enrolled based on these criteria; however, if time permits, they might also be called and secondarily screened to see whether they are social, communicative, and seem to have leadership qualities based on things like past volunteer experiences. Enrolled peer leaders will be asked to participate in 3 online training sessions of approximately 2-3 hours each where they learn how to interact with participants. Session 1 will focus on COVID-19 epidemiology; session 2 on benefits of the vaccine, as well as fears and myths surrounding the vaccine, and session 3 on the logistics of the study. Peer leaders who complete the training will be paid $20 per week in Amazon gift cards for emailing us a tracking form by the weekly deadline that documents their efforts attempting to communicate with participants during the course of the study.

Methods:
Participants will be randomly assigned to an intervention or control group (each group will have approximately 30 participants and approximately 6 peer leaders (depending on recruitment and people that may drop out)). There will be 5 control groups and 5 intervention groups total. Those in the control group will be assigned to a private and hidden Facebook group and told they can interact with each other as they wish. Those in the intervention group will be assigned to peer leaders, also in a private and hidden Facebook group, with each participant assigned to have approximately 2-3 peer leaders. Facebook groups will also become hidden once all group participants are in the group. The intervention will take place over 4 weeks, with a possible week 0 before the study officially starts to allow peer leaders and participants to become accustomed to each other and the Facebook group features. Each week of the intervention, peer leaders will reach out to participants by posting on the online group forum, either text, images, or videos and sending direct messages to participants, attempting to promote COVID-19 vaccination through comforting and educational information/content of their choice. Every 2 weeks through the end of the study, participants in both conditions will be invited to email us to receive information about and receive related resources for COVID-19 vaccination, such as pamphlet on vaccination information. At the end of the 4-week intervention, participants will complete the final survey. Participants will be paid $15 in Amazon gift cards for the baseline survey, $20 in Amazon gift cards for the final survey, and $15 in Amazon gift cards for providing proof of vaccination if applicable. Participants should expect about 4-6 weeks after completing respective tasks before receiving compensation. Participants will be contacted by phone and/or email to remind them to complete surveys as discussed above for the baseline survey.

All analyses will be conducted in R (version 4.1.2) We will assess the effect of the HOPE intervention on the primary outcome (whether a participant requested vaccine information during the study), and the secondary outcome (whether a participant got the vaccine during the study). We will adjust for race (dichotomized by Caucasian vs other), age (above vs. below 40), sex from birth, education (bachelor or below vs. grad school or above), and ethnicity (Latino vs. other).
The intervention effect on the primary outcome will be assessed using logistic mixed effects models or generalized estimating equations.
The intervention effect on the secondary outcome will be assessed using generalized estimating equations with an exchangeable correlation structure ([2]), which accounts for the clustering by Facebook group.
Engagement in the study is defined as participants that posted, commented, voted, or reacted to anything within a given week.

SECTION 6: PARTICIPANT COMPENSATION

Will participants be compensated?

IMPORTANT! Compensation should be offered on a prorated basis when the research involves multiple sessions. Additional considerations are required when using lotteries, raffles, and drawings, see UCI Lottery Guidance. For additional information about researcher's/department's responsibilities and current Accounting procedures, see UCI Policy Sec. 701-03.

☐ Participants will not be compensated. ***Skip to SECTION 7.***

☒ Participants will be compensated, ***address the following:***

Amount of Payment: Participants will be compensated $15 for the baseline survey, $20 for completing the 4-week survey, and an additional $15 if they show proof of at least the first dose of vaccination (send us picture of vaccine card). Up to a total of $50.

Peer Leaders will be compensated $20 for each week they turn in their complete response sheet on time. Total of $80 if all response sheets are turned in complete and on time.

Method: ☐ Cash ☐ Check ☐ Extra credit ☒ Gift card: Amazon Gift Card ☐ Other: Type Here

Schedule: ☐ After each study visit ☐ At the end of study ☐ Other : Type Here

SECTION 7: INFORMED CONSENT PROCESS

1. Identify the specific steps for obtaining consent.

IMPORTANT! For additional information, see Guidance for Consenting Process. Templates are available on the HRP webpage Application and Forms (see sub-section HRP, Consent Forms).

☐ **No consent process will take place (i.e., no contact with participants)** ***Skip to SECTION 8.***

☒ **Oral / Implied informed consent will be obtained – No signature is required (e.g., completion of a survey electronically)**

IMPORTANT!

