

DATE EFFECTIVE: 12/15/11	International Terms of Use-Physician	FORM: DIS.10bi REV: A
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www.fairfaxcryobank.com www.cryolab.com Email : info@fairfaxcryobank.com

We, the staff at Fairfax Cryobank, Cryogenic Laboratories, Inc. (CLI) collectively known as “Cryobank” are pleased that you have selected our services to assist your patients on their pathway to creating a family. We are here to help you help your patient with family-building plans. Our objective is to provide premier donor sperm services, and sperm, embryo and oocyte (egg) storage including transportation of cryopreserved reproductive material that emphasizes safety, security, and service. We work to provide safe, secure services using the latest cryopreservation technology, testing and screening that serves to protect your health and complies with state and federal requirements.

To help make sure your experience with Cryobank is as satisfactory as possible, this document explains what to expect from Cryobank’s donor programs and storage services. It also explains what the Cryobank needs from you. More detailed descriptions and terms for each program and service are described in our literature and websites (www.fairfaxcryobank.com, www.cryolab.com) and in the agreements, storage agreements, billing agreements and authorizations that you will be asked to sign during your involvement with us.

The Cryobank must receive a signed copy of this ‘Terms of Use’ letter (page 6 only) via fax, email or mail at least one business day prior to the first shipment of any Specimens to your clinic only if you wish to purchase samples for your patients. Patients who purchase their donor samples directly from Cryobank will sign a separate ‘Terms of Use’ letter and you will not need to sign this document.

Cryobank’s Donor and Storage Programs

Our donor programs consist of several distinct programs: anonymous sperm donors Identity Option (ID)donors, and where available directed sperm donors. We provide anonymously donated semen that is tested and screened for certain genetic and infectious diseases. Donor sperm purchased by an individual/couple is to be used solely by that individual/couple and is not to be resold or redistributed to another recipient. Distribution or sharing of the donor sperm beyond the originally intended recipient interferes with the proper tracking of pregnancies and dissemination of relevant medical history as needed. We provide information about the donor, including medical and personal profiles, donor audios, personality testing (Keirse), profile silhouettes, childhood and sometimes adult photos, and staff impressions to assist in the selection of the donor best for your patient. Such information and images are offered for personal use, and not for public dissemination. Cryobank also has a program (ID Option donors) where the donor’s identity may be provided to the child when he or she reaches the age of 18. If your patient wishes to order an ID Option donor, they will be required to sign a separate ‘Terms of Use’ as well as the ID Option Patient Agreement. we will also assist in screening, testing and storing semen from a directed donor (a man who is known to your patient who is not a sexually intimate partner with the patient). (Check with customer service to confirm availability of this service in your area.) We are pleased to assist individuals, married couples and unmarried couples in our donor programs.

In the general population, every pregnancy has about a 3%-4% risk of producing a child with a birth defect or mental deficiency. Cryobank reviews each donor’s personal and family medical history, has a physician examine each donor, and performs genetic and infectious disease screening to reduce this risk, *but it cannot eliminate the risk.* Cryobank performs the diagnostic tests listed in the Donor Sperm Section of our website (www.fairfaxcryobank.com). Although it is not possible to completely eliminate the risk of infectious diseases or genetic disorders, the tests performed by Cryobank reduce the likelihood of an anonymous or ID Option donor passing on an infectious disease or a genetic disorder. Please be aware that we do not test for *all* genetic disorders or infectious diseases because not all genetic disorders/diseases have tests, or it is impractical or otherwise not feasible to do such tests. Therefore, there is no guarantee that all donor specimens are completely free of genetic defects or diseases, that a pregnancy will result, or that a child born using our donor sperm will be free of disease or physical or mental defects.

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We also collect and store semen from men for use at a later time with a sexually intimate partner. These “Client Depositors” might be undergoing medical treatment such as chemotherapy/radiation treatment or surgery such as vasectomy that could impact their fertility. In other situations they may wish to store as backup for their partner’s future infertility treatments. (Check with customer service to confirm availability of this service in your area.)

Cryobank also stores embryos and oocytes. We will arrange the transport of your patient’s frozen semen and/or embryos/oocytes to and from a clinic in special liquid nitrogen vapor shipping containers designed to keep the Specimens frozen for up to 7 days. (Check with customer service to confirm availability of this service in your area.)

