

CRYOPRESERVATION INFORMATION BROCHURE

It has been known for several hundred years that sperm may be frozen and regain motility following thaw. Preserving the integrity of an embryo during freezing and thawing has been more of a challenge. However, through the 1940's, improvements in cryopreservation technologies and its application to laboratory animals and farm livestock led to developments enabling these techniques to be used in humans. Assisted Reproductive Technologies (ART) using frozen sperm and frozen embryos has resulted in millions of laboratory animal and farm livestock births with no increase in abnormalities or defects.

Attempts to use frozen sperm in humans began in the 1950's, with the first successful pregnancy accomplished in 1953. Since that time, there have been hundreds of thousands of human births reported from the use of frozen sperm (this number does not reflect the total number of babies born from frozen sperm since the procedure is now so commonly used that most births are not reported as using such ART procedures). More recent advancements in human embryo cryopreservation resulted in the first birth in 1984, following an ART procedure in an Australian laboratory, using embryos that had been frozen for two months. The rate of abnormalities in children of naturally conceived pregnancies may be as high as 5%. Based on current scientific knowledge, there has been no evidence of an increase in abnormalities or birth defects in children born from frozen sperm or frozen embryo specimens. However, there is no indication that the birth defect rate will be decreased and no guarantee that a higher birth defect rate will not occur with the use of frozen specimens.

Because variation exists with each patient, specimens from some individuals will not store as long or as well as specimens from others. The maximum time currently recommended, prior to reevaluation, for storage of frozen sperm specimens is five years. However, births have been reported from sperm specimens that have been frozen and stored up to 15 years and, in our laboratory, from embryos frozen and stored as long as 7 years.

The purpose of freezing and storing sperm and embryos is to establish a pregnancy at some point in the future. We devote our best effort to preserving the fertilizing ability of the sperm and integrity of the embryo. However, any individual submitting specimens for freezing and storage must understand that many factors beside the apparent ability of the specimen to survive freezing enter into conception. These factors include the partner, as well as other factors not related to the freezing and thawing process. ***Pregnancy with the frozen specimen, therefore, cannot be guaranteed.***

In order to attempt a pregnancy with the frozen sperm specimen, one of many ART procedures may be performed by a physician properly trained in this area. It will require precise timing of the partner's ovulation and proper technique. It may take several attempts at assisted reproduction prior to achieving pregnancy, and for this reason, we suggest that multiple specimens be frozen.

Pittsburgh Cryobank can receive specimens in the frozen state after they have been processed and frozen at other laboratories that are more conveniently located for Clients. If we did not perform the actual freezing process, we cannot be responsible for the quality of the specimen or the success of the freezing process utilized. In this case, the only information we have available are the preefreeze characteristics of each specimen and the results of any quality control tests

performed at the freezing laboratory. Pittsburgh Cryobank will NOT thaw any specimen unless directed by the Client in writing. Our only responsibility is to provide quality long-term storage and transportation of the specimen to the Client's physician upon request.

We emphasize that we cannot guarantee you will have a child with the specimens you cryopreserve. We assure you that we will employ our best efforts to see that the specimens are properly transferred, identified and returned in the most viable state. The American Association of Tissue Banks holds regular meetings to disseminate information on the most modern methods of tissue preservation. We will employ the best techniques available for the cryopreservation of the specimens. However, we are aware of no certain standards by which the adequacy and suitability of specimens for freezing may be tested. Further, each person is unique and factors in the patient and in the patient's partner will affect the probability of successfully achieving a pregnancy.

Why cryopreserve sperm?

The most common reason for sperm cryopreservation is to attempt to maintain fertility **prior to undergoing radiation therapy or chemotherapy for malignancy**. Other reasons may include individuals on a **medication regimen or undergoing medical treatments** known to decrease fertility. While not inevitable, such treatment can result in a decrease in fertility potential. Similarly, men may choose to cryopreserve sperm as a precautionary measure **prior to testicular or prostate surgery**.

Another common reason for sperm cryopreservation is involvement in an **Assisted Reproductive Technology (ART) procedure** such as IVF, ICSI, GIFT, or another similar procedure. In this case, the cryopreserved sperm sample would be available at the time of the procedure. The availability of the sample would be ensured when you are not available during the time of the your partner's ART procedure (in cases such as **frequent travel or active military duty**).

Men may wish to cryopreserve sperm **prior to a vasectomy for sterilization**. Vasectomy is a safe and effective method of birth control for those who do not desire to have children. A man should not undergo such an operation unless he is sure that he does not wish to father children. Nonetheless, the cryopreservation of sperm prior to vasectomy may be considered by some men who have made their decision to have the sterilization procedure performed. Again, it must be emphasized that pregnancy following sperm cryopreservation cannot be guaranteed and the decision to have a vasectomy should not be predicated on an assumption that pregnancy can be accomplished using a frozen sperm specimen.

Other men who may choose to cryopreserve include those who work in circumstances where there is a **risk of injury to the reproductive system**. This group includes those who are **exposed to chemical, biological, or environmental hazards** (herbicides, radiation, etc.). Individuals involved in **sports activities** (such as football or hockey) that may increase their risk of injury to the reproductive system may choose sperm cryopreservation as well.

