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SAMPLE CONSENT INFORMATION

RESEARCH PROGRAM TO DERIVE HUMAN EMBRYONIC STEM CELL LINES FROM CRYOPRESERVED EMBRYOS

You have received this invitation to participate in a research program to derive human embryonic stem cell lines, because you have participated in the *in vitro* fertilization program at the **(Facility)** and you previously signed a consent to donate your cryopreserved (frozen) embryos for research. You should understand that if you donate any embryos to research, and later want to have a child, this will increase your chance of requiring additional IVF hormone treatment and egg retrieval.

This invitation describes a specific embryo research program. This consent form should be completed if you decide that you would like to allow your frozen embryos that are no longer required for your reproductive purposes to be used for the research described below.

Purpose of the proposed research program

Human embryonic stem cells are special cells taken from human embryos, such as embryos produced by *in vitro* fertilization, that are not going to be used to try to establish a pregnancy. Human embryonic stem cells are special because they are undifferentiated cells. Undifferentiated cells have the potential to develop into all types of cells and tissues in the body. This means that human embryonic stem cells can be made to produce cells with a specialized function, such as liver cells, nerve cells, or heart muscle cells.

One eventual goal of human stem cell research is to establish cell lines of undifferentiated stem cells. A cell line is a group of identical cells that can be kept stable and growing for an indefinite time. Using this stem cell line, an unlimited number of differentiated cells can be produced that could be used in research involving patients who have diseases, or injuries that have caused their own differentiated cells to die or degenerate – diseases such as Parkinson's, diabetes, cirrhosis, heart disease, or spinal cord injury, to name just a few.

The purpose of this research program is to derive embryonic stem cells from frozen human embryos that are no longer required for reproductive purposes. These cell lines may be maintained for many years, distributed to other parts of the world, and used for various research purposes.

In addition to using the stem cell lines to make differentiated cells for research on the treatment of various diseases, they may be used for future therapies.

Description of the proposed research program

If you choose to participate in the proposed research program, the **(Facility)** will take the frozen embryos no longer required for your reproductive purposes that you decide to donate, remove all identifying information (make them anonymous), and transfer them to Dr. **(Name)**'s research laboratory at **(Institution where research is being conducted)**.



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Researchers in Dr. **(Name)**'s laboratory will maintain the embryos for a short time in a culture dish (between 2 to 4 days), then cells from the inner cell mass (the center of the embryo) will be removed and cultured. This process will destroy the embryos, but, hopefully, will provide the researchers in Dr. **(Name)**'s laboratory with the undifferentiated cells needed to develop embryonic stem cell lines.

The frozen embryos given to Dr. **(Name)**'s research laboratory at the **(Institution where research is being conducted)** will not be transferred to a uterus or used to create a pregnancy. Any human embryonic stem cell lines created from these embryos will not be mixed with an intact human embryo or used to make genetically identical whole human embryos (cloning). Dr. **(Name)**'s laboratory at the **(Institution where research is being conducted)** will dispose of any human embryos or embryo material that is not used to derive human embryonic stem cell lines.

Potential benefit to you

You will not receive any medical benefit from participation in the proposed research program. There will be no directed donation of the cells or cell lines to particular individuals.

You will not receive any financial benefit from participation in the proposed research program.

Potential benefit to others

The human embryonic stem cell lines that might result from this study may be used to make differentiated cells that might be used in future research designed to develop treatments for patients or any treatments that might result.

Potential risks associated with your participation

The research program will use your embryos that you have already produced through *in vitro* fertilization that are no longer required for your reproductive purposes. No additional IVF procedures will be performed in order to obtain embryos for research. Your participation in this research program will not result in any physical risk or discomfort.

If you choose to participate in the proposed research program, you agree to donate all or some of your embryos that are no longer required for your reproductive purposes for research. If you agree to donate all of your embryos that are no longer required for your reproductive purposes, then you will not have any of your own embryos in storage to achieve a pregnancy for yourself at a later date. If you choose to become pregnant in the future, you may have to undergo, again, all of the steps required for *in vitro* fertilization. To avoid this possibility, you may want to keep your embryos frozen for your own reproductive purposes.

