

Blank Application

Admin

Protocol ID 23-011
Panel No Panel Assigned
Student Investigator Tasha Yar
PI Type Student
Faculty Supervisor Jean-Luc Picard 04/09/2023
Faculty Supervisor Acceptance Status Not Yet Accepted
Review Type To Be Determined
Approval Status To Be Determined
Submitted By Tasha Yar
Date of Completion
Final Approval Date
Date Closed
Is this a multi-institutional, collaborative study? Yes
Department Research and Innovation

Consent Documents 04/11/2023 Consent Form.pdf
Assent Documents 04/11/2023 Assent Form.pdf
Additional Documentation 04/11/2023 Device Diagram.pdf

STUDY PERSONNEL

PI

Tasha Yar (04/09/2023)

PI Documents

- IRB Human Subjects Training Certification

File

– no entries found –

Department

Answer: .

Qualifications

Describe any relevant expertise or experience as it relates to this study which prepares this study team member to conduct research with the subject population(s) identified in this submission. Also describe any specialized knowledge of local community attitudes, cultural norms, and the cultural sensitivities necessary to carry out the research, if applicable.

Answer:

List the study activities to be carried out by this investigator (e.g., research design, recruitment/enrollment of subjects, obtaining consent, collecting data, analysis of data).

Answer:

.

Faculty Supervisor

Jean-Luc Picard

PI Documents

- IRB Human Subjects Training Certification

File

– no entries found –

Department

Answer: .

Qualifications

Describe any relevant expertise or experience as it relates to this study which prepares this study team member to conduct research with

the subject population(s) identified in this submission. Also describe any specialized knowledge of local community attitudes, cultural norms, and the cultural sensitivities necessary to carry out the research, if applicable.

Answer:

List the study activities to be carried out by this investigator (e.g., research design, recruitment/enrollment of subjects, obtaining consent, collecting data, analysis of data).

Answer:

External Study Personnel

List the names, affiliations, roles, and study activities of any external study personnel.

If you have human subjects research training certificates for external personnel, please upload the document(s) here.

Note: SJSU does not provide access to its CITI training subscription to external investigators.

Answer:

STUDY TIMING AND FUNDING

Anticipated Start Date

Please indicate your anticipated start date, making sure that it is not retroactive and allows enough time for review and approval of your protocol submission.

Important Note: The SJSU IRB does not review or approve studies retroactively. You are required to make sure your timeline is reasonable prior to submitting your protocol or submitting requested revisions to your protocol. Refer to our [website for information regarding review timelines for various types of research](#). Submissions with retroactive start dates will be withdrawn from consideration.

Answer: 04/01/2024

Funding

Is the study currently funded?

Answer: Yes

No

Are you applying for funding?

Answer: Yes

No

Please list the potential funding source(s).

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OTHER INSTITUTIONS

Names and roles of participating institutions

List any participating institutions that will be engaged in the research. Include specific information about the institution's role in the research.

Answer:

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Besides SJSU, do any of the participating institutions listed have their own IRB committee?

Answer: Yes

No

List the names of the participating institutions which have their own IRB.

.

Is the PI requesting that SJSU serve as the IRB of record/reviewing IRB for one or more of the participating institutions?

Answer: Yes

No, each institution will conduct its own IRB review.

No, an external IRB will be the IRB of record/reviewing IRB.

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Note: Please be aware that a single IRB review is mandated for multi-site federally sponsored collaborative studies. If this is a federally funded study, please contact the [SJSU IRB Office](#).

Provide information on whether and how SJSU will be involved as a campus in this multi-institutional, collaborative study (e.g., as a source of recruitment for subjects, as a source of secondary data, as a source of research personnel).

Answer:

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STUDY LOCATION

Where will the study be conducted? Select all that apply.

- Answer:
- Online
 - SJSU campus
 - External site

Name the external study location(s) where recruitment/enrollment, data collection, and other study procedures will take place.

Answer:

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Investigator(s) affiliation.

Disclose any affiliation that you or other investigators have with each external study site (e.g., employee, intern, collaborator, client, contractor) or state that you have no affiliation.

Answer:

.

External site engagement: Are personnel from external sites conducting any of the following procedures for this research while being overseen by the SJSU PI? Select all that apply.

