**Informed Consent – Purpose & Instructions**

**Purpose**

The purpose of an Informed Consent is to advise prospective participants about details of the research study they are invited to participate in. It is important that the informed consent submitted with the IRB application is complete and is tailored to the population targeted for the research (avoid jargon). An inadequate or incomplete informed consent submitted with the application can delay the IRB review and approval process.

**Basic Elements of Informed Consent – Checklist**

Information in the informed consent should include the following criteria and must be aligned with the information presented in the IRB application (e.g., risks, benefits, duration of study procedures, confidentiality):

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Yes | No |
| 1. | Heading on consent should have CSULB and college and/or department name.  |  |  |
| 2. | Include PI name with email contact. For student PIs also include the Faculty Advisor name with email contact. |  |  |
| 3. | Briefly explain why the participant is being asked to take part in the study (eligibility criteria). |  |  |
| 4.  | Briefly explain the purpose of the research. |  |  |
| 5. | Include a statement that the study involves research. |  |  |
| 6. | Describe the research activities (e.g., survey, interview) and the expected duration of participation. |  |  |
| 7. | Describe any reasonably foreseeable risks or discomforts and mitigations for any identified risks. |  |  |
| 8. | Describe direct benefits to the participant if any may reasonably be expected and describe any benefits to others (**Compensation/incentive not** **a benefit**). |  |  |
| 9. | Describe the extent to which confidentiality of data identifying the participant will be protected. |  |  |
| 10. | Include a statement that participation is voluntary. That refusal to participate or discontinuing participation will involve no penalty or loss of benefits the participant is otherwise entitled. |  |  |
| 11. | If appropriate describe any incentive/compensation that is provided and if provided include details of the incentive/compensation and when it is distributed. |  |  |
| 12. | Explain whom to contact for questions about the research (usually the PI) and whom to contact for questions about the rights of research participants (the IRB). |  |  |
| 13. | Statement at the end of the informed consent text: Signing this document means that you are at least 18 years of age, and information about the study has been explained to your satisfaction, the investigator has answered any questions you have about the study and that you voluntarily agree to participate. |  |  |

When research involves audio/video recording, the informed consent must clarify whether participants can decline such recording or recording is required for participation. For optional recording, provide the checkboxes below. The checkboxes should be placed at the bottom of the consent form, before the signature line, or in online forms, following the participation agreement checkbox.

 [ ]  I give consent to be (choose relevant media audio, video, zoom, etc.) recorded.

 ☐ I do not give consent to be (choose relevant media audio, video, zoom, etc.) recorded, but consent to researcher taking notes.

In the space provided at the end of the consent form the participant consenting to participate should print their name then a signature, and the date of consent. Participants should receive a copy of the consent form.

For multiple Informed Consent documents, please label them accordingly (e.g., Informed Consent – Survey, Informed Consent – Interview, Informed Consent – Focus Group, Informed Consent – Teachers, etc.).

**Online Consent**

If Informed Consent is obtained online it is important to develop the Informed Consent accordingly. The online consent should be the first page of an online survey and should include the **Basic Elements for Informed Consent** listed above. If applicable provide a text box for name and another for date. If participation is anonymous, delete the name/date text boxes.

When applicable add the following:

- “By clicking “I Consent”, you are confirming that you are at least 18 years of age and agree that you have read and understood the purpose, procedures, risks, and benefits of this study and you voluntarily consent to participate.”

- When setting up the Online Consent form for an online survey (e.g., Qualtrics, Google Docs, etc.), make sure that the consent question is set as REQUIRED and that clicking on “I do not consent” will take a participant to the survey end. If the survey end is to a link or a second survey to collect participant identifiers, instruct the individual who “does not consent” to close the consent page and/or close their browser.

- If you are doing an anonymous survey but want to collect identifiable information (email, phone number, name, etc.), you can create a link to a second survey. This way the research data will not be linked to the identifiable information (which should be included as a risk/mitigation).

**Consent Language**

The consent language should be in lay terms. Consent language at the 8th grade reading level is typically the standard. Please define all terms and acronyms for the first mention of the term(s) such as Institutional Review Board (IRB). Remember, most participants are not familiar with the subject matter of your field/department’s terminology.

