

Patient Informed Consent

Embryo Cryopreservation

INTRODUCTION

You have been informed that excess embryos may be produced from an in vitro fertilization (IVF) treatment cycle. Any excess embryos produced through these procedures can be frozen for potential future implantation, or they can be destroyed, in accordance with your wishes.

In authorizing these procedures we acknowledge that we have had the opportunity to discuss fully with the Physicians the nature and purpose of the procedure, the risks, the alternatives, the risks to the alternatives and that all of our questions have been answered to our satisfaction. Based on our discussions with the Physicians and the written materials explaining the procedure supplied to us, we understand the following concerning cryopreservation:

NATURE AND PURPOSE OF THE PROCEDURE

- 1) Excess embryos, which result from the in vitro fertilization of eggs from you, the wife, by sperm from you, the husband, will be frozen using a technique called cryopreservation.
- 2) The embryos will be stored in a frozen condition until the physician responsible for your care determines appropriate conditions exist in you, the wife's body, for transfer of the embryo(s) to you, the wife's uterus. Then some or all of the embryos will be thawed.
- 3) Each embryo will be examined to determine whether it is medically appropriate to transfer it to the uterus, and if so, the transfer will occur. If, after thawing, an embryo does not appear to be viable, then that embryo will not be transferred into the wife's uterus.
- 4) You understand that the world experience with freezing of human embryos **have not** shown an increased occurrence of congenital abnormalities for infants born from frozen embryos. However, no assurance whatsoever can be made concerning the survival of embryos after cryopreservation or of the absence of congenital abnormalities in a fetus developing to term from a frozen embryo.
- 5) You understand that an additional charge will be assessed for cryopreservation, storage, and reimplantation of embryos. Total cost for cryopreservation and implantation of such embryos may be discussed with the IVF financial counselor.
- 6) Only embryos which are deemed viable by the IVF team, based on the exercise of reasonable medical judgment, will be cryopreserved.

RISKS OF THE PROCEDURE

- 1) No embryos may survive the freeze/thaw process and therefore no embryos may be available for transfer.
- 2) Pregnancy is not guaranteed.
- 3) If a pregnancy is achieved, any obstetrical and gynecological risk and complication can occur. These include maternal complications of pregnancy, miscarriage, ectopic pregnancy, abnormalities in placental development, stillbirth or birth defects.
- 4) If pregnancy occurs, there is also the risk of multiple gestation and birth. Multiple gestation may present significant risks to the life and health of the mother and the fetuses such as pre-term labor and pre-eclampsia.
- 5) Operative or laboratory accidents may result in lost or damaged embryos.
- 6) Understand that with any technique necessitating mechanical support systems, equipment failure can occur. Neither the IVF team nor GMC are to be held liable for any destruction, damage, or improper freezing, maintenance, storage, withdrawal, or thawing, caused by or resulting from any malfunction of the freezing equipment, storage tank, or failure of utilities.

ALTERNATIVES

The Physicians have reviewed the alternatives to this procedure with us, including the risks and benefits of these alternatives.

DISPOSITION OF CRYOPRESERVED EMBRYOS

In vitro fertilization and embryo cryopreservation and transfer are new areas in which legal principles and requirements have not been firmly established. Consequently, to prevent potential future misunderstandings, several restrictions are placed on the storage and use of cryopreserved embryos.

Based on currently accepted legal principles regarding human sperm and eggs, you have been advised that each embryo resulting from the fertilization of the wife's egg by the husband's sperm shall be the joint responsibility of both of you, as the wife and the husband.

The consent of both of you will be required concerning the disposition of any and all such embryos except in circumstances where you both, in accordance with the applicable laws, agree to alternative arrangements for utilization or disposition of the embryos or where such use or disposition is controlled by applicable law or the final decision of a court or other governmental authority having jurisdiction over such decisions. Certain uses or disposition may also require approval by the IVF team or by the Medical Center.

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The current policies of the Geisinger Medical Center (GMC) and the IVF team provide that:

- 1) Each embryo resulting from the fertilization of the wife's egg with the husband's sperm will be stored by the Medical Center for the mutual benefit of the husband and wife.
- 2) The consent of both husband and wife will be required concerning the use and disposition of any and all cryopreserved embryos.
- 3) Cryopreservation of embryos is being done for the specific purpose of preserving embryos for implantation in the wife to achieve pregnancy.
- 4) In the event of divorce after cryopreservation of embryos, the written authorization of both husband and wife is required for disposition of cryopreserved embryos. Specifically, both husband and wife must agree to the transfer, anonymous donation, or early discarding of frozen embryos. Otherwise, in the absence of subsequent mutual agreement cryopreserved embryos will be discarded.
- 5) In the event of the death of **both** the husband and wife during the storage period, cryopreserved embryos will be discarded. In the event of the death of **either** the husband **or** wife during the storage period, the survivor shall have the use and disposition of any and all cryopreserved embryos.

Should GMC no longer maintain an embryo storage program, and embryos which have been cryopreserved remain in storage, you will be contacted and all reasonable efforts will be made to arrange for disposition of such embryos in accordance with your desires at such time.

CONFIDENTIALITY

We understand that GMC and the Physicians are actively involved in medical education and research. We agree that information concerning our treatment may be used in medical publications provided that our identities or identifying information is not revealed. All procedures carried out under this program will remain confidential between the involved couple and professional personnel.