**INSTRUCTIONS TO RESEARCHERS FOR COMPLETING THE SOCIAL BEHAVIORAL INFORMED CONSENT FORM**

This informed consent template was created by the UCR Office of Research Integrity and with appropriate edits can be used as an official consent document for your study. The best way to make use of this template is to modify the consent template according to your study, and ensure consistency with the details in your IRB application. Errors are commonly made when you simply fill in the blanks and do not read through the completed consent for clarity and consistency.

* Text in red parenthesis instruct how to address each section, and should be deleted after editing the template
* Researchers should use the sections of this document which are in bold type as applicable
* Editorial changes to the standard text (not in red) in each section may be made as long as they do not change information or intent
* Use language appropriate for the participant population
* At the bottom of each page, please identify the consent form version with an identifier (e.g., version date or version number), in order to keep track of future changes
* Please note that based on the details of your study, the IRB may require additional language not currently listed on the template to be included
* If this consent will be utilized as parental consent for children, change the appropriate language in each section. (e.g., update ‘you’ to ‘your child’, ‘you and your child’ etc.)

**Additional Points to Consider**

Consent forms should be written in lay language understandable by the targeted participant population. Typically this means that text should be at a group-appropriate reading level, unless otherwise required by participant education level. The way to approximately gauge the reading level of any given document would be to check the Flesch-Kincaid grade score, available as an option to turn on in Microsoft’s spelling & grammar options. If not, there are several websites available that allow you to input text directly to check the Flesch-Kincaid reading level. Additionally, if applicable, assent forms for children should also be written in a grade-appropriate reading level.

Please continue on to the next page for the consent template. If you have any questions, comments, or concerns, or wish to schedule a consult with our office, please email us at irb@ucr.edu.

***[STOP! Do not include this instruction sheet in your finalized consent form. Delete this page and ensure the headings, footers and page numbers are correct in your form.]***

## UC Riverside

# RESEARCH INFORMED CONSENT

# PARENTAL PERMISSION FORM *[Delete if not applicable]*

## Title of research study: ***[insert title of research study]***

## Investigator: ***[insert name of principal investigator or student]***

|  |  |
| --- | --- |
| Researcher: | [Name, Title][Department][Phone and Email] |

|  |  |
| --- | --- |
| Faculty Advisor:**[*Remove this section if not applicable*]** | [Name, Title][Department][Phone and Email] |

## Key Information about This Research Study

***[The federal regulations require a brief and concise set of statements at the beginning of the consent document that explain what a “reasonable person” would want to know about the study. This section is intended to fulfill that requirement.]***

## This section provides highlights of this research study to help you decide whether or not you should participate. Carefully consider this information and the more detailed information provided below the section. Please ask questions about any of the information you do not understand before you decide whether to participate.

* **Purpose**: This is a research study about *[insert brief description of general subject matter of study].*
* **Procedures:** Participation in this study will involve *[briefly provide a description of any procedures that the participant will experience]*. It is expected that your participation will last *[insert expected duration; if applicable, specify frequency].*
* **Risks:** Risks of this study are [significant/minimal]. Some of the foreseeable risks or discomforts of your participation include *[describe the most important risks. Consider those most probable and/or highest magnitude of harm]*.
* **Benefits:**You [may / will not directly] benefit from this research. Some of the benefits that may be expected include *[insert direct (if applicable) and/or societal benefits]*.
* **Alternatives:** Instead of being in this research study, your choices may include, *[briefly describe any study-specific alternatives]*. Your alternative to participating in this research study is to not participate.
* **Compensation:** You [will / will not] be paid *[if compensated, include payment details]* for your participation.
* **Voluntary Participation:** Your participation in this study is voluntary. You can decide to participate or not to participate, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled to or already have.

The remainder of this form contains a more complete description of this study.

##  Purpose

**[Note: If the full purpose is described in the Key Information section above, this section may be deleted.]**

You are being asked to participate in a research study. This is a research study about *[insert brief mention of general subject matter of study]*. The study researchers, *[insert name of investigator, if student include the name of the faculty advisor]* from the UCR Department of *[insert department name]*, will explain this study to you.

