

Notice of Informed Consent

Purpose & Instructions

Purpose: The purpose of the Notice of Informed Consent is to provide subjects with a concise summary of the research activities, risks, benefits and rights as a research subject. The information is designed to be a supplement to the conversation and verbal instructions the investigator provides to subjects. Try to keep the consent limited to one page. Remember the goal is to be concise.

Directions: Please use the template on the third page to create a Notice of Informed Consent. **All projects collecting data from human subjects must include this document with their IRB**

Submissions. Please remove the instructional pages prior to submitting to the IRB and prior to consenting subjects. The instructional pages are designed to provide some guidance on generating a complete Notice of Informed Consent. Remove all highlighting and instructional formats in the Notice of Informed Consent prior to submitting to the IRB and consenting subjects.

Subjects cannot provide consent to participate in your study until **AFTER** IRB Approval. All subjects must provide consent prior to participating in any project activities or collection of any data, including screening or demographic questions. Please include in the header or footer of each page of the Consent Notice, **“Approved by the CSULB IRB [Approval Date]”**, as indicated on your IRB Approval letter once the project is approved by the CSULB IRB.

Language

The consent language should be in laymen’s terms. The use of 8th grade reading level is typically the standard. Please define all terms and acronyms for the first mention of the term(s). Remember, most subjects 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...”.

Signatures

Subjects should provide their printed name (or pseudonym), signature and the date of consent. If participants will not provide a live signature, a proper justification should be provided in the IRB Application. The IRB must approve the waiver of documented informed consent prior to allowing. In the absence of a subject’s signature, the PI must provide his/her signature and date and a statement to the effect of, “I have read/subjects were provided with the notice of consent. The subject is aware of their rights as a research participant and had verbally provided consent”.

Options for Recording

If your project activities involve audio and/or video recording from a recording device or program application such as Zoom or Skype, subjects must indicate whether they agree to the recording. You should include an option at the end of the consent form such the one below for subjects to indicate:

☐ Yes, I agree to the [audio/video] recording

☐ No, I do not agree to the [audio/video] recording but, I agree to handwritten notes

Costs and Compensation

If subjects will incur costs to participation such as parking fees or the use of their own equipment or supplies, that should be clearly noted so subjects can choose whether the cost is worth participation. Additionally, if you are offering any form of compensation such as a course credit, gift cards, cash or any other incentive, you must clearly note:

- what the incentives are (\$25 cash, 2 course credits, \$5 coffee card, etc.)
- how subjects will receive the incentive (after the activities in person, emailed, U.S. Postal mail, raffle/drawing, etc.) and;
- note whether subjects will receive full compensation should they withdraw their participation or refuse to participate in certain aspects of the project.

Risks

The risks listed in the Consent Notice should be consistent with the risks listed in the IRB Application. The language does not have to be verbatim but the context should be the same.

Child Assent

For projects involving minors (children under 18 years old), the child must provide assent in addition to parental consent. The child assent should follow the same template as the Consent Notice but the title should read "Child Assent" and the language should be appropriate for the age group of subjects.

Children can only participate if both the child and parent provide consent. If the parent provides consent and the child refuses or vice versa, the child is not allowed to participate and an alternative activity must be provided if the project is in a school or classroom setting.

Parent Consent

Parents must provide consent to allow their child under 18 years old to participate. The language should describe what activities you are asking their child to participate in. Use language such as, "your child will be asked to complete a 10 minute survey...". The end of the consent notice should have the following:

Name of Child

Name of Parent

Signature of Parent

Date

Notice of Informed Consent

Project Title: [Insert Project Title]

Investigator(s): [Insert Name of PI first then Co-Investigator(s)]

Project Contact: [Insert email or phone number]

California State University, Long Beach (CSULB)

Office of Research and Sponsored Programs, 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 on sentence about the purpose]. If you decide to participate you will be asked to [list research activities] which are all for research purposes. The total time of your participation is expected to last [insert time duration]. The risks to participating in this study include [list risks]. The investigator will make every attempt to reduce these risks by [list mitigations]. 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 society or broader population].

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 appropriate provisions to access the information.

You may contact the Office of Research and Sponsored Programs at ORSPCompliance@csulb.edu, or calling (562) 985-8147, if you have questions about your rights as a research participant.

Signing this document means that all information about the study has been explained to you orally, the investigator has answered any questions you have about the study and that you voluntarily agree to participate.

Name of Subject (Printed)

Subject Signature

Date