

STANFORD UNIVERSITY Research Consent Form

IRB USE ONLY

Approval Date: September 11, 2012
Expiration Date: September 11, 2013

Protocol Director: Dr. Barry Behr

ep 10466

Protocol Title: The RENEW Biobank (RENEW: Regenerative Medicine through the Ethical procurement of Nonviable or Excess cellular Waste) - 2: Stanford IVF Sperm Research Consent

DESCRIPTION: You are invited to donate your excess sperm and/or testicular biopsy material, as well as your somatic cells (ordinary body cells or blood cells surrounding the sperm or testicular biopsy material) which would normally be discarded to The RENEW Biobank. These materials may be used for studies that analyze the efficiency of forming human spermatogonial stem cell lines (hSSCs) or in developing new diagnostics for male fertility.

PROCEDURES: This form gives you an opportunity to document your preferences regarding future uses of your donated materials. In addition to completing this consent form, you will also be asked to complete a health questionnaire about your fertility treatment history, your medical history and your family medical history.

Donated materials will never be used for the generation of human embryos or to make a baby.

Sperm, testicular biopsy material, and/or somatic cells may be donated to Class 1 or Class 2 or Both Classes:

Class 1: Genetic and Cell Biology Studies

This research is aimed at studying sperm and testis cells to learn more about the genetics of germ (sperm and egg) cell formation, studying abnormal vs. normal development, and improving IVF clinical outcomes. This research will not produce stem cell lines.

Class 2: Production of Stem Cell Lines

This research will try to make new stem cell lines from sperm and/or testicular biopsy cells. In some cases, spermatogonia stem cell (SSC) lines can develop and be used for establishing cell lines that are pluripotent (able to differentiate to many cell types of the body). Generation of SSC lines may involve genetic or chemical modification in order to generate a cell similar to an embryonic cell. Cells multiply by dividing in two, and the genetic material is replicated every time a cell divides. These cell lines, which can live indefinitely, will contain your DNA.

Male Donor

Date

I consent to donate my excess **sperm, testicular biopsy and/or somatic cells** which would otherwise be discarded to be used for genetic and cell biology research (**Class 1**) with no restrictions on future uses outlined in this consent.

Male Donor

Date

I consent to donate my **excess sperm, testicular biopsy and/or somatic cells** which would otherwise be discarded to be used for the Production of Stem Cell Lines (**Class 2**) with no restrictions on future uses outlined in this consent.

Using Cellular Materials for Future Research

Research using cellular materials is an important way to try to understand human disease. You have been given this information because the investigators want to include your cellular materials in a research project. There are several things you should know before allowing your cellular materials to be studied. Samples will be coded and stored with all personal

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identifiers removed. Donated materials may be stored for an indefinite length of time by the biobank before being released to researchers. If you consent to Class 2 research, cell lines derived from your donated materials may be stored by cryopreservation (freezing) or be grown in culture indefinitely. Class 2 research may result in the long-term propagation of living cells derived from the donated cellular reproductive materials. Any cell lines created or modified may be kept for many years and may be used in further studies, by researchers at Stanford or other researchers and entities outside of Stanford, which cannot be predicted at the present time. They may include research that involves genetic manipulation. It is possible that derived cells or cell products may be placed into humans or animals. There are no restrictions on the ultimate use or recipients of these derived cells, cellular materials or cell products. Researchers may choose to use materials only from donors who agree to all future uses without restrictions.

Any materials you have donated to research, or results of research including new products, tests, or discoveries, may be patentable or have commercial value. In some instances, research results may be developed and owned by the Investigators, Stanford University, and/or others. Under California law and rules, if you consent to donate materials to the biobank, you will have no legal or financial interest in any commercial development resulting from the research.

If you consent to Class 2 research, in the event the cell lines derived from your donation prove to offer a potential medical benefit, we may attempt to recontact you to get additional health information if you agreed by initialing below.

Male
Donor

Date

I consent to being re-contacted in the future should the investigators wish to ask **for additional health information.**

Male
Donor

Date

I do not consent to being re-contacted in the future should the investigators wish to ask **for additional health information.**

Use of Cellular Materials for Genetic Testing

As part of the analysis on your samples, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, 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. Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. 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. Investigators in this study may try to re-contact you in the future. If you are re-contacted and want to know what the investigators have learned about your tissue samples, you should understand the following:

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- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;
- You may be determined to carry a gene for a particular disease for which there is no current treatment;
- You may carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

Male
Donor_____
Date

I consent to being re-contacted in the future should the investigators wish **to let me know what they have learned from genetic testing** on my cellular materials.