- Answer:
- Obtaining research consent
 - Collecting information from individuals
 - Handling private, identifiable information
 - Not applicable

Describe any applicable site, location, or regional specific regulations, policies, or customs affecting the research at this external site:

.

STUDY DESIGN

Study Purpose

Provide an explanation of the purpose of the proposed research, written for a general audience. Include a concise statement of your research questions or hypotheses.

Answer:

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Study Background

Include a brief (1-2 paragraphs) review of any relevant and current scholarly literature that supports the purpose of the research or that led to the formulation of the study. Include citations and include a list of references, if applicable.

Answer:

.

Research Summary

Provide a brief outline of how you will achieve the study objectives and answer your research questions in the following ways:

Research design (experimental, descriptive, correlational, etc.).

Answer:

.

Data collection methods.

Answer:

.

Data analysis methods (describe the specific quantitative or qualitative analyses to be performed, if applicable).

Answer:

.

Does this study meet the definition of a clinical trial?

Options: Yes

No

SUBJECT POPULATION

Type of Subjects

Describe the participant pool or community from which you will enroll participants as specifically as possible (e.g., college students in a specific class, professionals in a specific field, random pedestrians). If you will be accessing secondary data about individuals or collecting biospecimens, describe whether you are targeting a specific population as part of the study analysis. If you will have multiple groups of participants, please answer the protocol application questions for all groups.

Answer:

.

Rationale for Subject Selection

Describe why this is the appropriate population for your study (i.e., is this population the logical choice for answering your research questions or for applying an intervention?). If you will be accessing secondary data about individuals only, describe the rationale for why access to records is needed.

Answer:

.

Number of Subjects

State the expected number of participants you wish to enroll in the study as well as what a reasonable sample size would be to answer your research questions. If applicable, explain how the number of participants needed to answer the research question was determined. If you will be accessing secondary data about individuals only, describe the approximate number of subjects whose records will be accessed if known.

Answer:

.

Inclusion and Exclusion Criteria

State any inclusion and/or exclusion criteria, including specific subject demographics (age, race, ethnicity, gender etc.), if applicable. If prospective participants will be screened via tests, interview, etc., prior to entry into the study, explain how, where, when, and by whom the screening will be done. Information on what will be done with the data of those who do not qualify for the study should also be provided in this section. If you will be accessing secondary data about individuals, describe the inclusion/exclusion criteria for record selection, if applicable, or state N/A.

Answer:

.

Selection Criteria

If participants will be selected from a specific group of eligible participants (e.g., only 10 students in a class of 30 eligible students will be selected), please indicate the selection criteria that will be applied.

Answer:

.

Subjects Ages

Select the age range of subjects who will be enrolled in this study. Check all that apply.

Answer: 18 years or older

Under 18 years

Unknown / Access to secondary data only

If you are focusing on specific age ranges, please indicate the age ranges here.

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:

Prior Associations with Research Team

Are the potential participants already known to the researcher or research team?

Answer: Yes
No

Explain how participants are known and to whom.

Potential Interpersonal Conflicts of Interest

Do any members of the research team have a supervisory role over potential participants, provide services to the targeted population outside of the research, or serve in a dual role that may result in a power imbalance between researchers and the participants (e.g., teacher/student, employer/employee)?

Answer: Yes
No

Identify which members of the research team have a supervisory role over potential participants or provide services (such as treatment, assessment, or training) to the targeted population outside of the research, and explain the nature of the relationship to potential participants.

Answer:

What precautions will be used to minimize the power imbalance or potential for coercion of participants who are also clients or individuals who receive services from members of the research team outside of the research context?

Answer:

RECRUITMENT

Recruitment/Enrollment Procedures

Explain how, where, and when prospective participants will be identified and approached for study participation. Make sure to be clear about how the research team will gain access to participants, what will be said to them, and to outline which members of the research team will conduct the recruitment. If you will be accessing secondary data about individuals, please describe how you have access to such data and what type of permission you have to access private and protected data (e.g., medical, academic, employment, or financial records). If you will have multiple groups of participants, please answer the questions for all groups.

Answer:

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Recruitment Materials Description

List any recruitment materials that will be used; note the type of media and where they will be posted.

