

# Specialists In Reproductive Medicine & Surgery, P.A.

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*Excellence, Experience & Ethics*



## Cryopreservation of Gonadal Tissue (CGT) and Cells *Patient Information*

### **General:**

Specialists in Reproductive Medicine & Surgery, P.A., (SRMS) will cryopreserve and store ovarian and testicular tissue (Cryopreservation of Gonadal Tissue: CGT) for future use. CGT is a process wherein gonadal tissue is stored at very low temperatures so that the tissue may eventually be thawed and used for conception.

It should be understood that it is commonplace to cryopreserve sperm and embryos. The cryopreservation of testicular and ovarian tissue is quite straightforward while the eventual thaw and use of these tissues remains *experimental*. SRMS provides the cryopreservation service assuming that techniques will be created in the near future that will allow for successful thaw and use of the tissue.

### **Specialists in Reproductive Medicine & Surgery:**

SRMS is a Reproductive Endocrinology and Infertility practice located in Southwest Florida. A Reproductive Endocrinologist, highly trained Andrologist/Embryologists as well as specially trained nurses and ancillary personnel staff the facility.

### **XYTEX Corporation:**

XYTEX is a licensed clinical laboratory for long-term storage of reproductive cells. It is located near the Medical College of Georgia in Augusta, Georgia. XYTEX adheres closely to Federal and American Society For Reproductive Medicine guidelines regarding the cryopreservation of sperm as well as a host of other regulatory agencies and has been open since 1975. At times, we use XTEX for as our long-term storage facility.

### **Cryopreservation Of Testicular Tissue:**

Prior to puberty, male patients who undergo surgery or medical therapy that may lead to sterility are candidates for surgical removal of testicular tissue with cryopreservation. The most common request for cryopreservation of testicular tissue occurs prior to cancer therapy.

### **Cryopreservation Of Ovarian Tissue:**

For the female who has entered puberty, it is possible to stimulate the ovary to produce eggs. Normally, these eggs would be fertilized by sperm with the resulting embryos cryopreserved for future use. If there is not enough time to stimulate the ovaries or no male partner exists (i.e., pre-puberty), the

eggs themselves can be cryopreserved in liquid nitrogen. The thawing and using these eggs in the future has been done although studies continue to be performed to increase the success rates. Therefore, the cryopreservation of mature eggs is to be considered *investigational* and is normally not a practical alternative.

For women and girls less than 40, patients who undergo surgery or medical therapy that may lead to sterility are candidates for surgical removal of ovarian tissue with cryopreservation. Request for cryopreservation of ovarian tissue occur prior to cancer therapy as well as instances where pelvic organs (uterus & tubes) are being removed for benign disease.

### **Future Use of The Testicular Tissue:**

The thaw and use of cryopreserved testicular tissue is *experimental*. It is possible, the tissue may be replaced back into the body, or more likely, sperm cells will be grown/extracted and used for reproduction. Techniques to use immature thawed testicular tissue are being studied but standardized therapy is not yet available. If the male patient is close to puberty and mature sperm cells are found in the testicular tissue, techniques such as In Vitro Fertilization with direct injection of the mature testicular sperm into the human egg (Intracytoplasmic Sperm Injection)

### **Future Use of The Ovarian Tissue:**

The thaw and use of cryopreserved ovarian tissue is *experimental*. It is possible the tissue may be replaced back into the body or the eggs may be successfully grown and used in the laboratory. Techniques for using thawed ovarian tissue continue to evolve but standardized therapy is not yet available.

### **How The Gonadal Tissue Be Obtained:**

For the male patient, a small incision will be made on the scrotal sac and the testicular biopsy performed. Normally, only one testicle will be sampled. This is considered an outpatient procedure although conditions may exist requiring a brief hospitalization. When necessary, some tissue will also be sent to pathology to evaluate to disease.

Ovarian tissue will be obtained though an outpatient laparoscopy or an open incision with in-patient hospitalization. Samples of the ovarian surface will be obtained. Only one ovary is usually sampled. When necessary, some tissue will also be sent to pathology to evaluate to disease. Occasionally, an entire ovary would be removed but the organ is simply too large to be cryopreserved successfully. In this case, some of the surface cortex will be removed and cryopreserved with the remaining tissue sent for pathologic analysis.

When space is available, the frozen tissue will be kept onsite. If space becomes limited, the tissue will be sent out of the area to a distant storage facility.

### **Ancillary Blood Testing:**

It is important that diseases such as Hepatitis and HIV be ruled out before obtaining and storing the tissue. If this blood work cannot be obtained prior to cryopreservation, the tissue will be placed in quarantine while frozen pending the results. If Hepatitis and/or HIV tests are positive, SRMS reserves

the right to thaw and destroy the tissue. Long-term storage facilities will often not store potentially contaminated tissue.

