Indicate the risk category for subjects under 18 years old:

Answer: Minimal Risk
Greater than Minimal Risk

Provide reasons for the greater than minimal risk to persons under 18 years of age.

.

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

Answer: Minors (any person under 18 years old)
Adults with impaired decision-making capacity
Prisoners
Pregnant women
Other
None of the above

Please describe the other vulnerable populations who will be recruited.
.

If human subjects are children, have impaired decision-making capacity, or are part of other legally restricted groups, please answer the following questions:

1. Explain the necessity of using these particular groups.

Answer:
.

2. Describe any special arrangements to protect their safety.
Answer:

Answer: Yes
No

Answer: Yes
No

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Answer: Y1NoÌ Ť Ö ŎH 2 ùù 2 ù Ŋ ² Ŏ 2 ŕ hĊg hÔ ù ╕ Ń ẙù ≈ 2

Explain what activities will be required as part of the normal class activities and what activities will be voluntary as part of the research (be sure to include this information on your consent and/or assent document).

Answer:

.

What will students who choose not to participate in the research do?

Answer:

.

If students will miss class to participate in the research, indicate how they will make up the work.

Answer:

.

Deception or Incomplete Disclosure

Does the study involve deception or providing incomplete information to participants initially?

Answer: Yes

No

Explain what the deception or incomplete disclosure will entail (e.g., the consent form will not reveal complete details about the purpose of the study).

Answer:

.

Explain why the use of deception or incomplete disclosure would fulfill the research purpose better than non-deceptive methods or full disclosure in terms of the study's prospective scientific, educational, or applied value (e.g., deception or incomplete disclosure is needed to minimize biased responses).

Answer:

.

Describe the plan to debrief the participants and include the debriefing text that will be used to explain the deception or incomplete disclosure to participants after their participation or after the study is completed.

Answer:

.

Costs to Participants

Are there any costs to participants (e.g., transportation to research location, parking expenses, child care, medical/clinical procedures such as labs or medical imaging)?

Answer: Yes

No

Answer: Yes

No

.

Will you need to collect identifying information about participants in order to award the incentive/compensation to them (e.g., names, addresses, social security numbers)?

Answer: Yes
No

Please list the type of identifying information that will be collected, who will collect it, and whether it will be shared with non-study personnel (e.g., academic departments, the Research Foundation, the sponsor).

Important Notes: *any direct identifiers collected for the purposes of awarding incentives/compensation to subjects must be listed in the data management plan section of this application and all relevant aspects of the data management plan must be filled out as it relates to the use of identifiers for awarding incentives/compensation (e.g., security, level of access, retention and disposition). Please only collect the minimum amount of identifying information necessary to award the incentive. In some cases the IRB may ask that the PI instruct participants to contact the department or office that is requesting the information for business accounting purposes rather than having the research team members collect the information.*

.

DATA INSTRUMENTS AND RECORDING DEVICES

Briefly describe the information to be gathered and the means for collecting and recording data. If previously collected secondary data is also to be used, describe both the previous and proposed uses of these data.

Answer:

.

Study Instrument Types
Check all that apply.

Answer: Survey/Questionnaire
Individual Interview
Group Interview
Test
Observational Notes
Other
No study instruments will be used

Please describe the other instrument(s) to be used.
.

Study Instruments Attachments

Review our user guide for file requirements before you upload any files. This is required reading if you will be uploading an attachment.

Answer:

Indicate what types of recording devices will be used.
Check all boxes that apply and answer any accompanying questions.

Answer: Audio recording only
Audio and video recording
Photography
Biometric or physiological recording (e.g., eye-tracking, blood pressure)
Other (e.g., note-taking on computer or pen and paper)
No recording devices will be used

Please describe the other recording device(s) to be used, what information will be recorded, and whether any identifying information about participants will be included.
.

Please explain:

1. What kind of device will be used?
2. What/who will be recorded?
3. Will the recording be transcribed or edited? If so, by whom (if possible, identify a specific person or vendor)? Will the transcription or edits contain identifying information or potentially identifying information about participants?
4. How will the recordings be used? Will the recordings be shared? If so, how and with whom?

Answer:

.

Please explain who will be photographed and whether and how the photographs will be shared.

Answer:

.

MEDICAL DEVICES

Will the study involve administering a medical device or mobile medical app or platform?

Answer: Yes

No

Provide the name(s) and a brief description of the function of the medical device(s) or mobile medical app(s) or platform(s) to be used in the study.

Answer:

.

Is this study designed to evaluate the effectiveness and/or safety of any of the above listed medical device(s) or mobile medical app(s) or platform(s)?

Answer: Yes

No

Please mark whether any of the below conditions apply to the investigational medical device or mobile medical app or platform.

Answer: The medical device/mobile app or platform under study is of an already cleared, commercially available medical device/mobile app or platform that is being investigated in accordance with the indications in the approved labeling.

The medical device/mobile app or platform under study is substantially equivalent to one in commercial distribution that is being investigated in accordance with the indications in the approved labeling.

The medical device/mobile app or platform under study is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more medical devices/mobile apps or platforms in commercial distribution, AND the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

The medical device/mobile app or platform under study is an in vitro diagnostic device that is (all 4 conditions must apply if this check box is selected):

1. Noninvasive;
2. Does not require an invasive sampling procedure that presents significant risk;
3. Does not introduce energy into a subject;
4. AND is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.

The device under study is a custom device AND the device is NOT being studied to determine safety and efficacy for commercial distribution.

The device under study is intended solely for veterinary use or shipped solely for research on lab animals (i.e., no human subjects).

None of the above conditions apply.

Describe how the medical device works. In the case of a mobile medical app or platform describe what service(s) it provides to users and how this is accomplished.

Answer:

.

Attach diagram(s) and photo(s) of the device that illustrate how it works. In the case of a mobile medical app or platform, attach screenshots illustrating or storyboarding how it will be used in the current study.

Answer:

Device Diagram.pdf 04/11/2023

Is the medical device/mobile app or platform a non-significant risk (NSR) device?

Data Inventory

What kind of direct identifying information will be known to the research team or collected from participants?

Answer:

.

What is the intended use for the identifying information?

Answer:

.

Do any of the data elements that will be collected or known fall into Level 1 or 2 of the SJSU Information Classification Scheme?

Answer: Yes
No

List the Level 1 or Level 2 data elements that will be collected or known.

.

Indicate the format for identifying information that will be recorded or collected. *Check one.*

Answer: Digital only
Paper only
Both digital and paper
Identifying information will be known but not recorded or collected

Storage, Security, and Safeguards

Modifications

Incident Reports

Event / Date	Status / Comments / Files	Submitted By
No Incident Reports Found.		

Deviations

Status	Deviations File/Comments	Submitted By
No Deviations Found		