Answer:

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Recruitment Materials Attachment(s)

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

Answer:

CONSENT

Indicate the type of consent document(s) that will be used.

If different consent documents will be used for different participants or methods, check all that apply. Links to the most commonly used consent document templates have been provided with each checkbox. If no link has been provided, refer to the [Informed Consent Handbook](#) posted on the SJSU IRB website for details about the consent type. For studies that include multiple consent documents, you will need to indicate the subject population or method to which each attached document applies as part of the file name. Please make sure that the consent documents that you will attach correspond to the checkboxes you have marked here. If the study involves only secondary data and it has been established that consent is not required, please mark the "no consent will be sought" checkbox.

Answer:

No consent will be sought

- Standard consent form** (written consent form, signed by participant)
- Standard consent form, unsigned** (you will use the standard template but are requesting a waiver of signatures; make sure to remove the signature lines from the template and replace with appropriate verbiage instructing participants to keep the document for their records)
- Consent notice** (written consent document with basic information, unsigned by participant; typically permissible only for research that qualifies for exemption)
- Parent or guardian permission form**
- Standard consent short form and script** (verbal consent only)
Note: this option should only be used if participants have limited literacy or are otherwise unable to read a consent document.
- Altered consent form** (some of the standard elements of consent are omitted).
Note: this option should not be checked if you are using a consent notice. This option is typically used when the study involves deception or incomplete disclosure on the consent document.

Please provide information on which elements of the **standard consent form** you wish to have waived and why.

Answer:

.

Consent Document Attachment(s)

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

Make sure that your consent document(s) are each submitted as separate attachments; that they meet the requirements for stamping by the IRB office; and that they are presented in their final form as participants will see them (no highlights or track changes).

Answer:

 Consent Form.pdf 04/11/2023 (Consent Documents)

Who will obtain consent and who will be available to answer participants' questions?

Please provide specific names if you listed multiple team members in the study personnel section.

Answer:

.

How, when, and where will consent be obtained (in person, by email, by mail, via web, signed, unsigned, etc.)?

Please note that if you plan on obtaining signed consent remotely, you will need to use a third party application like *DocuSign* via your SJSU single sign-on account. Email is not a method for getting signed consent unless you plan on having participants scan a signed version of the consent document.

Answer:

.

What language(s) will be used to obtain consent?

Answer:

.

Do you anticipate the need to obtain informed consent from a legally authorized representative (LAR) in cases where the subject population under consideration may have impaired decision-making ability?

Answer: Yes

No

Describe how you will identify an appropriate representative and ensure that their consent is obtained.

.

ASSENT

In addition to procedures outlined in the previous section for obtaining consent from a parent, guardian, or Legally Authorized Representative (LAR), does the study team plan to obtain assent from the minors and/or adults with impaired decision-making capacity?

Important Notes:

- *Minors or adults who have impaired decision-making ability should still be informed about the research and asked for their permission to participate, whenever possible, in a manner appropriate to their condition or age.*
- *Although consent must be first be sought from the parent, guardian, or LAR before assent is sought, in most social and behavioral research the wishes of the subject override the consent of the parent, guardian, or LAR.*

Answer: Yes

No

Who will obtain assent and who will be available to answer participants' questions?

Please provide specific names if you listed multiple team members in the study personnel section.

Answer:

.

How will assent be obtained in a way that takes into account the age, developmental ability, and cognitive capacity of the subject (e.g., verbal vs. written assent)?

Answer:

.

When and where will assent be obtained?

Answer:

.

What language(s) will be used to obtain assent?

Answer:

.

Indicate the type of assent document to be used.

Descriptions of the various types of assent documents are outlined in the *Informed Consent Handbook* posted on the SJSU IRB website. Check all that apply if the study includes different age groups or individuals with different cognitive capacities.

Answer: Assent form (written form, signed by participant)

Assent notice (written form, unsigned by participant)

Assent script (verbal assent only)

Assent Document Attachment(s)

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

Answer:

 Assent Form.pdf 04/11/2023 (Assent Documents)

STUDY PROCEDURES

Does the study involve accessing secondary data only?