Why cryopreserve embryos?

Women who undergo hormonal stimulation in preparation for an assisted reproduction procedure commonly produce too large a number of eggs to be used during one cycle.

Extra eggs can be fertilized in vitro and the resulting embryos cultured to stages suitable for cryopreserving for future use. Embryo freezing and storage provides multiple attempts at establishing pregnancy from one egg retrieval, resulting in less total cost and fewer invasive surgical procedures for both patients and egg donors.

What happens in the event of a power failure?

Since the specimens are stored in a liquid nitrogen refrigerator, there is no requirement for electricity. This eliminates the concern that a power failure may cause thawing of a specimen.

Can specimens be lost due to accidental thaw?

Pittsburgh Cryobank makes every effort to ensure that the liquid nitrogen refrigerators are kept in good condition. One may envision, however, that a defective refrigerator can allow evaporation or spill of liquid nitrogen and the subsequent thawing of specimens. The staff at Pittsburgh Cryobank maintains daily visual contact with the refrigerators to try to prevent such an unlikely occurrence. However, one must understand that unusual, unforeseen, or unpreventable circumstances can arise. Specimens can be lost as a result of these circumstances. A client must understand that while Pittsburgh Cryobank will expend its very best effort to protect the survival of specimens, such survival cannot be guaranteed.

What is the risk of birth defects?

We are unaware of any reported evidence, to date, that there is an increase of birth defects in children born from frozen sperm or frozen embryo specimens. However, this should not be regarded as a guarantee that frozen sperm or frozen embryo specimens will not contribute to, or cause, birth defects in children.

How is a specimen identified?

All semen specimens are immediately identified upon receipt by the Client's name, social security number, and date frozen. Likewise, directed donor specimens are identified by the donor's name, donor social security number, and date frozen. All embryos are identified upon receipt by the Client(s) name(s) and date frozen. This information is attached to the samples, cross-referenced in an inventory logbook and remains intact while in the frozen state.

Who has access to the specimens?

No one except the original Client(s) has access to the specimen. For legal purposes, Pittsburgh Cryobank considers sperm specimens the property of the producing male, excluding sperm donors, and recognizes only this male as the Client. If a Directed Donor is being utilized, Pittsburgh Cryobank considers the Recipient the sole Client. In the case of a Surrogate (non-sexually intimate female partner), Pittsburgh Cryobank considers the producing male the Client. Other situations not mentioned here may occur and will be evaluated on a case by case basis and addressed individually in their contract and/or agreement.

Pittsburgh Cryobank will conduct business with the Client **ONLY**. In the event of the Client's death, the partner will have access to the specimens only if legally specified in the Client's will or other legal court document filed within one calendar year from the Client's death.

Pittsburgh Cryobank considers embryos the property of two Clients except in the case of an unmarried woman. Any sperm and/or egg donor used to produce the embryo has no rights or responsibilities to the embryos and will not be considered a Client. Both Clients are required to sign a "Renewal Schedule for Embryo Storage" each year to continue storage of the embryos and endorse all written consents before the embryos can be released for use. Refusal of one Client to sign any form required by Pittsburgh Cryobank terminates all obligations of Pittsburgh Cryobank defined in the initial contract. Pittsburgh Cryobank will, however, grant a one year grace period ("State of Transience") to Clients for the sole purpose of rectifying any personal or legal discrepancy associated with continued storage or use of the embryos. In the event of one Client's death, the remaining Client will have access to the embryos only if legally specified in the deceased Client's will or other legal court document. If unspecified in the deceased Client's will, or in the event of both Clients' death, the embryos will be destroyed in a practicable manner.

How are sperm and/or egg donors acknowledged?

Any male willingly donating sperm or any female willingly donating eggs to produce a pregnancy and/or to produce an embryo has no rights or responsibilities to the final specimen and will **NOT** be considered a Client. All donors (egg, sperm, or embryo) sign appropriate contracts relinquishing them of all responsibilities prior to donating.

What is the procedure for withdrawing the specimens?

Pittsburgh Cryobank must be **notified in writing at least 10 days in advance** of the Client's (Clients') wish to withdraw any or all specimens. **Specimens will be shipped directly to a physician's office ONLY**, and will not be released from Pittsburgh Cryobank until all fees (storage, withdrawal, shipping, etc.) have been paid.

What is the procedure for destroying specimens?

In the event the Client(s) chooses to **discontinue storage of specimens**, a consent contract must be signed, notarized, and filed at Pittsburgh Cryobank. The specimens will then be destroyed in a practicable manner. The Client(s) remains responsible for all fees incurred to date.

Are there alternate methods of relinquishing responsibility of specimens other than destroying them?

Sperm specimens **CANNOT** be donated. If a Client(s) chooses to discontinue storage of frozen specimens, donation may be an alternate choice for embryos. Embryos may be donated to an accredited assisted reproduction program provided all appropriate testing, i.e. HIV, hepatitis, etc., is able to be performed on all parties involved.