Description
You are invited to participate in a research study to collect umbilical cord blood, a tissue that is typically discarded as post-partum medical waste. Your participation will play a key role in furthering basic, translational and clinical research here at Stanford.

You will be asked to provide your written consent for the anonymous donation of your cord blood (otherwise designated as post-partum biological waste) toward the advancement of biomedical research conducted at Stanford University. Apart from providing your informed written consent, no active participation will be required on your part.

Voluntary Participation
Your participation in this study is entirely voluntary. You may choose not to participate, without there being any negative effect on you or your medical care. You may also decide to participate now, but withdraw your consent and participation in the study at a later time without any loss of benefits or medical care to which you are entitled.

Tissue Sampling for Research
Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues in a research project. There are several things you should know before donating your umbilical cord blood.

Your cord blood may be stored for application in future research projects if not currently required; however, it will contribute toward pioneering research regardless of when it is utilized.

Because your cord blood will be de-identified and anonymously donated toward research applications, you cannot withdraw your consent to the use of your cord blood after it has been collected.

Tissue Sampling for Genetic Research
One particular branch of biomedical investigation that can be advanced through the contribution of umbilical cord blood is genetic research. Genetic research is research that studies genes and their implications in human disease. Genetic research may involve holistic analysis, connecting information about one’s DNA sequences, or genotype, to their physical appearance, or phenotype, as well as the overall study of coding sequences, genetic landmarks, biochemical traits, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Your cord blood, which is donated anonymously, is primarily used as a platform with which to further research into various blood and immune disorders, as opposed to a specimen to be studied itself. Therefore, you will not be directly notified of the progress of research to which

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your cord blood contributes; however, this research will, in most cases, be publicly available in scientific papers.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

Genetic Data
Information from analyses of your coded (de-identified) samples and your coded (de-identified) medical information will be entered into one of the National Institutes of Health (NIH) databases along with information from the other research participants for future research. These databases will be accessible via the Internet. Only anonymous information from the analyses will be entered into a completely public database, available to anyone on the Internet.

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be entered into the public database. While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to trace your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that the security of the computer systems used to store the codes linking your genetic and medical information to you could be compromised.

While these scenarios are unforeseeable, your privacy is regarded with the utmost priority, and will implement our best safety measures for its protection. Despite our best efforts, we cannot guarantee that your identity will never become known.

Stem Cell Research
Your cord blood may also be used for somatic stem cell research. This work would be conducted on the Stanford campus. No new stem cell lines will be developed from the donated cord blood cells. It is possible that adult (non-pluripotent) stem cells purified from the cord blood may be introduced into animals for research but only after approval is obtained from the relevant oversight committee. Introducing these cells into a non-human, animal model allows for the study of their biological function. Otherwise, there are no further restrictions on the ultimate recipients of these cells or cell products.

_______   Initials   _______   Date

Please be aware that the cord blood may be preserved for an extended period of time if not requested immediately, and therefore may be used by researchers at Stanford for purposes that are currently not foreseeable. These projects may involve genetic manipulation, but will be subject to the same (or perhaps more stringent) regulations regardless.

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**Risks and Benefits**
There are no risks associated with the collection of your cord blood for donation toward Stanford research. We cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your employment/medical care.

**Time Involvement**
Your involvement in this study is required only until your cord blood is collected.

**Payment**
You will not receive payment for the donation of your cord blood.

**Participant Rights**
If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The results of research that involves your cord blood in addition to the cord blood donated by others may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

**Withdrawal from Study**
The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.
Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

Umbilical cord blood is a rich source of human tissue that serves as a powerful tool for the advancement of biomedical research. By donating your cord blood, you are providing consent for your cord blood to be utilized in research conducted at Stanford toward the study of human disease. A cord blood coordinator will briefly screen your health information to confirm your eligibility for cord blood donation and utilization in research.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Matthew Porteus, Stanford University School of Medicine, Department of Pediatrics, Division of Stem Cell Transplantation and Regenerative Medicine, Lorry Lokey Stem Cell Research Building, G3045, 269 Campus Drive, MC 5462 Stanford, CA 94305.

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STANFORD UNIVERSITY Research Consent Form

Protocol Director: Matthew Porteus

Protocol Title: Collection of Umbilical Cord Blood for Research Purposes

Approval Date: March 29, 2017
Expiration Date: February 28, 2018
What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, age, ethnicity/race, disease status and biological sex of your baby.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Matthew Porteus
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2050 or when the research project ends, whichever is earlier.

________________________________                ______________
Signature of Adult Participant/Mother                                    Date

______________________________________________________________
Print Name of Adult Participant/Mother
Contact Information

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Matthew Porteus, at (650) 725-6520. You should also contact him/her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306

By signing below, you acknowledge that you agree to be in this study and that you were provided with a copy of this signed and dated consent form.

________________________________    ________________
Signature of Adult Participant/Mother     Date

_______________________________________________
Print Name of Adult Participant/Mother

______________________________________________  ______________________
(If available) Signature of Other Parent or Guardian                      Date

_______________________________________________
Print Name of Other Parent or Guardian

_______________________________________________
Authority to Act for Child

The IRB determined that the permission of one parent is sufficient in accordance with 45 CFR 46.408(b).
The following signatures are required only when using the short form consent process:

____________________________________   __________________
Signature of Person Obtaining Consent                         Date

____________________________________
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

____________________________________   ____________
Signature of Witness                                                              Date

__________________________________
Print Name of Witness

(e.g., staff, translator/interpreter, family member, or other person who speaks both English and the participant’s language)

- Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.
- The English consent form (referred to as the “Summary Form” in the regulations):
  - Must be signed by the witness AND the Person Obtaining Consent (POC).
  - The non-English speaking participant/LAR does not sign the English consent.
  - The non-English speaking participant/LAR should not sign the HIPAA participant line
  - If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR’s Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant’s wishes, as they are understood during the consent process.

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