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Cryogenic Laboratories, Inc.  
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**Welcome to Cryogenic Laboratories, Inc. CLI:**

We, the staff at Cryogenic Laboratories, Inc. (CLI), 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 CLI is as satisfactory as possible, this document explains what to expect from CLI's donor programs and storage services. It also explains what CLI needs from you. More detailed description and terms for each program and service are described in our literature and website and in the agreements, storage agreements, billing agreements and authorizations that you will be asked to sign during your involvement with us.

**CLI must receive a signed copy of this 'Terms of Use' letter (page 5 only) via fax, email or mail at least one business day prior to 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 CLI will sign a separate 'Terms of Use' letter and you will not need to sign this document.**

**CLI's Donor and Storage Programs**

Our donor programs consist of several distinct programs: anonymous sperm donors, Identity Option-donors, and 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. CLI 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). 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. CLI 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*. CLI performs the diagnostic tests listed in the Donor Sperm Section of our website ([www.cryolab.com](http://www.cryolab.com)). Although it is not possible to completely eliminate the risk of infectious diseases or genetic disorders, the tests performed by CLI 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

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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.

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 treatments or a 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.

CLI 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.

NOTE: When placing specimens in storage at CLI 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 CLI 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 CLI and shall be either returned to inventory or destroyed by CLI. No refunds will be granted when specimens are abandoned. Until the billing agreement is received, we/I authorize the Cryobank to charge my 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 CLI 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, CLI will not disclose you or your patients identifying information to the donor.

CLI 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.

Your patient is the legal parent of the child/children born to them with the use of donated sperm. 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 the semen Specimens are collected, processed and stored at our facility, there is greater predictability in knowing the quality of the Specimens after thawing. When we accept Specimens that were collected and frozen by another facility and sent to CLI for storage, the Specimens are only as good as the facility that prepared them and sent them to us.

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CLI ships Specimens via Federal Express in specially designed liquid nitrogen vapor tanks. Although uncommon, shipping delays may occur due to bad weather, airplane mechanical problems or other similar events outside of our control. In addition, tanks can fail in transport resulting in thawed or otherwise spoiled specimens. In order to minimize this risk, CLI offers you the option of 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 several days prior to your patient’s anticipated insemination date. Same day shipping orders must be received by 2:00pm ET for FedEx. Courier orders must be placed prior to 11:00am ET, and orders for same day pick-up must be received by 12:00 noon ET. Saturday and Sunday deliveries are not available in all locations, so place orders appropriately to allow Monday-Friday delivery. Once donor sperm vials have been shipped out, CLI cannot accept them back for a credit. However, they can be returned and placed into a storage account (Physician account) for future use. Applicable storage fees apply.

CLI 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. CLI quarantines all donor Specimens for a minimum of 180 days and then retests for a variety of infectious diseases prior to releasing the Specimens. CLI utilizes CLIA certified and FDA registered testing laboratories and appropriate FDA-licensed, approved, or cleared donor screening tests for donor eligibility determination. Our commitment to quality means we test above and beyond the required infectious and genetic disease testing required by the FDA. (See our website for more information on our donor screening and testing.)

CLI 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. CLI 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, CLI 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. CLI prides itself on its 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 carefully 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.cryogeniclab.com/search.cfm>) on our website 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 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**

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. One of the conditions of the quality standard is that it is void after the specimens are offsite for more than 60 days. Please keep this in mind when shipping and storing specimens offsite at your office. CLI offers several onsite storage options including a 50% buy back for unused specimens that remain at CLI. See our website for details of this and other offers. 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. **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’s office must initiate a call to our Client Services department within 10 days of the thaw. Full details of the specimen quality standard are available on our website.

**Limitations on Donor Births**

CLI 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 our 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 CLI 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

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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 800-466-2796, 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 CLI

**SIGNATORY OR SIGNATORIES:**

We/I have read this document and understand the important considerations when using donor sperm from CLI. 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 CLI for my/our patients that I/We do not need to sign this document and that my/our patients who purchase directly from CLI 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: \_\_\_\_\_

Phone number: \_\_\_\_\_ Clinic contact email: \_\_\_\_\_

***CLI 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 5 in order for this document to be considered valid.***

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