***IMPORTANT: ALL SECTIONS ARE REQUIRED UNLESS OTHERWISE NOTED. BEFORE FINALIZING & UPLOADING THIS DOCUMENT, REMOVE: THIS SECTION, ALL [RED INSTRUCTIONAL TEXT] AND BLUE EXAMPLES.***

**UNIVERSITY OF CALIFORNIA, IRVINE**

**ASSENT ADDENDUM FOR MINORS ABLE TO GET PREGNANT**

***[Title of Study]***

*[If the study title is overly-technical, consider adding a lay title here]*

**RESEARCH TEAM**

**Lead Researcher:**

Name and Title

Department

Telephone number and e-mail address

24 Hour Telephone number *[Required for medical studies and clinical investigations]*

**Faculty Sponsor** *[If not applicable, please remove]*

Name and Title

Department

Telephone number and e-mail address

**Other Researchers** *[If not applicable, please remove]*

*[List only those researchers qualified to be involved in the informed consent process*

**STUDY LOCATION(S):**

**WHAT IS THE PURPOSE OF THIS ADDENDUM?**

This form is being given to young people (minors) who are 1) interested in participating in the research study **AND** 2) are also able to get pregnant. Since *[specify: medications and / or procedures]*can hurt a pregnancy *[specify: or a breast-feeding baby]*, you must have a pregnancy test before you begin this study. If the test shows that you are pregnant, you cannot be part of this study.

**WHAT ARE THE ADDITIONAL STUDY PROCEDURES FOR YOUNG PEOPLE (MINORS) WHO CAN GET PREGNANT?**

If you and your parent(s)/legally authorized representative decide to participate in this study, you will have some of your *[specify: blood and / or urine]* collected at different times in the study for the purposes of pregnancy testing.

*[Revise the following text as applicable]*

The effects of the study *[treatment/device]* and procedures may have some risks that we can’t predict or don’t yet know about on ability to have a baby or to a baby before it is born. For this reason, if you take part in this study, you should not become pregnant. If you are able to get pregnant, the study doctor will talk to you about how to protect your body from pregnancy and for how long. If you think that you might be pregnant at any time during the study, you must tell the study doctor or member of the study team.

**WHAT IF YOU HAVE QUESTIONS?**

You can ask questions any time. You can ask now, or you can ask later. You can talk to the study doctor, your parent(s) or guardian, or you can talk to someone else on the study team.

**DO YOU HAVE TO BE IN THE STUDY?**

You do not have to be in the study even if you have already signed the main study Assent Form.

No one will be mad at you if you can get pregnant but don't want to take the pregnancy test. If you are able to get pregnant and don’t take the pregnancy test, you cannot be in this study. Tell the study doctor if you don’t want to be in the study.

If you do want to be in the study, tell the study doctor. You can say yes now and change your mind later. It is up to you to decide.

**WHAT WILL HAPPEN TO YOUR PREGNANCY TEST RESULTS?**

**Per California Law, pregnancy test results will be provided to your parent(s) or guardian only with your permission.**

For those that are able to get pregnant, the study doctor will not discuss the results of your pregnancy test with your parent(s) or guardian unless you say it is okay.

There may be times where the study team must reveal to reveal this information, even without your permission. For example, if your life or someone else's life was at risk or if abuse was suspected, it may be necessary to inform your parent(s) or guardian(s) of a positive pregnancy test. If we believe it's necessary to tell your parent or guardian of a positive pregnancy test without your permission, we would meet with you first in private to discuss our concerns prior to telling your parent(s) or guardian any information regarding your pregnancy.

Signature of Minor Age Date

Printed Name of Minor

Signature of Researcher Date

Printed Name of Researcher

***A witness signature is required on this consent form only if: (Researchers: check which one applies)***

**IMPORTANT! If no witness signature is required, this witness signature section of the consent form may be left blank.**

Consent is obtained from the subject via the Short Form process, as approved by the IRB.

The subject has decision-making capacity, but cannot read, write, talk or is blind.

The subject’s guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.

The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive

research procedures).

**For the witness:**

I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

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**Witness Signature Date**

*Note: Refer to Human Research Policy # 35 for implementation of a witness signature.*

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**Printed Name of Witness**