- **Customize the Study Information Sheet template.**
- **If obtaining consent online, participants should:**
  - **View the Consent/Study Info Sheet prior to participation**
  - **Be prompted to verify they meet the eligibility criteria, and**
  - **Indicate their willingness to participate in the research (e.g., click "Yes").**

☐ **Written (signed) informed consent will be obtained – A signature is required.** UNCOMMON

IMPORTANT! Customize the Informed Consent Document template.

2. Will this study include Non-English Speaking Participants?

☒ Only individuals who can read and speak English are eligible for this study.

☐ The English version of the consent materials will be translated for non-English speaking participants. An interpreter will be involved in the consenting process.

3. If study team members will approach their own students or employees:

a. Explain what precautions will be taken to minimize potential undue influence or coercion.

b. Explain how compromised objectivity will be avoided.

c. When prospective medical students, residents or fellows are included, it is expected that a statement be added to the Study Information Sheet indicating that their agreement to participate will have no impact on their current or future positions/ opportunities at UCI. This is particularly relevant if the Lead Researcher is also in a position to make hiring or appointment determinations. The following is a suggested text that may be used:

"Refusing to participate will not impact current or future residency or fellowship opportunities or your ability to progress at UCI."

IMPORTANT! UCI expects that appropriate provisions are in place to engage with this potentially vulnerable population. See HRPP Policy (#40) for more information on this topic. In addition, visit the HRPP webpage on this topic.

☒ The study team will not approach their own students or employees.

☐ The study team will approach their own students or employees:

a. Specify how undue influence or coercion will be minimized. ***Check all that apply:***

☐ The student's experimental results, performance, or any confidential information will not be given to whomever is grading the student, except for stating whether the student participated or not. If this is not feasible, then the student's experimental results, performance, or any confidential information will not be accessed until after grades have been posted.

☐ The student's participation must not be required for course credit to be given. Instructors who wish to involve students in simulations of human experimentation and course-assigned data collection for educational purposes only (as opposed to research purposes) may require such participation as part of the class requirements.

☐ Other; specify: Type Here

b. Specify how compromised objectivity will be avoided: Type Here

4. Will this study include access to (both UCI and non-UCI) student records?

IMPORTANT! Researchers interested in accessing UCI Student Records for research purposes are directed to the UCI Registrar website on Confidentiality of Students Records. The disclosure of information from student records is governed in large measure by the Federal Family Educational Rights and Privacy Act of 1974, by the State of California Education Code, and by University policy and procedures implementing these laws. Generally, documentation of informed consent is required to access private student information.

☒ The study team will not access student records

☐ The study team will access student records and evidence of FERPA[3] compliance has been / will be obtained (and on file) from the local school/district site or the UCI Registrar prior to the initiation of research.

[3] *34 CRF 99: Family Educational Rights and Privacy Act (FERPA) applies to this research.*

5. Will this study involve Deception or Incomplete Disclosure?

IMPORTANT! Per Federal regulations, the use of deception or incomplete disclosure may only be exempt (and considered for a Self Determination of Exemption at UCI) if the (prospective) 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. If advanced disclosure is not possible, submit an Application to the IRB for Expedited review.

☒ There is no deception or incomplete disclosure involved.

☐ There is deception or incomplete disclosure and consent materials will include an initial disclosure to prospective subjects that he or she will be unaware of or misled regarding the nature or purposes of the research and a subsequent debriefing upon conclusion of the research.

SECTION 8: RESEARCH PROCEDURES

1. Specify where the research procedures will take place (e.g. Irvine High School, Starbucks, UCI Douglas Hospital – Cardiac Care Unit, UCI Main Campus – Hewitt Hall, etc).

2. If research will be conducted at non-UCI locations, confirm whether Letters of Permission or other documentation are required. *See Guidance for Letter(s) of Permission and Template Letter of Permission.*

Location(s) of research procedures: All research procedures will be conducted online.

☒ ***Check here to confirm Letter(s) of Permission has been / will be obtained for non-UCI private locations and kept on file.***

3. List the data collection procedures in chronological order using the table format below.

Procedure and/or the Data Collection Instrument	Is the Procedure/ Instrument already being completed as part of a program evaluation or an educational activity?	Is the Procedure/ Instrument a standardized measure?	List the frequency and the time required for participants to complete the Procedure/ Instrument	Describe the setting where data collection will take place	Confidentiality: Are participant identifiers (IDs) recorded during data collection?
EXAMPLE: ***ABC Satisfaction Survey via Amazon Turk***	☒ N/A ☐ Yes ☐ No	☐ N/A ☐ Yes ☒ No	***Survey will be completed 3x during the academic year. Takes no more than 20 mins. to complete***	***Amazon Mechanical Turk***	☒ No IDs ☐ Code with link to IDs ☐ Yes IDs
Online Screener	☐ N/A ☐ Yes ☒ No	☐ N/A ☐ Yes ☒ No	Takes a couple minutes to complete.	Internet	☐ No IDs ☐ Code with link to IDs ☒ Yes IDs

