**INSTRUCTIONS TO RESEARCHERS FOR COMPLETING THE CLINICAL-BIOMEDICAL 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 made when you simply fill in the blanks and do not read 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 if 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. As applicable, assent forms for children should also be written in a grade-appropriate reading level.

**Additional Information for Handling Health Information and Complying with HIPAA**

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 has [specific requirements](https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html) for use of identifiable information from medical records (which HIPAA calls *Protected Health Information or PHI)*. HIPAAuses different terminology from other human subject protection regulations. Under HIPAA, research subjects must give *authorization* for use of their PHI. For almost all studies, UCR requires using separate forms for research consent and for HIPAA-specific authorization for research access to health information. Under HIPAA, any disclosure of PHI that is not specifically included in an individual’s *authorization* is prohibited and is subject to penalties.

Researchers accessing PHI **must be familiar** with the [UCR HIPAA Guidance](https://research.ucr.edu/ori/committees/irb-clin/hipaa.aspx).

**Additional Information for Incidental Findings**

Researchers utilizing “clinically relevant tests” such as **MRI, EKG, blood assays, etc**. must refer to UCR’s [Incidental Findings Guide](https://research.ucr.edu/media/32243/incidental_findings_guide.pdf). In cases where an incidental finding may occur that has unknown clinical relevance, additional information is required to be added to the IRB application and consent form to cover these potential risks.

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

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

## UC Riverside

# RESEARCH INFORMED CONSENT

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

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

**[*Remove this section if not applicable*]**

|  |  |
| --- | --- |
| Faculty Advisor: | [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, drugs, and/or devices 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***

You are being asked to participate in a research study. This is a research study about *[insert brief description 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 (pro@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?

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 timeline description of the procedures that will be performed. If practical, prepare a timeline 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
* *If information about the research subject will be collected from medical records, by questioning the individual, or by any other means, describe what information will be gathered. If additional information will be gathered over time, say so.*

***[Sample procedures:]***

* *You will view two 15-minute videotapes; one will be of pleasant content and the other of unpleasant content*
* *While viewing both videotapes, you will be asked to undergo a structural and/or functional neuroimaging session. This will involve magnetic resonance imaging (MRI)*
	+ *MRI is a giant magnet that can be used to create images of the brain. You will be asked to lie on a bed in the MRI tunnel and passively view stimuli on a screen*
	+ *You will also hear tapping noises which are made by the MRI machine and are not harmful or very loud. However, you will be provided with earplugs or headphones to minimize the noise*
	+ *This imaging session will last approximately 1.5 hours, where you will be in the MRI scanner. Frequent breaks will be offered throughout the session and you can stop participating at any time*
* *Afterward, you will be given a questionnaire to complete concerning your reactions to the videotapes. It should take about 15 minutes to complete this questionnaire*

***[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 digital 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 digital recording will then be destroyed*

***[If the research involves biospecimens, one of the following is required:]***

* The research [will / might] include whole genome DNA or RNA sequencing.

***[OR]***

* The research will not include whole genome DNA or RNA sequencing.

***[Include the following procedure statement(s) as appropriate, otherwise, delete:]***

* **Placebo:** An inactive substance
* **Blood drawing (venipuncture):** If you agree to be in this study, you will go to *[location]* and give a blood sample. A blood sample will be drawn by inserting a needle into a vein in your arm. Each sample will be approximately *[XXX]* teaspoons. This will take about five minutes.
	+ *If there will be multiple blood draws over time, describe the frequency and include the total amount of blood to be drawn in the course of the study*
* **X-ray:** You will have an x-ray of your *[Body part]*, done *[frequency]* in order to check *[description]*. Each x-ray will take about *[XXX hour(s)]*
* **MRI:** An MRI is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. If you agree to participate, you will be asked to complete a screening form. This screening form contains questions to help us figure out if you can safely participate in this study. Also, because the risks to an unborn baby are not known, we have to make sure that females of child-bearing age are not pregnant. Following completion of the screening procedures, you will be asked to have an MRI scan. You will be asked to lie down on a bed that can be slid into the center of the magnet. A plastic coil will be placed around your head and foam pads will be placed to help keep your head still during the scan. You will then be slid into the magnet and asked to lie still for about *[XX]* minutes. The MRI machine will then create images of your body. At different points during this scan, you will be asked to perform certain tasks *[provide description].* You will be given a break from doing these tasks every 5-10 minutes. You can take breaks more frequently if you want.

Study location(s): 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?

