DESCRIPTION: The goal of Assisted Reproductive Technology (ART) is to help infertile couples to become pregnant. During treatment, some reproductive tissues are collected or produced which may not be further required for your treatment. These include embryos, oocytes, sperm, ovarian tissue, testicular tissue, and cells and fluid collected during oocyte retrieval (follicular fluid). All cellular material to be used in this research would normally be discarded because you, the patient, have chosen to discard the material (e.g. frozen embryos which you no longer require for your treatment which will be referred to as normal embryos in excess of clinical need).

You are invited to donate reproductive tissue generated during your IVF/ICSI treatment which you no longer require for your treatment to The RENEW Biobank. These materials may be used to further examine the In Vitro Fertilization process and the causes of infertility, to better understand early human development and/or for human stem cell research.

PROCEDURES: This form gives you an opportunity to document your preferences regarding future uses of your donated cellular 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.

You may choose donate **reproductive tissue** according to Class 1 or Class 1 and Class 2 of research described below. Both Class 1 and Class 2 research will produce valuable information. Only Class 2 research will result in the long-term propagation of living cells derived from the donated embryos.

Donated embryos will be manipulated and destroyed during the research procedures. All embryos will be destroyed when they reach twelve days of age. Donated materials will never be used to make a baby.

Facility where reproductive tissues are currently located :
_____Stanford Fertility and Reproductive Health
_____If other, please list name of the clinic:_____

Catalog of reproductive tissues to be donated:
*As part of the informed consent process, we will review in detail the quantity of each of the following materials you would like to donate and this will be recorded separately.

____ Embryos
____ Oocytes
____ Sperm
____ Ovarian Tissue
____ Testicular Tissue
____ Follicular fluid

_____ Partner 1 Initials _____ Partner 2 Initials _____ Date

Class 1: Early Human Development

This research is aimed at studying reproductive tissues such as embryos, oocytes and sperm to learn more about early human development, embryo quality, abnormal vs. normal development, and improving IVF clinical outcomes. This research will not produce cell lines (see definition of cell lines in next paragraph).

Class 2: Genetic Reprogramming and/or Production of Cell Lines

The specimens that you donate to the bank may be used to create induced pluripotent stem cells. Most stem cell research begins with the establishment of new stem cell lines. There are several ways to make these lines. One way is to derive stem cell lines by using cells in tissues taken from the body, such as blood, adipose (or fat) tissue, or skin. It is possible that these stem cell lines, which can live indefinitely, may contain all or part of your DNA. Stem cell lines from tissues can usually be made without changing the genetic information by artificial means.

Another way of making stem cell lines is to introduce certain genes into somatic cells and "reprogram" them to become pluripotent, or able to become any cell in the body, such as brain, liver, or heart cells. Such cells are called induced pluripotent stem cells, or iPS cells.

You should be aware that your tissues, cells or other materials derived from these tissues may be kept for many years and may be used by researchers at Stanford or by researchers at entities outside of Stanford in future studies, which are not foreseeable now. They may include research that involves genetic manipulation. You have the right to refuse to allow your tissues to be studied now or saved for future study; however you cannot withdraw derivatives and other products made from cells isolated from that tissue once they have been distributed, reprogrammed or incorporated into other cells or cellular materials. It is possible that derived cells or cell products may be placed into humans or animals. There can be no restrictions placed on the ultimate recipients of these derived cells or cell products. The results of the study of your samples will be used for research purposes and tissue derivatives may also be used in human therapies.

Partner 1 Initials	Partner 2 Initials	Date	
_____	_____	_____	I/We consent to donate **reproductive tissue** which would otherwise be discarded to be used for Human Development research **(Class 1)** with no restrictions on future uses outlined in this consent.
_____	_____	_____	I/We consent to donate **reproductive tissue** which would otherwise be discarded to be used for genetic reprogramming and/or Production of Cell Lines **(Class 2)** and Class 1 as described above 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 materials to be studied. Samples will be coded and stored with all personal identifiers removed. Donated embryos 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 cellular materials will be stored by cryopreservation (freezing) or be grown in culture indefinitely. Any cell lines created or modified in Class 2 research 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, that 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 recipients of these derived cells 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.

_____ Partner 1 Initials	_____ Partner 2 Initials	_____ Date	**I/We consent to being re-contacted** in the future should the investigators wish to ask **for additional health information**.
_____ Partner 1 Initials	_____ Partner 2 Initials	_____ Date	**I/We *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 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:

- 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.

_____ Partner 1 initials	_____ Partner 2 initials	_____ Date	**I/We consent to being re-contacted** in the future should the investigators wish **to let us know what they have learned from genetic testing** on our cellular materials.
_____ Partner 1 initials	_____ Partner 2 initials	_____ Date	**I/We *do not* consent to being re-contacted** in the future should the investigators wish **to let us know what they have learned from genetic testing** on our 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) 498-7911.

RISKS AND BENEFITS: The donation of embryos generated during your IVF/ICSI treatment that would otherwise be discarded involves no additional immediate, direct medical risk to you, but could affect your psychological state of mind. If you consent to being re-contacted 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 for donating your embryos 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.

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.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or specimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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 your excess embryos to The RENEW Biobank and to provide health information, which the researchers will use in coded form (without direct identifiers). Research on in vitro fertilization and the human embryo prior to implantation is necessary if we are to 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 someday 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, type of IVF treatment, and treatment outcomes may be analyzed together with the data that are generated from your donated embryos).

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 participation in the research) prior to the collection of donated embryos by the research team. After the biobank has provided your embryos 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: Liesl Nel-Themaat, Ph.D, Stanford Fertility and Reproductive Health, 1195 W Fremont Ave Sunnyvale CA 94087.

What Health Information Will Be Used or Disclosed?

You will be asked to provide identifiable health information to the biobank that receives your embryos 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, gamete donor name (for data retrieval only), age, date of IVF cycle, number of embryos, cause of infertility, number of previous IVF attempts, number of prior pregnancies and live births, fertilization rate, number of embryos, characteristics of each embryo in the cohort, any other clinical data related to infertility treatment or other medical conditions, such as duration of infertility, polycystic ovarian syndrome or 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 (Liesl Nel-Themaat, Ph.D) and her 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:

- 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)
- The National Institues of Health
- 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 Partner 1	Signature	Date
_____	_____	_____

Printed Name of Partner 2 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. Nel-Themaat, 408-688-9826. You should also contact 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, 1705 El Camino Real, Palo Alto, CA 94306.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____ _____
Printed Name of Partner 1 Signature Date

_____ _____ _____
Printed Name of Partner 2 Signature Date

_____ _____
Signature of Person Obtaining Consent Date

_____
Print name of Person Obtaining Consent