Baseline Survey	☐ N/A ☐ Yes ☒ No	☐ N/A ☐ Yes ☒ No	Takes 15 minutes to complete	Internet	☐ No IDs ☐ Code with link to IDs ☒ Yes IDs
4-Week Survey	☐ N/A ☐ Yes ☒ No	☐ N/A ☐ Yes ☒ No	Takes 15 minutes to complete	Internet	☐ No IDs ☐ Code with link to IDs ☒ Yes IDs
Proof of Vaccination	☐ N/A ☐ Yes ☒ No	☐ N/A ☐ Yes ☒ No	If participant reports receiving the vaccine, participants may text/email us a picture of their vaccine card.	Internet/Phone	☐ No IDs ☐ Code with link to IDs ☒ Yes IDs

To add more procedures/data collection instruments, click into this space, then click the new + button ➡

4. Will any of the study procedures include collecting photographs, audio recordings and/or video recordings?

☐ No photos, audio or video recordings will be taken.

☒ Photos, audio or video recordings will be taken. Text regarding the photos or recordings will be included in the consent document and specific permission to record identifiers will be obtained from participants.

Check all that apply:

- ☒ Facial image will be in video or photo
- ☐ Participants' names will be collected or recorded in either video, photo or audio recording
- ☐ Collecting photographs, as well as audio and video recordings will be optional for the participant

☐ Other: Type Here

SECTION 9: CONFIDENTIALITY OF RESEARCH INFORMATION

1. How will how information be stored and secured? *Check all that apply:*

Questions regarding best practices for data security and/or privacy may be addressed to UCI Information Security and Privacy at security@uci.edu.

☒ Information will be maintained electronically. Information will be password protected and maintained in an encrypted format. *Researchers may access UCI-contracted data sharing and storage tools through UCI OIT.*

☐ Information will be maintained in hard copy. Information will be stored in a locked area that is not accessible to non-study team members.

☐ Other; specify: Type Here

2. Will any participant identifiers be retained in the research records (i.e., for recruitment, consent, analysis, and/or compensation)? *Check all that apply:*

☐ No participant identifiers will be retained.

☒ Participant identifiers will be retained as selected below:

☒ Names ☒ Phone or fax number ☐ Web URLs

☒ Email Address ☐ Postal address ☒ IP address numbers

☒ Facial Photos/Images ☒ Other unique identifier (specify): Facebook Username

3. Will a code be used to link participant identifiers with the research information?

☐ No participant identifiers will be retained.

☒ Participant identifiers will be retained; ***check <u>one</u> of the following:***

☒ A code will be used. Participant identifiers will be **<u>kept separately</u>** from the information, linked by the code.

☐ A code will not be used. Participant identifiers will be **<u>kept separately</u>** from the information.

☐ A code will **<u>not</u>** be used. Participant identifiers will be **<u>kept directly</u>** with the information.

4. Specify how long ALL participant identifiers will be retained. This includes the identifiers stored in paper format, stored electronically, video/audio recordings, photographs, etc.

☐ No participant identifiers will be retained

☒ Participant identifiers will be retained as selected below:

☐ Destroyed after recruitment/consent process

☐ Destroyed after data collection

☐ Destroyed after compensation

☐ Destroyed after data analysis

☒ Destroyed after publication/presentation or end of study

☐ Maintained indefinitely for undefined future research

5. Will identifiable information be disclosed in publications and/or presentations?

☒ No

☐ Yes: Identifiable information will be shared. Text regarding the disclosure will be included in the consent document specific permission to disclose identifiers will be discussed with participants.

☐ ***Check here to confirm that <u>Release Form</u> will be obtained from each participant and kept on file***

6. Will information be shared with other researchers outside of the study team (i.e., UCI / non-UCI researchers) for purposes within the scope of the current study?

IMPORTANT!

- **When transferring data to a non-profit, please contact Grace J. Park at parkgj@uci.edu.**
- **When transferring data to a for-profit, please contact the Industry Contract Officer at UCI Beall Applied Innovation assigned to your department.**
- **When transferring tangible research material to an organization, please contact UCI Beall Applied Innovation at MaterialTransfer@uci.edu.**

☐ No

☒ Yes: Text regarding the information sharing will be included in the consent document and specific permission to share information will be discussed with participants.