The point of view (POV) should be in second person using phrases such as, “you are invited to participate...” and “you will be asked to complete the following activities…”.

**Costs and Compensation**

If participants will incur costs to participation such as parking fees or will use their own equipment or supplies should be clearly noted in the consent form so participants can decide whether the cost is worth participating.

If any form of compensation is offered such as course credit, gift cards, cash, or any other incentive, create a for compensation section after the risks/mitigations that includes:

* What the incentives are ($25 cash, 2 course credits, $5 coffee card, etc).
* How and when participants will receive the incentive (after the activities in person, emailed, U.S. Postal mail, raffle/drawing, etc.).
* Whether participants will receive full compensation should they withdraw their participation or refuse to participate in certain aspects of the project.

Effective January 1, 2022, CSULB Financial Aid collects identifying information for CSULB students who receive a research incentive, when CSULB students are the sole recruited subject group, and the research incentives are funded “state-side,” in any amount (if ASI, $50 or more per gift card). The student’s name and CSULB number are collected by Financial Aid for re-evaluating a student’s financial aid award.

**Note the conditions that trigger the CSULB Financial Aid reporting policy**:

* CSULB student status,
* CSULB students are the sole subjects recruited for the research, **and**
* Incentives are funded/processed through CSULB “state-side” sources, including CSULB Foundation.

**The application of the CSULB Financial Aid reporting policy is narrow and DOES NOT apply to**:

* Non-CSULB students participating in research at CSULB;
* CSULB students participating in research outside of CSULB;
* CSULB students doing CSULB research aimed at broader groups e.g. students outside CSULB); **or**
* CSULB students doing incentivized research that is not funded through “state-side” sources (e.g., funding is managed at another institution; CSULB source is ASI and incentive is below $50 per gift card; or PI funds incentives out-of-pocket)

If applicable, insert the following text in the consent form regarding the CSULB Financial Aid policy:

“As an incentive for engaging in this human subject research project, once you complete the activities (a. b., c…), we will provide you with a gift card in the amount of $\_\_\_. CSULB Financial Management requires campus ID #s and names for CSULB students receiving incentives from CSULB-sponsored research, and they will use this information to determine whether it has any Financial Aid and/or tax implications. If you choose not to accept the gift card, your campus ID# will not be included in the report required by CSULB Financial Management. Please note that we will keep your personally identifiable private information confidential, and no connection will ever be made to the data you provide (survey responses, interview, health info) and the financial report.”

**Final Consent Form**

All participants must provide consent prior to participating in any of the proposed research activities or collection of any data with identifiers. After IRB approval, include in the header or footer of each consent page: “Approved by the CSULB IRB [Approval Date]” – indicated on the IRB Approval Letter.

**Hardcopy Consent Signatures**

In the space provided participants should print their name (or pseudonym) then a signature, and the date of consent. Participants are to receive a copy of the consent form.

Below is an Informed Consent Hardcopy template to use as a guide to develop an informed consent for your proposed research. Ensure information requested in the yellow highlighted fields is provided or delete the field. **REMOVE** ALL YELLOW HIGHLIGHTS BEFORE submitting the informed consent with the IRB application. Read your final draft to ensure the applicable Basic Elements for Informed Consent are included, and the consent makes sense.

Informed Consent (HARDCOPY)

**California State University Long Beach**

**Project Title:** [Insert Project Title]

**Investigator(s):** [Insert name of PI first, then Co-Investigator(s)]

**DELETE IF NOT APPLICABLE Project Contact:** [Insert email or phone number for PI/Project Contact]

**DELETE IF NOT APPLICABLE Faculty Advisor(s):** [Insert name(s) of Faculty Advisor(s)]

**DELETE IF NOT APPLICABLE Faculty Advisor(s) Contact:** [Insert email(s) or phone number(s)]

**California State University, Long Beach (CSULB)**

 **ADD DEPARTMENT/COLLEGE NAME, CSULB: 1250 Bellflower Blvd., Long Beach, CA 90840**

You are being asked to participate in a research study. You are asked to participate in this study because you [include inclusion criteria or subject characteristics].

The purpose of this study is to [insert a sentence or two about the purpose]. If you decide to participate you will be asked to [list research activities]. The total time of your participation is expected to last [insert amount of time and if applicable the duration for each session/visit and number of session/visits and total time].

