**Title of Study**

Enter the title of your study here

**Principal Investigator**

Name

Department

Email

**Other Personnel**

|  |  |  |
| --- | --- | --- |
| Select a Role | Name | Email |
| Select a Role | Name | Email |
| Select a Role | Name | Email |
| Select a Role | Name | Email |

**Review Type**

[ ]  Exempt

[ ]  Expedited

[ ]  Full Board

**Dates for Research** Start date through End date

**Version Date** Date of last revision

**Purpose of the Study**

Describe the purpose of your study here, including specific aims, objectives, hypotheses, and research questions.

**Study Design**

Describe the design of your study here. Your description should include (if applicable):

* Timeline for interaction with individuals participating in the study as well as the overall anticipated duration of the study
* Method for contacting and recruiting participants (include communications as a separate attachment in your submission)
* Site of intervention and/or data collection
* Method of intervention as well as the method of determining test and control groups
* Method of data collection (such as surveys, interviews, focus groups, observations, etc.)
* Brief description of data collection materials (include surveys, interview scripts, rubrics, or other data collection forms as a separate attachment in your submission)
* Method of analysis

**Number of Study Participants**

Enter the anticipated number of study participants here

**Vulnerable Populations in the Study Sample**

[ ]  Individuals under 18 years of age

[ ]  Pregnant individuals (where research may affect the pregnancy or fetus)

[ ]  Prisoners or other detained individuals

**Compensation for Participation**

Describe any compensation in the form of money or gifts that will be provided to participants. Include the method of payment, financial value of the compensation, and when the compensation will be provided. If not all participants will receive the same compensation (such as due to a raffle), describe the process for determining who will receive the compensation. Describe how you will ensure that the compensation will not be coercive to economically disadvantaged individuals.

If there is no compensation, enter “N/A”.

**Risk to Participants**

[ ]  Not more than minimal risk

[ ]  More than minimal risk

Describe the risks involved with participating in the study. Include potential negative outcomes if participants’ identifiable data were unintentionally made public.

**Benefits to Participants**

Describe the potential benefits (beyond compensation) that individual participants may experience from taking part in the study. Do not include benefits to society or others.

**Consent Process**

Describe the process you will use to obtain informed consent from your participants. A template including all of the elements of informed consent is available here. If using a written consent document, include a copy of that document as a separate attachment in your submission. If seeking to waive or alter the elements of informed consent, describe how the study involves no more than minimal risk to the subjects, will not adversely affect the rights and welfare of the subject, and could not practically be carried out without the waiver or alteration.

If the study involves participants under the age of 18, describe the process for obtaining consent from those participants’ parents. If requesting a waiver of parental consent for minors, provide a rationale for waiving parental consent and describe extra efforts taken to keep the recruitment process from being coercive to the potential participants.

**Incomplete Disclosure or Deception**

If the study involves incomplete disclosure or deception, describe the nature of that disclosure or deception and explain why it is necessary for the study. If not, enter “N/A”.

Additionally, describe the debriefing process that will be used to inform participants of the incomplete disclosure or deception of the study, including their right to withdraw any record of their participation.

**Data Sharing**

If data from the study will be shared, describe whether the shared data will be identifiable (with justification if it will be), with whom the data will be shared, and the intended purpose or use of the shared data.

**Confidentiality and Data Security**

Describe the steps that will be taken to protect the privacy and identity of participants. Include a description of the nature of the data collected and how that data will be transported, stored, and secured to ensure that identifiable data will not be shared with unauthorized individuals. In addition, describe plans for the data or artifacts at the conclusion of the study.

**Ensuring Participant Safety**

Incidents may arise that require investigators to break confidentiality for the sake of participants’ safety, or due to mandatory federal reporting requirements (such as Title IX). Please describe the plan you have in place to monitor the information gathered that may be related to depression, self-harm, sexual assault, or other sexual misconduct; the individual(s) you will make a referral to when confidentiality much be broken (such as the CalArts Director of Care and Well-being or the Institute Diversity Officer); and the conditions under which such a referral will be made. Keep in mind that you must also inform the IRB of any situation in which the confidentiality expected by research participants is broken, as such incidents may require a report be file with the Office of Human Research Protections.

**Funding**

If the study is funded, either through internal or external grants, describe those sources of funding here. Otherwise, enter “N/A”.

**Training & Conflicts of Interest**

|  |  |  |
| --- | --- | --- |
|  | Has completed sufficient human subjects research training as described in the IRB Guidelines and Definitions | Has conflicts of interest to disclose |
| Name | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| Name | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| Name | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| Name | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| Name | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |

If any of the investigators or key personnel have conflicts of interest to disclose, describe those conflicts of interest here. Otherwise write “No conflicts of interest to disclose”.

**Certification**

By placing your name and date below you are digitally certifying that the information you have provided is thorough and accurate. In addition, you will immediately notify the IRB of any amendments, unanticipated risks, adverse effects, or other concerns that arise during the course of the study, with the understanding that deviating from an approved research protocol may result in the suspension of the study.

|  |  |  |
| --- | --- | --- |
| Name of Principal Investigator |  | Date |
| *Principal Investigator* |  | *Date* |