STANDARD CONSENT FORM
UNIVERSITY OF CALIFORNIA, DAVIS
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: The National Children's Study Delivery Specimen Pilot Study (Project 18)

INTRODUCTION

This is a research study conducted by Drs. Cheryl Walker and Suzanne Pontow from the Departments of Obstetrics & Gynecology and Internal Medicine. Participating in research is voluntary. You have the right to know about the procedures, risks, and benefits of the research study to you and/or society so that you can make the decision whether or not to participate. This is called informed consent. Please take your time to make your decision and discuss it with your family and friends.

You are being asked to take part in this study because you will be delivering your baby at the University of California, Davis Medical Center and are at least 18 years of age. We hope to learn more about the best way to collect and process samples of umbilical cord blood, umbilical cord, and placenta for a series of studies to be done in the future in a national study called the National Children's Study. In order to participate in this study, it will be necessary to give your written consent by signing this form.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn about the best way to collect and process samples of umbilical cord blood, umbilical cord, and placenta. Ultimately, with knowledge gleaned from this study, the investigators hope to design and implement better processes to collect these biological specimens for a large national study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Twelve pregnant women will take part in this study at UC Davis.

BEFORE YOU BEGIN THE STUDY

You will be asked to allow us to collect blood from your baby's umbilical cord after your baby has been born. We also want to collect your placental tissues.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you decide to participate in this study, you will be asked to do the following:

- Sign a consent form agreeing to our study requirements;
- Allow us to collect medical information from you and your baby;
- Allow us to collect cord blood after your baby is born. This blood is usually discarded after delivery and letting us take it will not harm you or your baby in any way;
- Allow us to collect placental tissues after they have been expelled naturally from your body. These too are usually discarded after delivery. Letting us take it will not harm you or your baby in any way.

The following procedures are part of regular care and may be done even if you do not join the study: Usually the doctors or nurses assisting in the birth of your baby will collect some blood from your baby's umbilical cord after the

birth. This is done to run standard tests on your baby. This will not be affected in any way. The remaining blood in the umbilical cord and placental tissues are usually discarded once the birth has been completed.

The following procedures are NOT PART OF REGULAR CARE AND WILL ONLY BE DONE IF YOU JOIN THE STUDY: After the birth of your baby we will collect blood from the umbilical cord of your placenta as well as the entire placenta to our laboratory here at UC Davis and to other laboratories at the University of Rochester and the University of Wisconsin. They are usually discarded, and your giving them to us will not harm you or your baby. We will process these tissues in the lab, and test a number of things. One test will be to separate out cellular material called DNA and RNA and determine the best time and way to collect it. Another will be to collect samples to look for contaminants in our environment, including metals like mercury, again determining the best time and way to do that. Finally, we will separate out special cells called stem cells, and test them to see how they work after certain periods of time and storage conditions.

HOW LONG WILL I BE IN THE STUDY?

You will be asked to participate in this study until your baby is born. After you are finished with the birth and we have taken the cord blood and placental tissues, your participation in the study will be over.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. Tell the research Investigator if you are thinking about stopping or decide to stop. You can decide to stop at any time. You are under no obligation to provide any information or specimens. You have the right to refuse to participate in any aspect of the study or to withdraw from the study at any time. The research Investigator will remove you as a subject from this study if you ask us to.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

You may experience a minor delay in the delivery of your placenta of about 1 to 2 minutes at the time when the researcher collects the cord blood and placental tissues during your delivery. If you experience any other side effects, during the collection of specimens or after, please make the researcher/investigator aware of them immediately.

Risks and side effects related to the collection of cord blood and placental tissues for our study include:

Likely

- A minor delay lasting 1-2 minutes in the delivery of your placenta

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You will not benefit from taking part in this research. The greatest potential benefit would be to society at some time in the future. The information we get from this study may help us to understand the best way to collect and handle these types of samples for many kinds of research.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your alternative is not to take part in this study. If you choose not to take part in this study, your present and future care at University of California Davis Medical Center / UC Davis Health System will not be affected.

WILL MY INFORMATION BE KEPT PRIVATE?

