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| **INSTRUCTIONS TO PERSON PREPARING THE CONSENT FORM:**   1. Use this template with the [currently posted companion document](https://irb.ucsf.edu/consent-and-assent-form-templates#consent-templates). The companion document provides guidance and IRB-approved statements that can be pasted into the template. 2. Some subsections are optional and can be deleted if not relevant to your study. Do not otherwise change the section numbering of this template. 3. All instructions are in italics. Delete these before submitting to the IRB. 4. Do NOT change the margins, the font, or the font size. 5. Delete this text box. |

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO**

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

|  |  |
| --- | --- |
| Study Title |  |
| Principal Investigator  (Person in charge of this study) | *Name, degree, title*  *UCSF department*  *Phone and e-mail* |
| Study Coordinator | *Name*  *Phone and email* |
| Study Contact Information | *Phone and/or email* |

|  |  |
| --- | --- |
| Clinicaltrials.gov National Clinical Trial (NCT) Number | *Enter NCT# or “Not yet assigned.*”  *Remove this box if this is not a clinical trial.* |

**1. Why have I been given this document?**

*[Include the following statement as written. Do not edit or add to it.]*

To see if you are interested in taking part in a research study. A research study is a planned project done to learn more about a topic.

**2. Do I need to take part in this research study?**

*[Include the following statement as written. Do not edit or add to it.]*

No. Taking part in research is voluntary. If you don’t want to take part there will be no penalty and you will not lose your current benefits. The Principal Investigator, or another member of the study team, will explain the study to you. Please ask questions. Take your time deciding if you want to be in this study. You can talk with your health care team, your family, and friends before deciding.

**3. This section describes key information to consider about this study**

**3.1 Why is this study being done?**

*[Limit the explanation to 1-3 sentences in plain language. See companion document for examples.]*

**3.2 How long would I be in this study? How many study visits are there?**

*[See companion document for examples.]*

**3.3 What are the procedures with the most risk in this study?**

*[List 1-3 bullet points. See companion document for examples.]*

The procedures with the most risk in this study are:

* *[Example 1]*
* *[Example 2]*

**3.4 What risks and discomforts are most severe? What risks and discomforts are most common?**

*[List 1-3 examples for each item. See companion document for guidance.]*

Possible risks and discomforts of this study that are most severe are:

* *[Example 1]*
* *[Example 2]*

Possible risks and discomforts of this study that are most common are:

* *[Example 1]*
* *[Example 2]*

We will tell you more about risks and discomforts later in this form.

**3.5 Are there benefits to taking part in this study?**

*[See companion document for IRB-approved statements.]*

**3.6 What are my other options if I don’t want to take part in this study?**

*[See Companion Document for IRB-approved statements.]*

**3.7 What is the usual care for my condition?**

*[Include for treatment studies only, otherwise delete this subsection. See the companion document for examples.]*

The usual care for your condition is…

**3.8 If my condition improves while taking the study drug, can I continue taking it after the study?**

*[Include for drug treatment studies, otherwise delete this subsection.]*

Some studies may allow you to continue taking the drug after the study ends. Some studies may not. It is important to talk to the study team and ask them about the rules and your options.

**4. How many people will take part in this study?**

*[Fill in the blanks below. See companion document for examples.]*

About *[insert number]* people will take part in this study at UCSF. *[If this is a multisite study, include:]* About *[insert number]* will take part in this study at all research sites.

**5. Who is paying for this study?**

*[See companion document for guidance.]*

This study is being paid for by *[enter funding source(s)]*

**6. Do any UCSF researchers of this study have financial interests that I should know about?**

*[See Companion Document for options.]*

**7. What are the research procedures of this study?**

*[See* *Companion Document for proposed formatting & IRB-approved wording for common study procedures.]*

**7.1 Where do the procedures happen?**

*[If different procedures will take place at different locations, or if the study is conducted online or remotely, specify accordingly. See companion document for examples.]*

Study procedures will be done at *[name location(s).]*

**7.2 Will clinically relevant research results be shared with me?**

*[Include this section if you might observe clinically relevant results from the research procedures. If so, see the Companion Document for guidance. Otherwise, delete this subsection.]*

**8. What are the risks of this study?**

*[See companion document for formatting instructions & IRB-approved wording for common risks.]*

**9. Will I be paid if I take part in this study?**

*[See companion document for IRB-approved statements.]*

**9.1 Will I share in any profits from this study?**

*[Include if the study involves biospecimens or data derived from biospecimens, otherwise delete this subsection.]*

No. Your specimens or information obtained from your specimens may be used for commercial use. If this happens, you will not share in any profits.

**10. Will I be reimbursed for expenses if I take part in this study?**

*[See companion document for IRB-approved statements.]*

**11. How will my information be used?**

*[See companion document for IRB-approved statements about the use of data and specimens.]*

**11.1 Genetic testing statement**

*[Include if this study involves genetic testing, otherwise delete this subsection. See companion document for IRB-approved statements.]*

**11.2 How will my genetic information be shared?**

*[Include if this study is subject to the NIH* [*Genomic Data Sharing Policy*](https://irb.ucsf.edu/nih-genomic-data-sharing-gds-policy-and-genome-wide-association-studies-gwas)*, otherwise delete this subsection.]*

We may use your genetic information and some medical record data to do research in the future. We will remove your name and other personal information before sharing it with other researchers. We may share this information with other scientists or companies not at UCSF or SFVAHCS (if this study involves SFVAHCS). This information may be put into an unrestricted or controlled access government health research database. Even though no personal information will be included, we cannot guarantee that no one will ever be able to use this information to identify you.

