**Informed Consent – Purpose & Instructions**

**Purpose**

The purpose of an informed consent is to advise prospective participants about details of the research study. It is important that the informed consent is complete and tailored to the target population (avoid jargon). An inadequate or incomplete informed consent can delay the IRB review and approval process.

**Basic Elements of Informed Consent – Checklist**

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. |  |  |

**Hardcopy Consent**

At the end of the consent form, the consenting participant should provide their printed name (or pseudonym), signature, and date of consent. Participants should then receive a copy of the consent form.

**Online Consent**

The online consent form should be the first page of an online survey (e.g., Qualtrics, Google Docs, etc.) and should include the **Basic Elements of Informed Consent** listed above.

When setting up the online consent form, ensure to create an “I consent” and “I do not consent” options at the end of the form. Please ensure that clicking “I consent” is requirement for moving forward with the online survey and that clicking on “I do not consent” will take a participant to the survey end. The survey end should instruct the individual who “does not consent” to close the consent page and/or close their browser.

If you are conducting an anonymous survey but need to collect identifiable information (e.g., email, phone number, name, etc.), then you can include a link to a second survey. This ensures that the research data will not be linked to the identifiable information, which should be disclosed 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). Note that participants are not familiar with the subject matter of your field/department.

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, then this should be noted in the consent form so they can decide whether the costs are worth participating.

If any form of compensation is offered such as course credit, gift cards, cash, or any other incentive, then please create the compensation section after the risks/mitigations section using the following criteria:

* 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.

**Audio/Video Recording**

When research involves audio/video recording, the informed consent must clarify whether the recordings are optional. If yes, please provide the checkboxes below right before the signature line. For online consent forms, the checkboxes would be placed after the “I consent” checkboxes.

 [ ]  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 studies involving focus groups or similar studies where selective recording is not practical, it is recommended to make audio/video recording a requirement for participating in the study. This must be clearly stated in the informed consent form.

**Final Consent Form**

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.

Below is a Hardcopy Informed Consent template to use as a reference. 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.

Informed Consent (HARDCOPY)

**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]

**Faculty Advisor(s):** [Insert name(s) of Faculty Advisor(s)]

**Faculty Advisor(s) Contact:** [Insert email(s) or phone number(s)]

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

You are being asked to participate in a research study. 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 risks of participating in this study include [list any foreseeable risks or state no known foreseeable risks]. The investigator will make every attempt to reduce these risks by [list mitigations as needed].

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 for participating is [describe incentive and whether it is paid if participant doesn’t complete study.

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.

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, that all information about the study has been explained to your satisfaction, that the investigator has answered any questions you have, that you have received a copy of the informed consent, and that you voluntarily consent to participate.

[If the research involves any form of media recording, then use the following checkboxes]:

[ ]  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.

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

Name of Participant (Printed)

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

Participant Signature Date

Below is an Online Informed Consent 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.

Informed Consent (ONLINE)

**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]

**Faculty Advisor(s):** [Insert name(s) of Faculty Advisor(s)]

**Faculty Advisor(s) Contact:** [Insert email(s) or phone number(s)]

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

You are being asked to participate in a research study. 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 risks of participating in this study include [list any foreseeable risks or state no known foreseeable risks]. The investigator will make every attempt to reduce these risks by [list mitigations as needed].

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 for participating is [describe incentive and whether it is paid if participant doesn’t complete study.

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.

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.

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

[ ]  I give consent.

 [ ]  I do not give consent.