Male
Donor_____
Date

I do not consent to being re-contacted in the future should the investigators wish **to let me know what they have learned from genetic testing** on my cellular materials.

PARTICIPANT'S RIGHTS: Your decision to participate in this study is voluntary. You have the right to withdraw your consent at any time prior to the release of your cellular reproductive materials to researchers. However, once the materials are provided to researchers, you will not be able to withdraw them from the research because they would be processed immediately. To withdraw from the study you must notify the protocol director or research staff at (650) 725-9977.

RISKS AND BENEFITS: The donation of cellular reproductive materials generated during your IVF/ICSI treatment that would otherwise be discarded to research involves no additional immediate, direct medical risk to you, but could affect your psychological state of mind. If you consent to being recontacted regarding genetic testing results, there is a risk that you may learn information about your health that may cause you psychological distress.

This research is not intended to provide direct medical benefit to you or anyone else. Cell lines that are derived may not be available for your treatment in the future. You may not receive any information about subsequent research, or study results using your donated materials. **We cannot and do not guarantee or promise that you will receive any benefits from this study.**

TIME INVOLVEMENT: Your participation in this research will not require any extra time from you, other than the time it takes to sign this consent form and complete the health questionnaire.

PAYMENT: You will not be paid to donate your discarded reproductive materials to the RENEW Biobank.

ALTERNATIVES: Neither consenting nor declining to donate materials for research will affect the quality of care provided to you by this facility. Clinical decisions about your care will not be influenced by your participation. The researchers will not be involved in your direct clinical care.

Participant ID: _____



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CONFIDENTIALITY: The researchers studying the donated materials will not know your identity. All identifiers associated with the donated materials will be removed prior to their release for research. In place of the identifiers, the Research Study Coordinator will assign a code to these donated materials. The Study Coordinator will maintain the code in a secure location and will not disclose it to the researchers. The researchers will have access to necessary clinical information (such as infertility diagnosis and IVF treatment outcome) only in coded form so that they can determine if there is a correlation between research results and clinical diagnosis and treatment outcome. If you have consented to be recontacted for additional health information, if applicable the researchers will contact the study coordinator with the tissue code number and the study coordinator will de-code and contact you to obtain that information. If you have consented to be recontacted to learn genetic testing results on your cellular materials, if applicable the researchers will contact the protocol director with the tissue code number and the protocol director will contact you to give that information. Data generated from related studies may be published without any identifying information and may be shared by Stanford University with multiple researchers and research institutions and ultimately with commercial developers, again without any identifying information.

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 without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your identifiable health information will be used or disclosed in research conducted in connection with The RENEW Biobank. Your information will only be used and disclosed 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?

You are being asked to donate materials to The RENEW Biobank and to provide health information, which the researchers will use in coded form (without direct identifiers) for research described in the consent form. Research on developing new diagnostics for male fertility is necessary if we are to better understand human development and treat a wide range of human disorders including infertility. In the future, human cell lines derived from donated materials may be useful for cell-based therapies. Advances in human stem cell research may some day lead to new treatments for human diseases. The success of the research may be different depending on health status. In particular, your health information, such as age, medical conditions, fertility history, and treatment outcomes may

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be analyzed together with the data that are generated from your donated cellular reproductive materials (i.e. sperm and/or testicular biopsy).

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.

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 research) prior to the collection of donated samples by the research team. After the biobank has provided samples for research, the researchers would not be able to remove the data from our project. 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: Barry Behr, PhD; 300 Pasteur Drive HH333, Stanford, California 94305-5317.

What Health Information Will Be Used or Disclosed?

You will be asked to provide identifiable health information to the biobank that receives your specimens for use in research. Your health information will be coded, so that researchers cannot link your information to your identity. Your coded health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, infertility diagnosis and IVF treatment outcome, any other clinical data related to infertility treatment or other medical conditions, such as diabetes as complicating factors.

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 (Barry Behr, PhD) and his coordinating staff
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Third parties that Stanford hires for oversight or legal purposes

Who May Receive / 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:

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- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Food and Drug Administration (FDA)
- The California Institute for Regenerative Medicine (Study Sponsor)
- Third parties that Stanford hires for oversight or legal purposes

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 expire on December 31, 2060, unless you revoke (cancel or withdraw) it sooner.

Printed Name of Donor_____
Signature_____
Date

CONTACT INFORMATION: Questions, Concerns, or Complaints: 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, Dr. Behr, (650) 723-0951. You should also contact him 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, Stanford, CA 94305-5401.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

Signature of Male Donor_____
Date_____
Signature of Person Obtaining Consent_____
DateParticipant ID: 