Important Notes:

- If you will be doing an intervention, interacting with, observing, or collecting data from human subjects, select NO.
- If you will be initiating an anonymous survey, this is still considered to be an interaction even if you have no in-person contact and even if participants are anonymous - please select NO in this case.
- If you will be doing a mixed methods study that includes secondary data analysis along with interaction or collecting data from participants, please select NO.

Answer: Yes

No

Description of Procedures

List procedures in which the participants will take part in a chronological manner.

Include only those procedures that involve the participants (e.g., interventions/interactions, data collection procedures). Do not include procedures that the researcher will be doing separately (e.g., literature review, transcribing recordings, data analysis).

Answer:

.

If applicable, describe the content of and procedures for any intervention that will be applied with participants. Please also delineate the nature of the intervention - behavioral, educational, or physical.

Answer:

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If applicable, describe the content of cognitive, psychological, or usability tests that will be employed using a computer or mobile device. You will be asked to provide screenshots of any computer stimulus in the Data Instruments and Recording Devices section later in this application.

Answer:

.

Explain who will conduct the procedures and where and when they will take place.

Please provide specific names if you listed multiple team members in the study personnel section. If you will be using an online or third party vendor or application to disseminate your data instruments to participants, please provide the name of the online or third party vendor/application.

Answer:

.

Indicate the frequency and duration of each procedure as well as the total time commitment for participants in the study.

Answer:

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Describe appropriate alternative resources, procedures, or courses of treatment, if any, that are available to prospective participants who choose not to participate or are excluded from the current study.

Answer:

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Classroom Setting

Will the study take place in a classroom setting (whether in-person or online) with student participants?

Note: this question does not pertain to a lab setting where students may arrive because they have signed up to be part of an experiment.

Answer: Yes

No

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

Explain what the costs are to participants and whether the research team will arrange to cover any expenses.

Incentives or Compensation for Participants

Will any incentives or compensation be provided to participants in the study (e.g., cash payment, gift card, extra credit, free treatment, free materials)?

Answer: Yes

No

List the incentives/compensation type and amounts to be provided to participants.

Important Notes:

- If your research is funded, make sure that the sponsor allows the form of incentive/compensation you wish to provide.
- If students will receive extra credit, please indicate the amount and describe the alternative equivalent method(s) that will be available for earning extra credit for those who do not wish to participate in the research. Repeat on the consent document.
- If you will be offering only partial incentive/compensation for those who do not complete the entire study, or if the study will include attention checks that could potentially disqualify participants from receiving the incentive/compensation, please disclose this here and on the consent document.

Answer:

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?

Answer: Yes
 No

The study does not require submission of an Investigational Device Exemption (IDE) application to the FDA unless the IRB or study sponsor informs you otherwise, but the PI or study sponsor must ensure that **abbreviated requirements are followed**.

SUBJECT IDENTIFIERS

Will investigators know, have access to, or collect any direct identifying information about participants or data subjects?

Examples of direct identifying information: names or signatures on the consent form, names via teleconferencing software (e.g., Zoom screen name), names via social media profiles, contact information for participants (including email addresses comprised of names), unique ID numbers not created for the study (e.g., student ID, social security number, medical record number, employee ID), unique device numbers (IP addresses), biometric information (fingerprints, eye scans), labeled biological specimens, photographs, and video recordings.

Important Notes:

- In most interview situations, the identity of the participants is known to the research team, even if names are not recorded. Unless special interview procedures are in place to ensure that the identity of participants will not be known to the research team, please mark yes here.
- You must mark yes in this section even if study personnel have plans to de-identify or discard direct identifying information.

Answer: Yes
 No

Will investigators know, collect, or have access to any indirect identifying information that, when combined, could reasonably result in the identification of participants or data subjects (either to the research team or to anyone with access to the study report/results)?

Examples of indirect identifying information that could be combined to identify participants include gender, racial or ethnic identity, age, date or place of birth, location information, employment information, social media handle/username, certain metadata, physiological characteristics like weight and height.

Important Notes:

- You do not need to mark yes here if the number of indirect identifiers that will be collected is low and/or the number of participants is high. Please use your best judgement in estimating whether it may be possible to reasonably identify participants.
- Keep in mind that if the subject population is known to members of the research team it may be easier to identify participants based on indirect identifiers. For example, if you are collecting data from students in a class that you teach and you ask study participants to provide their age, race, and gender, the participants may be reasonably identified, especially if the demographic information is combined with other contextual information collected by your study instruments.