NOTE: When storage is available and when placing specimens in storage at Cryobank a storage agreement and billing agreement must be completed and returned to the Cryobank signed by the owner of the specimens (sperm, embryos, oocytes). Ownership is determined by the purchaser of the samples or by the producer of the samples. If you return donor samples to Cryobank for storage that are designated for or owned by one of your patients, you can elect to have the samples placed into storage under their name (individual account) or placed into a storage account under your account number (physician/clinic account). Storage fees are assessed to each individual account storing specimens. Failure to pay storage fees or return of the aforementioned agreements within 60 days will result in abandonment of the specimens. A \$100 administrative fee will be charged to your account as well as the specimens will become the sole and exclusive property of Cryobank and shall be either returned to inventory or destroyed by Cryobank. No refunds will be granted when samples are abandoned. Until the billing agreement is received, we/I authorize the Cryobank to charge may account or the credit card used for the original order for applicable monthly storage fees.

We maintain confidential medical information, and work diligently to keep it private.

What We Need from You

You agree that the Specimens are for personal use by your patients only. You recognize that you have no right to learn the identity of an anonymous donor, and that Cryobank will not disclose identifying donor information or assist you or your patient in any way to contact a donor. (ID Option donors can be known to offspring at age 18.) You and/or your patients do not have the right to seek a donor’s identity by other means available to you, and should we discover that attempts have been made to do so, we will pursue any and all appropriate action to protect the donor’s interests. In turn, Cryobank will not disclose you or your patients identifying information to the donor.

Cryobank finds pregnancy reporting and tracking very important. If your patients become pregnant by an anonymous donor, we ask that you or your patient notify us so we can monitor the number of children born from an individual donor. Pregnancy reporting can be completed on our website. You agree that you will maintain diligent records on your patients and pregnancy outcomes and report to the Cryobank. The ability to track pregnancies is imperative so Cryobank can contact recipients in the event an adverse medical event is reported or updated donor medical information becomes available.

Your patient is the legal parent of the child/children born to them with the use of donated sperm per the laws of the country of birth or province/state of birth within that country. Your patient is solely responsible for their support and custody. The donor has given up all of his rights and is released from any obligations to children born using his sperm.

Limits to Our Services

When Specimens are collected, processed and stored at Cryobank, there is greater predictability in knowing the quality of the Specimens after thawing. Where available, we accept Specimens that were collected and frozen by another facility and sent to Cryobank for storage, the Specimens are only as good as the facility that prepared them and sent them to us for storage.

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Cryobank ships Specimens in specially designed liquid nitrogen vapor tanks couriered by various delivery vendors (example: FedEx, Purolator, DHL, etc.). Although uncommon, shipping delays may occur due to bad weather, airplane mechanical problems or other similar events outside our control. In addition, tanks can fail in transport resulting in thawed or otherwise spoiled specimens. In order to minimize this risk, Cryobank offers you the option to having samples shipped in separate tanks however, you would be responsible for the additional shipping cost of the second tank. Therefore, please take this possibility into account when requesting shipments. We recommend that you place your shipping order (M-F) at least 10 business days prior to the date samples may be needed for insemination of your patients. Cryobank will make every effort to have the samples arrive M-F since Saturday and Sunday deliveries are not available in all locations. Once the samples have been shipped to a clinic or other storage facility, Cryobank cannot accept them back for credit. However they can be returned and placed into a storage account under the clinic/physician’s name for future shipments. Applicable storage fees apply.

Cryobank does not, and is not able to guarantee or in any way represent, suggest, or promise that use of our Specimens will result in a pregnancy for your patients. We do, however, provide via our website information on donors whose semen samples have produced reported pregnancies. In addition, we offer a specimen quality standard that provides for full or partial refunds if a Specimen does not meet our standards.

Even if donor testing shows normal results, the tests have limitations and may not always be reliable, even when properly administered. This means that Specimens may not be disease free even though the test results for such Specimens indicate otherwise, in addition there can be disease for which the specimens are not tested. Cryobank quarantines all donor Specimens for a minimum of 180 days and then retests for a variety of infectious diseases prior to releasing the Specimens. Cryobank utilizes CLIA certified and FDA registered testing laboratories and appropriate FDA-licensed, approved, or cleared donor screening tests for donor eligibility determination. (See our website for more information on our donor screening and testing.)