You are being asked to take part in this study because you are/have *[specify prospective participant’s condition, situation, or other reason for recruitment to study, e.g., "You are being invited to take part in this study because you have come to the emergency room three times in the past six months." Or "You are being asked to take part in this study as a healthy volunteer."]*

***[Required if there could be the appearance of a conflict of interest, otherwise delete section]: Investigator Financial Conflict of Interest***

No one on the study team has a disclosable financial interest related to this research project.

***[If a researcher thinks they have a disclosable financial interest, please contact the UCR PRO Committee (mwro@ucr.edu) who will discuss this with you and if need be, develop specific language detailing the financial interest.]***

## What happens if I say yes, I want to be in this research?

**[Note: If the full procedures are described in the Key Information section above, this section may be deleted.]**

If you decide to participate in this research study, the researchers will ask you to:

***[List and describe all procedures/tests/activities and their frequency under the categories below, using bulleted format. Indicate the location where procedures will be done. See examples below.]***

[Tell the participant what to expect using lay language and simple terms. Whenever appropriate include the following items:]

* A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* The length, duration and frequency or schedule of visits and procedures
* Who the participant will interact with
* Where the research will be done
* When the research will be done
* List experimental procedures and therapies and identify them as such
* If digital recordings are used, whether they are required for participation
* When applicable indicate that the participant will be contacted for future research.

***[Sample procedures:]***

* *You will view two 15-minute videotapes; one will be of pleasant content and the other of unpleasant content.*
* *After viewing both videotapes, you will be asked to take part in a focus group discussion led by Dr. XXX or Ms. XXX.*
	+ *Everyone in this focus group will have viewed the tapes. You and the other group members will be asked to discuss reactions to scenes in both tapes. An audiotape will be made of this discussion. This discussion is expected to last about 30 minutes.*
	+ *You will be given a questionnaire to respond to about your reactions to the videotapes. It should take about 15 minutes to complete this questionnaire.*
	+ *You will also be given a standard paper-and-pencil personality test. It should take about one hour to complete this test.*

***[For interviews:]***

* *The researcher will interview you for about an hour in a private office. The researcher will ask you to describe your experiences with….*
* *The researcher will make a sound recording of your conversation. After the interview, someone will type into a computer a transcription of what’s on the tape and will remove any mention of names. The sound recording will then be destroyed.*
* **Study location:**All these procedures will be done at *[Insert study locations. If different procedures will take place at different locations, specify accordingly].*

## Is there any way being in this study could be bad for me?

**[Note: If all the risks are disclosed in the Key Information section above, this section may be deleted.]**

[Include for minimal risks research with no reasonably foreseeable risks, otherwise delete]: We do not anticipate any foreseeable risks or discomforts to you participating in this study other than those encountered in day-to-day life.

[Include for research with foreseeable risks, otherwise delete. ***The information listed in this section should be equivalent to what was reported in the IRB application.***]: Participating in this research study may involve risks or discomforts that include:

[List the risks associated in the study and indicate how the risks will be minimized including:]

* Physical risks
* Psychological/emotional risks
* Social risks
* Legal risks

## Will being in this study help me in any way?

**[Note: If all the benefits are disclosed in the Key Information section above, this section may be deleted.]**

[Include the following if direct benefits are anticipated, otherwise delete]: We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include *[list direct benefits from participating in research. NOTE: Compensation or reimbursement is not considered a direct benefit from research participation].* This research may help others by *[List benefits to society/others]*.

[Include the following if there are no direct benefits, otherwise delete]: There are no benefits to you from your taking part in this research. This research may help others by *[List benefits to society/others]*.

## What happens to the information collected for the research?

Information [and/or specimens] collected for this research will be *[Include information regarding maintaining data including 1. how data will be maintained (e.g., de-identified, coded, pseudonyms, use of encryption, etc.), 2. where data will be maintained and 3. for how long. If data will be made publically available or shared outside of the research team, provide those details. If digital recordings are collected, specify how the recordings will be maintained. Include details on how data will be maintained should a participant withdraw as well as any limitations of data withdrawal (e.g., online data collected anonymously cannot be located for withdrawal.]*

***[If the research involves the collection of identifiable private information, one of the following is required:]***

Identifiers might be removed from the identifiable private information. After such removal, the information could be used for future research studies or distributed to other investigators for future research studies without additional informed consent from the subject or the legally authorized representative.