Check one of the following:

☒ Only de-identified information will be shared (i.e. research subjects cannot be identified by other researcher)

☒ ***Check here to confirm that study team will remove ALL of the identifiers listed in Section 9.2 above prior to distribution.***

☐ Identifiable information will be shared

Name of other researcher/entity: Type Here

List of **all** identifiers to be shared: Type Here

Provide justification for why it is necessary to share identifiers: Type Here

☐ ***Check here to confirm that all appropriate data use agreements will be finalized before sharing.***

7. Will information be shared, used again, or stored for undefined future research purposes beyond the scope of the current study?

☐ No

☒ Yes: Text regarding the information sharing will be included in the consent document and specific permission to share information will be discussed with participants.

Check one of the following:

☐ No subject identifiers will be retained by the study team beyond initial collection (i.e. information cannot be linked to an individual). Requests for de-identified information will be managed by the UCI study team.

☐ ***Check here to confirm that all appropriate data use and/or materials transfer agreements will be finalized before sharing.***

☐ De-identified information will be retained and managed in an established non-UCI biorepository (i.e. not managed by the UCI study team). Specify the non-UCI biorepository: Type Here

☐ ***Check here to confirm that all appropriate data use and/or materials transfer agreements will be finalized before sharing.***

☒ Other; specify: Once results are published, only deidentified information will be retained and managed by the study team. Requests for de-identified information will be managed by the UCI study team.

8. Indicate how long research information and/or biospecimens will be retained.

IMPORTANT! In accordance with UCOP policy, information/biospecimens must be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement.

Choose the longest retention period applicable:

☐ There is no contract or award associated with this research. Information/biospecimens will be retained for **10 years** after the end of the calendar year in which the research is completed.

☐ The contract or award associated with this research requires that information/biospecimens be retained for the following period; specify time frame: Type Here

☐ The study is conducted under an IND or an IDE investigation, information/biospecimens will be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per FDA sponsor requirements.

☒ This research includes the potential for future undefined research using information/biospecimens which will be stored and **maintained indefinitely.**

☐ Other; specify timeframe and provide rationale: Type Here

SECTION 9: LEAD RESEARCHER ASSURANCE

The Lead Researcher (and Faculty Sponsor – if applicable) assure the following.

As Primary Lead Researcher and Faculty Sponsor, we have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and applicable UCI policies, as well as state statutes for research involving human subjects.

We hereby assure or acknowledge the following:

1. The information provided in this application is accurate to the best of my knowledge.

2. All named individuals on this project have read the procedures outlined in the protocol, are aware of and have reviewed relevant HRPP Policies and Procedures and understand their role on the study.

3. All named individuals on this project have completed the required electronic educational research tutorials and have been made aware of the "Common Rule" (45 CFR Part 46) and acknowledge the importance of the Belmont Principles - Respect for Persons, Beneficence and Justice in conducting research involving human participants. Also UCI has signed the Federalwide Assurance (FWA) that is available for review on the Human Research Protections (HRP) website.

4. Minor changes to the research that do not increase risk to participants, or significantly alter the study aims or procedures, such as the addition or removal of students researchers, do not require additional self-confirmation of exemption or approval from the IRB. Major changes that increase risk or constitute substantive revisions to the research including procedural changes will require a new self-confirmation of exemption or approval from the IRB.

5. When conducting research at a non-UCI location outside of California (but within the United States), Lead Researchers must comply with the requirements and policies of the location and State laws regarding human research procedures.

6. When collaborating with another entity (e.g., another UC, CHOC, CSUF, or a local school district), the collaborators who are engaged in human research activities are responsible for securing their own (non-UCI) IRB exemption/approval.

7. The Exempt Self-Determination, consent documents including recruitment materials and data collection materials will be maintained by the Lead Researcher or Faculty Sponsor for 10 years beyond the completion of the research. If you will cease your affiliation with UCI during this 10 year period and intend to transfer your identifiable data to a new institution, please notify your Faculty Sponsor and Department to determine whether this is permissible.

8. This research study is subject to routine monitoring by the Human Research Protections (HRP) unit of the Office of Research. Through the Education Quality and Improvement Program (EQUIP) program, HRP staff conduct periodic quality improvement monitoring and educational outreach.

Please sign below, indicating that you agree with the above.

 **Lead Researcher's Signature**	**6/8/2021** **Date**
Faculty Sponsor's Signature (if applicable)	**Date**