### **The Responsibilities of SRMS:**

SRMS agrees to process and store the gonadal tissue. As previously stated, long-term storage is often accomplished at a distant storage facility.

### **The Responsibilities of The Long-Term Storage Facilities:**

The long-term storage facility will store the tissue as long as storage fees are paid. The storage fees are necessary to cover malpractice insurance as well as pay for the storage facilities needed. Upon written request, the facility will discontinue storage at any time.

### **Consequences of Using Frozen Gonadal Tissue:**

The liquid nitrogen will slow but not stop the aging process of the gonadal tissue. This aging process may eventually lead to a loss of fertility potential although it is currently uncertain how long this will take.

### **Insurance and Payment Concerns:**

Medicaid and Medicare will generally not cover these procedures. If the gonadal tissue is being obtained for medical reasons such as the treatment of cancer or benign disease, insurance carriers may pay for some of the fees. Private insurance companies infrequently cover long-term storage fees although they may assist in the screening blood work and consultations. SRMS will provide the patient with the necessary information to file but will not file directly to an insurance company unless it is a covered service and SRMS participates in the insurance program.

The patient is billed directly from the long-term storage facility for their fees. Payment is respectively requested at the time of service.

These issues are covered in greater detail in the “Proposed Fees For The Cryopreservation of Gonadal Tissue” patient information sheet.

### **Legal Issues:**

There is no guarantee of future survival of cryopreserved gonadal tissue. Even if the tissues survive the freeze/thaw process, no guarantee is given regarding the capacity of the tissue to result in a pregnancy. Your long-term storage facility reserves the right to withhold the transfer of the specimens if outstanding payments have not been paid. Your long-term storage facility also reserves the right to dispose of the semen in the event of failure to pay within a reasonable period of time.

If your long-term storage facility is not notified of a change of address, and the account is six months past due, they may remove the tissue from storage. This may seem harsh, but the potential of storing thousand of straws or vials for an indeterminate amount of time is concerning.

The offspring that are created after the death of an individual from cryopreserved gonadal tissue may or may not be entitled to inherit from the deceased parent’s estate. This issue remains relatively untested in many States. It would appear that the following might assist some families in securing the inheritance and/entitlements (i.e., Social Security) of the potential future offspring:

1. It must be clear that the child that is created from the cryopreserved tissue is related to the parent who passed away. DNA fingerprinting with a secure chain-of-evidence (provided by SRMS) may assist in this.
2. It needs to be established that the dead parent consented to and desired the “posthumous” (after death) conception. This may need to be outlined in a Last Will & Testament or in some other document such as a consent and/or acknowledgment.
3. It is urged that the parent, before death, make it clear, in writing, if possible, that they want the child/children to be supported (i.e., inherit the estate).

It is clear that the above comments should not be misconstrued as legal advice. Upon request, we would be happy to refer you to a Southwest Florida Attorney, Harold S. Eskin, Esq., who is well versed in Florida reproductive law ([www.LegalSurrogacy.com](http://www.LegalSurrogacy.com)).

**This Packet Of Information And Additional Legal Documents:**

SRMS has done the best they can to simplify the cryopreservation process. Even so, there are a number of complexities that must be reviewed.

It is essential that you read this entire packet and understand all of the material. ***Be sure, however, to read all materials thoroughly before making the appointment.***

Below is a summary of the enclosed XYTEX documents:

<b>Document Title</b>	<b>Comments</b>
<a href="#">Billing Information For Transferring Client Depositors From Another Bank</a>	<input checked="" type="checkbox"/> This simply reviews the billing of the transfer of your sperm from SRMS to XYTEX. Please fill out what you can and SRMS will complete the rest of the information.
<a href="#">XYTEX Tissue Services Release To Transfer Form</a>	<input checked="" type="checkbox"/> This consent allows SRMS to send the cryopreserved specimens to XYTEX. Please fill out what you can and SRMS will complete the rest of the information.
<a href="#">XYTEX Semen Storage Agreement</a>	<input checked="" type="checkbox"/> This is the most complex section of the consents. Please take your time. Please remember that there are many reasons that men cryopreserve their sperm and they may not pertain to your particular situation. Most often, the “Client Depositor” reflects your current circumstances.  <input checked="" type="checkbox"/> Please pay particular attention to “7. Disposition Upon My Death:” segment. This topic should also be covered in your Last Will & Testament.

SRMS will require that all of these materials be completed and we will forward them to XYTEX with your specimen(s).

**Additional In formation:**

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K:/docs/forms/Cryopreservation of Gonadal Tissue (CGT) and Cells Patient Information.doc

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