[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

***[Include for research utilizing applicable procedures, otherwise delete.]***

* **Randomization risks:** You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments
* **Placebo risks:** If you are in the group that receives placebo, your condition will go without the active (study) treatment for *[XXX weeks]*
* **Blood drawing (venipuncture) risks:** Drawing blood may cause temporary discomfort or the needle stick may hurt. There is a small risk of bruising and fainting, and a rare risk of infection
* **HIV testing risks:** Being tested for HIV may cause anxiety regardless of the test results.  A positive test indicates that you have been infected with the HIV virus. If you test positive, we will refer you to a source of medical care and treatment. Receiving positive results may make you very upset.  If other people learn about your positive test results, you may face discrimination. If your test is negative, there is still the possibility that you could be infected with the HIV virus and test positive at some time in the future
* **Safe Handling of Medications:** Handling *[Medication name]* and having contact with any urine, feces or vomit from patients receiving *[Medication name]* may pose some risk to you and your caregivers. To avoid exposure to *[Medication name]* and any associated risks, you and your family members/caregivers will be educated by a member of the study team on how to safely handle *[Medication name]*, properly dispose of *[Medication name]*, and how to clean products that may be contaminated with *[Medication name]*
* **MRI risks:** While there are few risks from MRI and the scan is painless, this study may involve some minor risk and discomfort. You may be bothered by the loud sound the machine makes, such as beeping or hammering. Disposable earplugs will be given to you to help lower the noise. Also, some people may become fearful of being inside the small space while inside the scanner. People who have a history of this, known as claustrophobia, will not be asked to participate in this study. You may also feel a gentle tapping or a sensation of mild electric shock. During the session, we will still be able to talk with you via an intercom. If you feel uncomfortable and don’t want to participate anymore, please let us know and we will stop the scan. The magnets in the MRI are very strong and will attract any metal brought into the room. You must be careful to leave any metal objects outside the room. People who have pacemakers, heart problems, or certain metal implants cannot participate. Make-up that has metallic pieces in it, such as nail polish or blush, should not be worn because it could cause irritation.

This scan is part of a research study and is not supposed to provide the same kind of examination that your doctor can do. However, if the study team finds something unusual on your scan, you will be notified and your scan can be sent to your family doctor upon your request.

* **Incidental Findings risks:** This *[EEG, EKG, Blood draw, MRI, fMRI, etc.]* is done for research purposes only. The *[EEG, EKG, Blood draw, MRI, fMRI, etc.]* test or scan being done is designed to answer research questions, not to medically examine you or provide a clinical diagnosis. The *[EEG, EKG, Blood draw, MRI, fMRI, etc.]* test or scan is not a substitute for one a physician would order. It may not show problems that would be picked up by a medical *[EEG, EKG, Blood draw, MRI, fMRI, etc.]* test or scan. The researchers are not professionally qualified to act as your medical provider. However, if we see something unusual in your scan, we will inform you so that you can obtain appropriate follow-up evaluation by your physician. We will also provide you or your physician with a copy of the scan results upon request. Any follow-up evaluation or treatment that youseek will be at your own expense. Even if your physician rules out any problems, you may be unnecessarily worried if a problem is suspected
* **Unknown Risks:** The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study
* For more information about risks and side effects, ask the *[PI / study doctor]*

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

[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 or identifiable biospecimens, one of the following is required:]***

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

***[OR]***

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

***[If specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained. Include if specimens cannot be withdrawn if the participant later changes their mind. Provide an opt-in option for the subjects. (See last page signature option for bio-specimens) Opting out does not prevent subjects from enrolling in the study, if applicable. Include the following information as applicable, otherwise, delete:]***

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research, or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

*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 promise complete confidentiality 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.

***[As part of this section, include how HIPAA protected health information (PHI), if applicable, will be transmitted, used and/or stored as well as the privacy protections the research team will take.]***

***[Include if your study involves medical records and study tests conducted as part of the research, otherwise delete:]***

If you do not have a *[name of clinic]* medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your *[name of clinic]* medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record.

***[Include if your study involves HIV, hepatitis B, or hepatitis C testing with participants who have not already been diagnosed with those conditions, otherwise delete:]***

California regulations require laboratories to report new cases of HIV, hepatitis B, and hepatitis C infection to the county public health department. The reports include the patient’s name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. Personally identifying information will not be reported to other departments or agencies.

***[Certificate of Confidentiality: If this research is funded by the NIH, you must include this language. Or, if you have submitted or plan to submit an application for a Certificate of Confidentially, you must include this language.]*** This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH). The researchers with this CoC may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. For example, the information collected in this research cannot be used as evidence in a proceeding unless you consent to this use. Information, documents, or biospecimens protected by this CoC cannot be disclosed to anyone else who is not connected with the research, except:

* To a federal agency sponsoring this research when information is needed for auditing or program evaluations;
* To meet the requirements of the U.S. FDA;
* If a federal, state or local law requires disclosure such as a requirement to report a communicable disease;
* If information about you must be disclosed to prevent serious harm to yourself or others such as child abuse, elder abuse or spousal abuse;
* If you consent to the disclosure, including for your medical treatment, to an insurer or employer to obtain information about you; or
* If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

This CoC also does not prevent you or a family member from voluntarily releasing information about yourself and your involvement in this research.

## [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?

 ***[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?

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]*.

***Will I receive results from this research?***

***[Required if the study will produce clinically relevant research results, otherwise delete. Explain whether subjects receive research results, and if so, under what conditions. This section is meant to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results. Note: ORI generally recommends that individual research results of genetic or other genomic testing for research purposes rather than clinical reasons should not be shared with subjects or their families.*** Additionally, if results of testing are experimental or are not performed at a CLIA certified lab, you cannot provide results to subjects.***]*** Clinically relevant research results, including individual research results, will be disclosed to subjects [*describe the conditions under which results will be returned*].

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

## 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 the 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 at irb@ucr.edu.

## 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 UCR 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

***[STOP! Include this signature line as part of the consent if bio-specimens will be taken from participants:]***

If you agree to share the biological specimen(s) collected from you, please initial here:

Otherwise, your specimens will be *[identify how specimens will be handled (e.g., destroyed) following study completion]* at the end of the research.