Cryobank relies totally upon the representations of the donor that (1) Specimens produced by the donor are the donor's own (all donations are made at our laboratories); and (2) donor has the genetic and hereditary characteristics and health profile claimed in the donor profile completed by the donor. Cryobank has protocols in place to assure the identity of each donor (e.g. verification of photo IDs) who provides Specimens, as well as a tracking mechanism to track the Specimen during the processing stages. However, Cryobank makes no independent investigation of a donor's representations, nor is it obligated to do so. Due to the anonymity and confidentiality issues involved with semen donation, we must respect the privacy of our donors and rely on our screening methods to detect inconsistencies. Cryobank uses stringent screening process whereby a donor must complete a detailed medical and genetic family history, personal profile, and have an in-depth personal interview. Each step is monitored for inconsistencies, and we take care to ensure accurate information is provided. We come to know our donors well and we respect their commitment to our program.

Donor Availability

All donors will sell out, and the timing is unpredictable. We sell sperm units on a first come, first served basis. Our donor search (<http://www.donorsearch.fairfaxcryobank.com> and <http://www.cryogeniclab.com/>) on our websites lists donors who are expected to have availability either now or in the future. If there is currently no availability but units are expected to release soon, your patient can place their name on a limited Waitlist (see our Waitlist FAQ’s on our website) by calling Client Services . Once a donor sells out, his number will no longer appear on the complete list of all donors. Yet entering his number in the Fairfax Cryobank or CLI donor search in the donor ID field will allow him to appear even if he is sold out. He will be listed as “Inactive” with “No Availability” when you click on his number, so be sure and check availability before you order. We DO NOT give preference for full siblings when units are sold or waitlist names taken. We have had clients who wish they had bought extra units of their donor to ensure his availability for having full siblings later, but were disappointed to learn that their donor is sold out when they are ready to order again. Consider advising your patients to buy and store when units are available to avoid this situation.

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Specimen Quality Standard

Specimen Type	Total Motile Cells/ milliliter (TMC)	Clinical Use
IUI	10 million/vial	Pre-washed vials, ready for intrauterine insemination (IUI)
ICI	18 million/vial	CLI: Ready for intracervical insemination (ICI) or can be washed for IUI specimen
ICI	10 million/vial	Fairfax: Ready for intracervical insemination (ICI) or can be washed for IUI specimen
IVF	5 million/vial	Ready for ICI or can be washed for use as an IUI or IVF with/without ICSI

Our specimen quality standard provides assurances that our specimen quality meets specific standards for total motile sperm cells at the time the samples are thawed at the physician’s office. See our website for full details of the Specimen Quality Standard.

The physician/clinic must follow the Cryobank’s printed thaw procedures enclosed in each shipment. Thaw procedures may vary among specimen types. In certain situations, if a specimen does not meet the expected total motile cell count at the time of the **thaw** (but *prior* to any processing done at the physician’s office), we offer a full or partial credit or refund for the cost of that specimen. This would not include shipping costs or any other associated costs. A client is not eligible for a refund if pregnancy is achieved, regardless of the count, or if the correct thaw procedure included with the specimen at the time of shipment was not followed at the physician’s office. The quality standard only applies to cell counts *prior* to any additional processing that your physician’s office may wish to do. A pre-processing count must be taken to determine if the specimen meets the Specimen Quality Standard. **Sperm counts will vary 10-30% depending on the lab personnel and counting method and this is taken into consideration when processing a complaint.** If you feel the quality standard has not been met and a refund is desired, the physician/clinic must report specific specimen data and submit a complaint within 10 business days of thawing. Notification is to be made by calling your distributor to file a complaint over the phone with our Client Services department.

Our shipping tanks will keep specimens frozen for 7 days. Physicians or laboratory personnel who receive our tanks containing specimens should check the tank upon arrival to be sure that the specimens arrive frozen. If you suspect that specimens have thawed, please call the distributor immediately and speak with a Client Services Representative. Shipping costs cannot be refunded unless specimens arrive thawed.