Answer: Yes
 No

Please list the indirect identifiers that may potentially identify participants or data subjects when combined.

Answer:

.

What security measures will be used to protect the indirect identifying information?

Answer:

.

Will any of the indirect identifiers that may potentially identify participants or data subjects be reported or shared outside of the research team?

Answer: Yes
 No

Please list the indirect identifiers that will be reported or shared outside of the research team and provide information about who will receive the indirect identifiers and/or how they will be reported.

Repeat this list on the consent document, indicating that the reporting of this information can potentially result in identification of participants.

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DATA MANAGEMENT PLAN

Data Inventory

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

Answer:

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What is the intended use for the identifying information?

Answer:

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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

Where will digital or paper files containing direct identifying information be stored and what specific devices will be used for the storage of digital data?

Describe the location for storing papers that contain identifying information and any personal device(s), institutional device(s), institutional shared drive(s), etc. for storage of identifying information in digital format. Identify the data elements to be stored in each location. If data will be stored on portable devices (phones, memory sticks, laptops), please also explain where the portable devices will physically be stored when not in use.

Answer:

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What kind of security features (physical and/or technical safeguards) will be in place for each of the files, devices, cloud-based locations, or papers where direct identifying information will be stored?

Examples of safeguards include password protection for digital files and locked storage containers for physical files.

Answer:

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If research data will be de-identified, please explain the method and timing of the de-identification procedures, as well as who will be responsible for de-identification.

Refer to the [SJSU Data Management Handbook](#) for a table of de-identification methods.

Answer:

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If data are coded in order to retain a link between the data and identifiable information, explain where the key to the code will be stored and how it will be protected. Likewise, if consent forms will be stored separately from the data, please state where each will be stored.

Answer:

If members of the research team will be traveling internationally with identifying information, describe any additional security protocols that will be in place for the devices on which data will be stored during travel.

Please see the [Office of Research International Travel Guidance page](#) for more information.

Answer:

Access

Which of the team members listed in the personnel section of this application will have access to identifying information about participants?

If applicable, list the identifying data elements that each team member will have access to, as well as which team member will be given passwords, coding keys, and other access tools. Student-led research must allow the primary investigator/faculty supervisor to have access to all research information.

Answer:

Will access to identifying information be granted to individuals, institutions, or vendors who are not part of the research team or who do not have a contract with SJSU?

This includes vendors not contracted with SJSU to which you may direct participants (e.g., online experiment or usability platforms) or which you will use for data processing or analysis (e.g., transcription or translation services).

You do not need to mark "yes" if the research team will be using SJSU licensed software (e.g., Qualtrics, Zoom, Google Forms) as long as the software will be accessed and implemented via SJSU single sign-on.

Answer: Yes
 No

Please identify:

1. Who else will have access and what specific data elements will be provided to the third party.
2. The rationale for providing the access.
3. How access will be provided.
4. What steps will be in place to ensure proper handling of the identifying information by third parties.

Note: depending on the level of sensitivity of the data to be shared, the study PI may be instructed by the IRB to establish a contract between SJSU and the vendor, institution, or individual who will have access to the data. You will be provided with further information about this, if necessary.

Answer:

Dissemination

Will any information that could result in the identification of participants be reported in the research findings?

Answer: Yes
 No

What mechanisms will be used to maintain the confidentiality of identifying information in the reporting of the research findings?

Use of a coding system, pseudonyms, reporting data in aggregate, etc., are examples of mechanisms used to maintain confidentiality. Repeat on consent document, if applicable.

Answer:

Are there any limits to your team's ability to maintain confidentiality?

*Examples include **mandated reporting requirements**; **Title IX reporting requirements**; group interviews, where researchers cannot guarantee that participants will not disclose what was shared outside of the group; a small number of subjects where highly specific demographic or contextual information is being disseminated.*

Answer: Yes
 No

Please explain the limits to confidentiality. Repeat on consent document, if applicable.

Will data or research findings be shared with any external institutions from which subjects were recruited or from which secondary data were obtained (for example, to school administrators at a secondary school where students were recruited)?