If embryonic stem cell lines are successfully isolated, the cell lines would become the property of Dr. **(Name)**'s laboratory at the **(Institution where research is being conducted)**. Because of the possibility that differentiated cells derived from embryonic stem cells might one day be used to treat human diseases, or for future therapies, the cell lines might have commercial value. Dr. **(Name)**'s laboratory at **(Institution where research is being conducted)**, or companies or organizations that the **(Institution where research is being conducted)** deals with, may have ownership of the cell lines, their properties and uses, or the techniques used to isolate them. With



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this ownership, Dr. **(Name)**'s laboratory at the **(Institution where research is being conducted)**, or those companies or organizations, may obtain financial benefits from the commercial development of the stem cell lines or their derivatives. You will not share in those financial benefits.

None of the researchers involved in this research have a direct financial interest in any of the companies or organizations that the **(Institution where research is being conducted)** deals with.

Confidentiality

The human embryos given to Dr. **(Name)**'s laboratory at the **(Institution where research is being conducted)** will be provided anonymously. This means that no identifying information about you will be provided to the researchers at the **(Institution where research is being conducted)**, or the companies or organizations they deal with.

Some general information will be provided about your age, ethnicity, and health, such as genetic abnormalities known at the time of donation. There will be general information about how long the embryos have been stored, and the developmental stage (or cell number) at which they were frozen. This information is important to the use of the embryos and the embryonic stem cell lines to be derived. The researchers (and companies or organizations they deal with) will not know who provided the embryos. A coding system will be developed and kept by the IVF clinic to protect your confidentiality.

Only if legally required will the coding system be used by the **(Facility)** to link the embryo providers with the stem cell lines. Otherwise, the only people who will know that you participated in the research are the physicians and other staff at the **(Facility)** who handle the transfer of the embryos to the research facility, the staff of the research ethics board that may conduct audits, and possibly third party reviewers retained by Health Canada or by the **(Institution where research is being conducted)**. That is, if successfully derived human embryonic stem cell lines have any potential future therapeutic or commercial value, third party reviewers may need to review the signed consent forms to determine the authenticity of these forms. These third party reviewers would be from the governing body responsible for ensuring the safe and ethical use of the cell lines, such as Health Canada, or the United States Food and Drug Administration. As a result, they may see your name, but they are bound by rules of confidentiality not to reveal your identity to others.

Changing your mind

When you signed your consent to *in vitro* fertilization therapy, you indicated that you were willing to donate your embryos no longer required for your reproductive purposes to research and you were told that you would be able to change your mind. If you now agree to this specific research project to derive and establish human embryonic stem cell lines, your embryos will be anonymized and transferred to Dr. **(Name)**'s laboratory at the **(Institution where research is being conducted)**. Until the embryos are actually used for research, you may change your mind and withdraw your consent. However, if you withdraw your consent after the embryos have left the clinic, then the embryos will no longer be suitable for reproductive use and will have to be



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destroyed. Once the embryos have been used for research to create stem cell lines, there will be NO opportunity to change your mind as the embryos will have been destroyed, nor can the stem cell lines be requested or removed from the research program.

Alternatives to participation

You may choose to keep your embryos that are no longer required for your reproductive purposes for your own later use in seeking to establish a pregnancy. If you do not want to use the embryos for your own reproductive purposes, you may choose to donate them to another couple seeking fertility treatment. You may also choose to leave your embryos in storage to donate for other research purposes in the future, or to discard them.

If you do not wish to participate, your care will not be affected

Participation in the proposed research program is voluntary. If you choose not to participate in the research, your decision will not influence your care in any way.

Please take as much time as you need to think this over

You are welcome to ask any questions about this research program, now or in the future.

If you have any questions about your rights as a research participant, or about the conduct of this study contact: **(Director, Office of Research Ethics), (Institution where research is being conducted), (Phone no.)**.

If you have any questions about the research program, contact: Dr. **(Name), (Institution where research is being conducted), (Phone no.)**.