The potential risks of participating in this study include a potential loss of confidentiality [list any other foreseeable risks if any]. The investigator will make every attempt to reduce these risks by [list mitigations as needed]. Any information collected from you in this study will be stored in a secure location and will not be shared with anyone who does not have authorization to access the information.

You [may/may not] directly benefit from participating in this study [list benefits, if any]. However, the results of this study may benefit [list benefit(s) to others or broader population].

Your participation is voluntary. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your consent and discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The incentive/compensation for participating in this study is [describe incentive/compensation and whether it is paid if participant does not complete study otherwise state there is no incentive/compensation for participation. (If appropriate insert CSULB Financial Aid reporting information text).

If you have any questions about the research, you may contact [Insert name of PI and, if applicable, Co-Investigator(s)] at [email address] or if applicable my Faculty Advisor [Insert Name of Faculty Advisor] at [Faculty Advisor’s email address]. If you have questions about your rights as a research participant, you may contact the CSULB Institutional Review Board (IRB) at IRB@csulb.edu, or call (562) 985-8147. An IRB is a committee that reviews research to ensure that the rights and welfare of research participants are protected.

Signing this document means that you are at least 18 years of age, and all information about the study has been explained to your satisfaction, the investigator has answered any questions you have about the study and that you voluntarily agree to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant (Printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Signature Date

Below is an Online Informed Consent template to use as a guide to develop the informed consent for your proposed research. Ensure information requested in the yellow highlighted fields is provided. **REMOVE** ALL YELLOW HIGHLIGHTS BEFORE submitting the informed consent with the IRB application. Read your final draft to ensure the Basic Elements for Informed Consent – Checklist are included, and the consent makes sense.

**Informed Consent** (**ONLINE**)

**California State University Long Beach**

**Project Title:** [Insert Project Title]

**Investigator(s):** [Insert name of PI first, then Co-Investigator(s)]

**Project Contact:** [Insert email or phone number for PI/Project Contact]

**[IF APPLICABLE OTHERWISE DELETE] Faculty Advisor(s):** [Insert name(s) of Faculty Advisor(s)]

**[IF APPLICABLE OTHERWISE DELETE] Faculty Advisor(s) Contact:** [Insert email(s) or phone number(s)]

**California State University, Long Beach (CSULB)**

 **ADD DEPARTMENT/COLLEGE NAME, CSULB: 1250 Bellflower Blvd., Long Beach, CA 90840**

You are being asked to participate in a research study. You are asked to participate in this study because you [include inclusion criteria or subject characteristics].

The purpose of this study is to [insert a sentence or two about the purpose]. If you decide to participate you will be asked to [list research activities]. The total time of your participation is expected to last [insert amount of time and if applicable the duration for each session/visit and number of session/visits and total time].

The potential risks of participating in this study include a potential loss of confidentiality [list any other foreseeable risks if any]. The investigator will make every attempt to reduce these risks by [list mitigations as needed]. Any information collected from you in this study will be stored in a secure location and will not be shared with anyone who does not have authorization to access the information.

You [may/may not] directly benefit from participating in this study [list benefits, if any]. However, the results of this study may benefit [list benefit(s) to others or broader population].

Your participation is voluntary. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your consent and discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The incentive/compensation for participating in this study is [describe incentive/compensation and whether it is paid if participant does not complete study otherwise state there is no incentive/compensation for participation. (If appropriate insert CSULB Financial Aid reporting information text).

If you have any questions about the research, you may contact [Insert name of PI and, if applicable, Co-Investigator(s)] at [email address] or if applicable my Faculty Advisor [Insert Name of Faculty Advisor] at [Faculty Advisor’s email address]. If you have questions about your rights as a research participant, you may contact the CSULB Institutional Review Board (IRB) at IRB@csulb.edu, or call (562) 985-8147. An IRB is a committee that reviews research to ensure that the rights and welfare of research participants are protected.

By clicking “I Consent”, you are confirming that you are at least 18 years of age and agree that you have read and understood the purpose, procedures, risks, and benefits of this study and you voluntarily consent to participate.

[ ]  I give consent.

 [ ]  I do not give consent.