***[OR]***

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

*Will information about me be kept private?*

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy and if required by the law, your personal information may be disclosed. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

* The Institutional Review Board (IRB) that reviewed this research
* Representatives of the Sponsor *[List Sponsor name(s), as applicable]*
* Representatives of the National Institutes of Health ***[remove if this is not an NIH-funded study]***
* Representatives of the University of California
* *[list any other agencies – in or outside the US – that might inspect research records]*

 *[****Recommended wording if focus groups are used, otherwise delete:****]*

The researchers will ask you and the other people in the group to use only first names during the group session. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.

## [If Applicable, otherwise delete section]: Can I be removed from the study without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include *[list reasons for termination from study by the researcher]*. The researcher will notify you if this occurs.

## Can I stop being in the study at any time?

You can stop taking part in the study at any time. If you would like to stop, please *[list procedures for withdrawal (e.g. contact the researcher at…)]*.

## Will I receive payment for being in this study?

**[Note: If the compensation is fully described in the Key Information section above, this section may be deleted.]**

 ***[Include if there will be no compensation, otherwise delete]*** You will not be compensated for taking part in this study.

[Include if participants will be compensated, otherwise delete.] If you agree to take part in this research study, we will compensate you [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion.]

[Include if participants will be reimbursed, otherwise delete.] Because your involvement in the study may cost you *[include expenses, e.g., travel and child care]*, we will reimburse you *[indicate amount]* for these costs.

The results of this study may have commercial value to the sponsors, UC Riverside, and/or the researchers. Please know you will have no legal or financial interest in any commercial development resulting from the research or from the information or materials collected.

## Are there alternatives to being in this study?

**[Note: If the alternatives have been fully disclosed in the Key Information section above, this section may be deleted.]**

An alternative to being in this study is to not participate.

[Include if participants will be given research credit through the Psychology Department Subject Pool, otherwise delete.] An alternative to earning research credit is to complete the alternative assignment identified by the Psychology Department Subject Pool.

[Include if participants will be given class/extra credit, otherwise delete.] An alternative to earning class/extra credit is to *[list alternative assignment/activity]*.

## What else do I need to know?

[Include for research that involves greater than minimal risk, otherwise delete]: It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor *[List sponsor name]*, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may contact the UCR Office of Research Integrity via telephone at 951-827-4802 or via email irb@ucr.edu.

[Include if researchers will be providing research results, otherwise delete.] If you are interested in receiving the research results following completion of the study, please contact the researcher via *[list phone number or email address]*.

## Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team].

If you have questions about your rights or complaints as a research subject, please contact the IRB Chairperson at (951) 827 - 4802 during business hours, or to contact them by email at irb@ucr.edu.

[Omit the signature block if there is no written documentation of consent. For verbal consent, researchers may revise the consent statement to request that the participant verbally respond if they would like to proceed with participation.]

***CONSENT***

You have been given a copy of this consent form to keep.

Participation in research is voluntary. The decision to participate, or not participate, is solely up to you. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled to or already have.

If you wish to participate in this study, you should sign below.

Date Participant's Name (Print)

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

 Participant's Signature for Consent

**[*If digital recordings are used, add the following]:*** As the research study includes digital recordings, please specify below if you wish to be recorded. ***[If the study requires recordings, please state this].***

\_\_\_ Yes, I consent to be *[Audio/video recorded or photographed]*

*\_\_\_* No, I do not consent to be *[Audio/video recorded or photographed]*

**[*If Protected Health Information as defined by HIPAA will be accessed, used, created, or disclosed, add the following]:*** You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

***[STOP! Only include the following signature line below if you may consent non-English speaking participants using the short form consent method AND this request has been addressed in the IRB application.]***

Date Witness – Only required if the participant is a non-English speaker

***[STOP! Do not use the following signature lines unless third party consent is being requested and has been addressed in detail in the IRB application.]***

AND/OR:

Date Legally Authorized Representative

Date Person Obtaining Consent

OR:

*The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.*

Date Parent or Legal Guardian

OR:

*The person being considered for this study is unable to consent for himself/herself because he/she has diminished capacity. By signing below, you are giving your permission for your charge to be included in this study.*

Date Caregiver or Legal Guardian