*[Include the following paragraph if* ***IDENTIFIABLE*** *genetic data will be stored for future research.* ***This should be very rare.*** *Best practice is to anonymize or de-identify data whenever possible.]*

If you change your mind about your genetic data that can be linked to you being used for future research, tell the Principal Investigator. This person’s contact information is on Page 1 of this form. The study team will destroy any data they still have that can be linked to you. We cannot destroy data that has already been shared with other researchers.

**12. How will information about me be kept confidential?**

*[See the companion document for IRB-approved statements.]*

**12.1 Who may review my research information?**

*[Delete any bullet points that do not apply to your study.]*

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

* Representatives of the University of California
* Representatives of the Sponsor *[List Sponsor(s), as applicable]*
* Representatives of the Research Consortium *[name the Consortium OR remove if this is not a Consortium study]*
* Representatives of the National Institutes of Health *[remove if this is not an NIH-funded study]*
* Representatives of the Food and Drug Administration (FDA) *[remove if this is not an FDA-regulated study]*
* Representatives of the Office of Human Research Protections (OHRP) *[remove this if the study is not conducted or supported by an HHS entity, e.g., NIH, CDC, FDA, AHRQ, CMS, HRSA, etc.]*
* Representatives of the Department of Veterans Affairs *[remove if this is not a VA consent form or a VA-funded study]*
* *[list other agencies – in or outside the US – that might inspect research records]*

**12.2 Certificate of Confidentiality**

*[Include if the study has a* [*Certificate of Confidentiality*](https://irb.ucsf.edu/certificate-confidentiality-nih)*, otherwise delete this subsection. See the companion document for more information on certificates of confidentiality.]*

This study has something called a Certificate of Confidentiality. This helps keep your information private. Researchers can’t be forced to share your information with others like courts or law enforcement.

There are some things that the certificate does not stop:

* Reporting abuse of children or elders, or if you or someone else is in danger.
* Reporting of certain diseases.
* Groups (like those listed in 12.1) from checking the research records to make sure the study is going okay.
* Agencies from getting information if they need it for safety reasons.
* Your information from being used in other research if it follows the rules.

The certificate doesn't stop you from:

* Talking about being in this research study.
* Looking at your own medical records.

**13.** **Does this study involve testing of diseases and conditions that must be reported to the public health department?**

*[See companion document for guidance and IRB-approved statements.]*

**14. What happens if I am injured or feel harmed because I took part in this study?**

*[Include the following statement as written. Do not edit or add to it.]*

It is important to tell the Principal Investigator if you feel you have been injured or harmed because you took part in this study. The contact information for this person is on the first page of this form.

**14.1 Treatment and Compensation for Injury**

*[Required for* [*greater than minimal risk*](https://irb.ucsf.edu/levels-review#minimal) *studies (also called “full committee” studies) and Dept. of Veterans Affairs studies, otherwise delete this subsection.]*

If you get hurt because of this study, the University of California will give you medical treatment that you need. You might have to pay for this treatment, or your insurance might pay for it. It depends on different things. The University or the study sponsor might pay for the medical costs instead. But usually, they don't pay for other things besides medical care if you get hurt. If you want to know more, call the office of the Institutional Review Board at 415-476-1814.

*[See companion document for alternate statement for the following scenarios: MMSEA 111, PREP Act Declaration, Dept. of Veterans Affairs studies, NIH studies, and Sponsor wants to remain silent.]*

**15. Are there any costs to me for taking part in this study?**

*[See companion document for IRB-approved statements.]*

**16. Can I stop being in the study if I want to?**

*[See companion document for IRB-approved statements.]*

**17. Can I be removed from the study by the Principal Investigator?**

*[Include the following statement as written. Do not edit or add to it.]*

Yes. The Principal Investigator may stop you from taking part in this study at any time. This could happen without your permission. It could be because it is in your best interest, if you did not follow the study rules, or the study has been stopped.

**18. What are my rights if I take part in this study?**

*[Include the following statement as written. Do not edit or add to it.]*

You may choose to take part or not to take part in this study. It’s your choice. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

**19.** Who can answer my questions about this study?

*[Include the following statement as written. See the Companion Document for guidance about listing additional informational sources.]*

You can contact the study team with any questions, concerns, or complaints you have about this study. The contact information is on the first page of this form.

UCSF has an office that can answer questions about your rights as a research participant. This office is called the Institutional Review Board (IRB). The IRB is available to talk about any problems or concerns you have about the study. The UCSF IRB’s phone number is 415-476-1814.

19.1 Where can I get more information about this study?

*[Include if this study is a clinical trial and will be registered on clinicaltrials.gov, otherwise delete this subsection. See companion document for guidance.]*

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The National Clinical Trial (NCT) number for this study will be listed on the first page of this form. If the NCT number is not yet available, the study team will give it to you when it is available.

**20. Consent**

You will be given a copy of this form to keep.

*[Review the* [*guidance on the Experimental Subject's Bill of Rights*](https://irb.ucsf.edu/experimental-subjects-bill-rights#background) *(BOR) and determine if a BOR is needed for this study. If so, include this sentence:* You will also be given the Experimental Subject's Bill of Rights to keep.*]*

*[If Protected Health Information as defined by* [*HIPAA*](https://irb.ucsf.edu/hipaa) *will be accessed, used, created, or disclosed, include this sentence:* You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.*]*

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to say “No” to this study now or at any point without penalty.

If you wish to take part in this study, please sign below.

Date Participant's Signature for Consent

Date Person Obtaining Consent

**20.1** **Donation of Human Fetal Tissue for Research Purposes**

*[Only include if this study involves the collection of human fetal tissue from elective abortion for research purposes. Otherwise, delete this subsection. See companion document for IRB-approved statement.]*

**21. Additional Optional Research**

*[Include if this study has additional optional research, otherwise delete this subsection. See the companion document for guidance.]*