Answer: Yes
 No
 Not applicable

Describe what materials will be shared and with whom. Repeat on consent document, if applicable.

Will identifying information be retained and/or shared for use in future research?

Answer: Yes

No

Please answer the below questions and repeat the information on the consent document, if applicable:

1. What identifying information will be retained for your own future research use?
2. What identifying information will be shared with other investigators or repositories?
3. Whether or not participants will be contacted and consented for future uses and data sharing of identifiable information.
4. Whether participants will be able to withdraw their data by contacting you, other investigators, or repositories.

Who is the intended audience for the study report and what is the presentation/reporting method to be used, if known (e.g., journal article, conference presentation)?

Answer:

Retention and Disposition of Identifying Information

How long will identifying information and/or keys to coded data be kept?

Important Notes:

- This question refers to identifying information and not all research data.
- Keep in mind that federal requirements and CSU retention policy is to retain research records for three years after the study is completed. We recommend applying the three year time-frame to items that must be retained for compliance purposes, such as signed consent forms. Identifying information that is only needed for contacting or tracking participants may be destroyed as soon as it is no longer needed, which may be less than three years.

Answer:

How will identifying information be destroyed when it is no longer needed?

Please list the specific disposition methods for various media, including paper documents, digital documents on devices, and digital documents on shared drives, in the cloud, or email.

Answer:

Who will conduct the disposition/destruction of identifying information?

Please indicate the name of the individual if multiple team members were identified in the Study Personnel section of the application.

Answer:

RISKS AND BENEFITS

Are there any potential risks to participants or data subjects associated with this study that can be anticipated?

Examples of risks include: physical injury, aggravation of an existing condition, pain, loss of privacy, the release of potentially damaging personal information, psychological risk (e.g., anxiety, stress, depression), and uncomfortable emotions (e.g., anger, fear, sadness).

Answer: Yes

No

List any known potential risks and discomforts to individual participants or data subjects that can be anticipated – whether physical, psychological, economic, social, legal, or other - and assess their likelihood and seriousness.

Answer:

Describe the procedures for protecting against or minimizing each potential risk listed above.

Describe special safety procedures, as needed, to avoid harm to participants. List any psychological and/or medical help available in the event of harm. For example, if the risk of emotional discomfort is high, the investigator should provide the participants with a list of referrals for counseling and attach this information to the informed consent document.

Answer:

Describe if there are plans for provision of treatment for study-related injuries and how costs of injury treatment will be covered.

Answer:

Do you anticipate a potential indirect risk of group harm?

For example, can the community from which participants are selected be made vulnerable by the investigation?

Answer: Yes
 No

Describe the nature of potential group harm and the procedures for mitigating group harm.

For example, community consultation or identifying stakeholders as mediators.

Are there any potential direct or indirect benefits to participants or data subjects associated with the study that can be anticipated?

Answer: Yes
 No

List any potential direct or indirect benefits to participants or data subjects.

Note: compensation or incentives are not considered a benefit and should not be listed in this section.

FINANCIAL CONFLICTS OF INTEREST

Do you or any investigator(s) participating in this study have a financial interest related to this research project?

Answer: Yes
 No

Provide the names of any research team members who may have a financial interest, and provide information about whether and how the conflict will be mitigated. Please also refer to the [Office of Research Conflicts of Interest page](#) for more information and requirements.

OTHER STUDY ATTACHMENTS

If applicable, provide any other attachments related to the study that were not specifically included within the application (e.g., permissions or letters of support, list of references, list of support services for participants). If you have multiple attachments, please be sure to create a clear file name so that the IRB can easily identify what type of document it is.

Please note that even if you have a web link to a study document, the SJSU IRB still requires that you attach all documents to your application.

Answer:

 Device Diagram.pdf 04/11/2023 (Additional Documentation) (Existing)

OTHER ISSUES - OPTIONAL FREE-TEXT SECTION

If there are any other issues which the IRB should consider and which do not fall into any of the application sections, please describe them here.

Answer:

Miscellaneous

Publications

Cont Reviews

Modifications

Incident Reports

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

Deviations

Status	Deviations File/Comments	Submitted By
No Deviations Found		