**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO**
**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

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| Study Title | Commercial or Open Source Closed Loop Impact on Pregnancy (COSCLIP) Study |
| Principal Investigator (Person in charge of this study) | Nasim Sobhani, MD MAS<br>Department of Obstetrics, Gynecology, & Reproductive Sciences<br>Nasim.Sobhani@UCSF.edu |
| Study Coordinator | Molly Killion, RN CDCES<br>Molly.Killion@UCSF.edu |
| Study Contact Information | COSCLIPStudy@UCSF.edu<br>(415) 307-9319 |

**1. Why have I been given this document?**
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?**
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?**
This study is being done to better understand what happens when pregnant people with type 1 diabetes (T1D) use automated insulin delivery (AID) systems. We want to learn about the clinical, glycemic, and behavioral outcomes associated with the use of AID systems in pregnancy.

**3.2 How long would I be in this study? How many study visits are there?**
You would be in this study for the duration of your pregnancy and up to 2 months after the pregnancy ends. There are no study visits. All study procedures will be performed remotely.

**3.5 Are there benefits to taking part in this study?**
There will be no direct benefit to you from participating in this study. The information learned from this study may help others in the future.

**3.6 What are my other options if I don't want to take part in this study?**
You may be able to take part in another study if one is available.

**4. How many people will take part in this study?**
At least 500 pregnant people will take part in this study, and up to 500 of their infants.

**5. Who is paying for this study?**
This study is being paid for by the Department of Obstetrics, Gynecology, and Reproductive Sciences at UCSF.

**6. Do any UCSF researchers of this study have financial interests that I should know about?**
No.

**7. What are the research procedures of this study?**
If you choose to take part in the study, you will complete the following:

- Remotely share data from your AID system with the research team. At the beginning of the study, you will give the research team access to the system(s) that you use for diabetes data management. The research team will use these secure online portals to collect information about glucose values, insulin delivery, and other metrics once a week while you are in the study.
- Complete an online Type 1 Diabetes Distress Assessment Scale (T1-DDAS) survey. The T1-DDS is a survey that helps people with T1D talk about how much stress or worry they experience in relation to diabetes. The survey includes 30 questions about different topics like emotional burden, daily diabetes care, impact on relationships, and interaction with healthcare providers. You will be asked to complete this survey up to 4 times while you are in this study – once in the first trimester (8-12 weeks), once in the second trimester (20-24 weeks), once in the third trimester (32-36 weeks), and once after delivery (4-8 weeks postpartum). Depending on when you enroll in the

study, you may complete the survey fewer than 4 times. The survey will be sent to your email through a secure online platform (REDCap).

- Sign an authorization to release health information to allow the research team to request your medical records. You will be asked to complete this form when you enter the study. After this form is signed, the research team will directly contact your healthcare providers to request information medical records related to your pregnancy and diabetes. This includes information like whether you developed pregnancy complications (for example, preeclampsia); how you delivered (for example, vaginal delivery or cesarean delivery); and whether you had diabetes complications (for example, diabetic ketoacidosis). This request will be made after you pregnancy ends.
- Sign an authorization to release health information to allow the research team to request your baby's records. You will be asked to complete this form after you deliver. After this form is signed, the research team will directly contact your and/or your baby's healthcare providers to request information medical records related to your baby's health in the first 2 months after delivery. This will include information like how old your baby was at delivery (i.e., gestational age at delivery), how much your baby weighed at delivery, and if your baby needed special care at the time of delivery.

**7.1 Where do the procedures happen?**
All study procedures will be completed remotely, through phone calls, videoconference, and online survey requests.

**7.2 Will clinically relevant research results be shared with me?**
No.

**8. What are the risks of this study?**
Risks and side effects related to this study include:

- Survey questions about sensitive topics. Some of the questions you will be asked may cause you to feel uncomfortable or cause you anxiety. You may skip any questions that you do not feel comfortable answering.
- Loss of privacy. Participation in research may involve a loss of privacy, but information about you and your child will be handled as confidentially as possible. Your name and your child's name will not be used in any published reports about this study.

**9. Will I be paid if I take part in this study?**
In return for your time and effort, you will be paid up $50 after each T1-DDS survey is completed, for a maximum total of $200 for the whole study. Payments will be made in the form of Amazon gift cards.

**10. Will I be reimbursed for expenses if I take part in this study?**
This study does not involve any expenses to research participants.

**11. How will information about me and my child be used?**
Researchers will use your and your child's information to do this study. Once the study is done, we may use your and your child's information for other research studies in the future. We may share it with other researchers to be used in their studies. We will not share your or your child's name or other information that could identify you or your child. We cannot promise that this will prevent future researchers from figuring out who you or your child are. We will not ask you for additional permission to share this de-identified information.

**12. How will information about me and my child be kept confidential?**
If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you and your child is kept confidential. But we cannot guarantee total privacy. Some information from your or your child's medical records may be collected and used for this study. Your or your child's personal information may be given out if required by law. Information from this study may be published or presented at scientific meetings. If it is, your or your child's name and other personal information will not be used.

**12.1 Who may review my research information?**
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 Food and Drug Administration (FDA)

**13. Does this study involve testing of diseases and conditions that must be reported to the public health department?**
No, this study does not involve testing for reportable diseases and conditions.

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

**15. Are there any costs to me for taking part in this study?**
There will be no costs to you for being in this study.

**16. Can I stop being in the study if I want to?**
Yes. You can decide to stop at any time. If you are thinking about stopping, tell the study team so they can discuss any risks of stopping with you.

If you stop being in the study, any data or specimens we have already collected will remain part of the study records. The study team may still get information from your medical records if it is important to the study. This information may include information like laboratory results, treatment courses, or health outcomes. If you do not want this information to be collected after you decide to stop being in the study, you must tell the study team.

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

**20. Consent**
You will be given a copy of this form to keep. You will also be given the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you and your child.

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.

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| Date | Participant's Signature for Consent |
| Date | Person Obtaining Consent |

If you wish for your child to take part in this study, please sign below. The person being considered for this study is unable to consent for themself because they are a minor. By signing below, you are giving your permission for your child to be included in this study.

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| Date | Parent or Legal Guardian |