We will do our best to make sure that the personal information will be kept private. However, we cannot guarantee total privacy. Your personal information may be released if required by law.

The personal information we collect about you will be separated from your identity. The code linking ID numbers to personal identifying information will be kept in a locked file cabinet, and in electronic files that do not contain any other information and do not exist on computers containing any other information. No analytic databases will contain any personal identifiers. Data will be summarized across groups of subjects so that your personal information will not be revealed in a way that can lead back to you. If information from the study is published or presented at scientific meetings, your name and other personal information will never be used. Five years after completion of the study analyses all personal identifier information will be eliminated from the hard copy files.

Designated University officials, including Institutional Review Board, and the research sponsor, the University of California, Davis, have the authority to review your research records.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

If you are injured as a direct result of research procedures, you will receive reasonably necessary medical treatment at no cost. The University of California does not provide any other form of compensation for injury. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department.

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WILL I BE COMPENSATED FOR BEING IN THIS STUDY?

[redacted]

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice and completely voluntary. 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 and you will not lose any of your regular benefits. Leaving the study will not affect your medical care here at UC Davis Health System.

The research investigator may withdraw you from participating in this research if circumstances arise which warrant doing so even if you would like to continue.

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

DOES THE RESEARCHER HAVE A FINANCIAL INTEREST IN THIS RESEARCH STUDY?

The Investigator does not have any personal or financial interest in this study.

WILL SPECIMENS (tissue, blood, urine or other body materials) TAKEN FROM ME BE USED FOR FUTURE RESEARCH PURPOSES?

During the course of the research, the investigator will remove cord blood and placental tissues. We would like to keep some of the cells that are left for future research purposes. Your specimens will only be used for research purposes. If you agree, these specimens will be kept and used to learn more about environmental contaminants, DNA, and the development of the blood system during pregnancy.

Biological specimens, such as cord blood and placental tissue, taken from you for this study, will become the property of the National Children's Study, [redacted]. The specimens could lead to discoveries or inventions that may be of value to the University of California or to other organizations. Under state law you do not have any right to money or other compensation stemming from products that may be developed from the specimens.

Your name, address, phone number and any other directly identifying information will be removed from the specimen before it is given to another researcher. Because your personal information is not attached to specimens, if you change your mind about sharing specimens later, we may not be able to retrieve it.

For further information on the use of specimens for future research purposes and your rights as a research participant, please visit: http://research.ucdavis.edu/IRBAdmin/Participants.

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WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have questions, please ask us. You can talk to the Investigator about any questions or concerns you have about this study at:

Cheryl Walker, MD at phone number 916-734-6670 or 530-902-1841

Suzanne Pontow, PhD at phone number 916-703-9313

For questions about your rights while taking part in this study call the IRB Administration at (916) 703-9151 or write to IRB Administration, CTSC Building, Suite 1400, Room 1429, 2921 Stockton Blvd., Sacramento, CA 95817. The IRB Administration will inform the Institutional Review Board which is a group of people who review the research to protect your rights. The IRB Administration has also developed a web site designed to make you familiar with your rights. The web site discusses your basic rights as a research participant, an explanation of the informed consent process, the basic requirement that written consent be in a language understandable to you, and suggested sample questions to ask the research investigator regarding your participation in the study. This web site can be accessed at: www.research.ucdavis.edu/IRBAdmin.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant, you have the following rights that include but are not limited to your right to:

1. **Be informed of the nature and purpose of the experiment;**
2. **Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;**
3. **Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment;**
4. **Be given an explanation of any benefits to the subject reasonable to be expected from the experiment, if applicable;**
5. **Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits;**
6. **Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise;**
7. **Be given an opportunity to ask any questions concerning the experiment or the procedures involved;**
8. **Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice;**
9. **Be given a copy of the signed and dated written consent form;**
10. **Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision**

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My signature below will indicate that I have decided to participate in this study as a research subject. I have read and understand the information above. I understand that I will be given a signed and dated copy of this consent form and the Bill of Rights.

Signature of Subject or Legal Representative

Print Name

Date

Signature of Person Obtaining Consent

Print Name of Person Obtaining Consent

Date

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