One of the conditions of the quality standard is that it is void after the specimens are offsite for more than 60 days. We do not have control over the storage and handling practices of outside laboratories or at other storage facilities. Please keep this in mind when shipping and storing specimens offsite at your doctor’s office. Cryobank offers several onsite storage options including a 50% buy back for unused specimens that remain at the distributor. See our website for details of this and other offers.

The Cryobank's liability for any deficiency in specimen quality will be limited to supplying a replacement specimen or full or partial refund for the cost of the specimen only, excluding shipping fees, at the Cryobank's discretion. The Cryobank will in no event be liable for any consequential or incidental damages, including but not limited to any additional or associated expenses incurred by the patient during infertility treatment.

This specimen quality standard is void if ownership of specimens is transferred to a patient different than the original patient owner prior to use.

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Limitations on Donor Births

Cryobank limits the total number of births for any donor based on the application of several criteria. Specifically, a donor’s sales will cease when *either* of the following criteria is reached: 1) Maximum of 25-30 family units (children from the same donor living in one home) reported within the U.S.; *OR* 2) Total number of units sold reaches our designated limit (actual numbers are not disclosed). Family units who have children by the same donor will be sold additional donor units, if available, as ‘Sibling Pregnancy Only’ units. In addition, we also monitor the reported location of births and limit the geographic distribution of a donor consistent with the guideline of the American Society of Reproductive Medicine (ASRM). In order to help us monitor the number of births associated with any donor, it is important that everyone be diligent in reporting births to us. We ask that the physician or patient to please go to the pregnancy reporting page on our website or call, fax, or mail us the patient’s information. If a donor has reached his maximum limits on family units or total sales, then reactivation of that donor may be available for sibling pregnancies. (Reactivation means that a donor can be asked to provide additional samples after he has left the program. The donor must first agree to be reactivated and if he does the client agrees to pay all costs which typically exceed several thousand dollars.)

Checking Donor Medical Status before Fertility Treatments

Donor Medical Status is a **donor classification** that indicates if a donor has been restricted due to a significant medical issue in an offspring. Not all medical issues reported result in a restriction. Those determined to increase the risk to other offspring do result in the donor being restricted. Any donor who is restricted or under investigation will be removed from our online donor search. To the best of our knowledge, all donors start the program without known significant medical or hereditary issues in themselves or their offspring. But a donor’s medical status can change with time. He may now be **restricted for medical issues** or be **under investigation**, in which case we want you and your patients fully informed. Read more about how we inform clients about these medical issues on the Fairfax Cryobank and Cryogenic Laboratories website on the check donor medical status page. **If your patients have purchased units and they are stored offsite, we are encouraging everyone with a Cryobank donor semen sample or an embryo created from that semen to check donor medical status online or by calling Client Services at 1-800-338-8407 prior to use in a fertility procedure.**

The Paper Process

We want you to read all agreements and documents that we provide. Ask questions and make sure you understand them. We will ask for signatures on the forms, and some will need to be notarized. This is to ensure that we are following your choices and directions. You may want to consult with your attorney, or other advisor to review the documents before you sign them. *If you have any questions about this document, please contact us at 800-338-8407, and you will be connected with the appropriate person to answer your questions.*

Once again, thank you for your confidence and trust in our services. We are committed to the conception of healthy babies and are excited to make this journey with you and your patients.

Sincerely,
The Staff of Cryobank

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SIGNATORY OR SIGNATORIES:

We/I have read this document and understand the important considerations when using donor sperm from Cryobank. This includes discussions on limiting donor pregnancies, donor availability and the specimen quality standard.

I/We understand that if I/We do not purchase samples directly from Cryobank for my/our patients that I/We do not need to sign this document and that my/our patients who purchase directly from Cryobank will sign a similar document instead.

Date _____

Clinic Name: _____

Contact person name: _____

Physician's Name: _____

Responsible Physician Signature: _____

Clinic Complete Address: _____

City where clinic located: _____ State: _____ Zip Code: _____

Country where clinic is located: _____ Phone number: _____

Fax number: _____ Clinic contact email: _____

Cryobank must receive signed Terms of Use via fax or mail at least one business day prior to placing a specimen order. We only require Page 6 in order for this document to be considered valid.

CLI and Fairfax Cryobank
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