

## CRYOBIO SPERM USE AGREEMENT

This sperm use agreement is made between CRYOBIOLOGY, INC., an Ohio corporation (“**Cryobio**”), and the RECIPIENT who intends to use Cryobio donor sperm and signs this agreement (“**Recipient**”).

If Recipient is using Cryobio’s services with a partner, both Recipient and partner need to read, initial, and sign this agreement and all applicable references to Recipient throughout the agreement will be considered to include both parties.

The parties agree as follows:

**1. Purpose of Agreement.** Cryobio provides the services of screening and testing of sperm donors, and collecting, processing, freezing, packaging, storing, and shipping sperm. Recipient is paying Cryobio a fee for these services so that Recipient can use assisted insemination or assisted reproductive technology in herself or a gestational carrier, to try and become pregnant and have a child.

**2. Cryobio’s Donor Selection Process.**

**a. Selection of Donors.** Cryobio’s donor selection process includes personal interviews, personal and family medical and social histories, physical exams, genetic disease and genetic carrier screening and testing, and viral and sexually transmitted disease screening and testing. Cryobio relies on the donor to truthfully report his and his family’s social and medical histories in this process.

**b. Screening and Testing Process in General.** Cryobio’s sperm donors are screened and tested according to Cryobio’s established procedures and quality control standards, which are based on industry standards and guidelines and federal and state regulations and laws. The medical and scientific communities’ ability to screen and test for diseases and conditions has changed a lot over the years, but the standards, guidelines, regulations, and laws have not changed as much. The industry standards, guidelines, regulations, and laws Cryobio follows are based on the scientific and medical knowledge at the time they were put into practice. The diseases screened and tested for are those diseases that are common in the general population and are required by regulatory authorities.

**c. Screening and Testing Process in Detail.** Cryobio’s sperm donors are currently screened and tested for viral and sexually transmitted diseases (HIV 1 and 2, Hepatitis B, Hepatitis C, HTLV I and II, Syphilis, Cytomegalovirus, Chlamydia, and Gonorrhea), some genetic conditions (Cystic Fibrosis, Spinal Muscular Atrophy, and Karyotyping) and undergo general health screens (CBC and Hemoglobin evaluation).

**i. Historical Genetic Testing.** Historically, additional genetic testing may have been performed according to the donor’s ancestry, for example, Tay-Sachs carrier testing for a donor with Ashkenazi Jewish ancestry.

**ii. Current Genetic Testing.** All donors that began donating in 2019 have undergone expanded carrier screening, which is a genetic testing panel that looks for carrier status unrelated to ethnicity for 283 recessive genetic conditions. The adoption of expanded carrier screening means that more donors than before will be labeled as carriers for recessive genetic conditions because their carrier status was detected with the expanded testing. This has led to a change in our policy as donors that may have been excluded historically are now available to use. This policy change is based on the idea that if Recipient or egg source is not a carrier for the same recessive genetic condition as the donor, the risk to any resulting children is significantly reduced based on the expanded carrier screening, but not eliminated as no testing is completely accurate.

**iii. Limits to Screening and Testing.** The screening and testing process and requirements may continue to change over time. This means that donors are not screened and tested for every single genetic, viral, and sexually transmitted disease that exists in the population. A donor participating in Cryobio's donor program has negative or acceptable screening and testing results according to laws, regulations, and industry standards; however, a negative or acceptable test result does not guarantee that a donor is free of disease or will not pass on a disease or condition.

**iv. Ways to Reduce Risk.** Recipient is obligated to read the selected donor's genetic test results and if you select a donor who is a carrier for a recessive condition, we recommend that you strongly consider undergoing genetic testing to see if you are a carrier for the same condition. Recipient is required to complete an additional informed consent if they select a donor who is a carrier for a recessive condition. Recipient should contact Cryobio senior staff with questions or concerns about specific screening and testing that was done on each donor or to arrange for further testing if possible. If Recipient has a personal or family history of genetic disease, Recipient is obligated to contact Cryobio senior staff to discuss the use of Cryobio donor sperm and consult with a genetic counselor and a physician.

### **3. Risks to Using Donor Sperm.**

#### **a. Genetic, Viral, and Sexually Transmitted Disease Screening and Testing.**

Cryobio's screening and testing process helps decrease, but does not eliminate the risk of transmitting genetic, viral, and sexually transmitted diseases when using donor sperm, including transmission of those genetic, viral, and sexually transmitted diseases to any resulting children. Furthermore, many birth defects occur spontaneously, so there is no way to prevent them even with adequate screening and testing. Recipient should not rely solely on using donor sperm to have a healthy baby, but Recipient should also undergo prenatal and in utero screening and testing. Recipient should strongly consider genetic screening and testing personally and on a different egg source, if used. Even if they are not required to do so per clinic policy or by federal or state regulations, Recipient, partner, or egg source may wish to be tested for sexually transmitted infections, as this can potentially help lessen the risk of transmission to anyone involved.

**b. Donor's Characteristics and Traits.** Recipient may have selected a donor based on certain characteristics or traits of the donor with the expectation that these characteristics or traits would transmit to any resulting children. *The inheritance of characteristics, traits, and appearance is an uncertain science and Cryobio does not guarantee*

*that the characteristics, traits, or appearance Recipient desires will occur in any resulting child.*

**c. Donor's Medical and Social Histories.** Many of Cryobio's donors participate in the donation program when they are in their early twenties, and so a donor's medical and social histories may be incomplete due to medical conditions that he or his family were not aware of during donation. The donor or his family may develop other medical conditions after the donor's participation in the program. Cryobio requests donor health updates on a routine basis during the donor's participation in the program and relies on the donor to truthfully report information.

**d. Screening and Testing Issues.** Cryobio uses independent, accredited reference laboratories for screening and testing. Cryobio relies on the accuracy of the test results and reports it receives from these laboratories. *All laboratory screening and testing has the potential for error and Cryobio cannot and does not guarantee that the screening and testing is completely accurate.* A donor with a negative test result can still transmit disease. Donors are screened and tested for viral and sexually transmitted diseases multiple times before the sperm is released for use. This repeated testing of the donor decreases the likelihood of inaccurate or misinterpreted test results. A donor is only genetically screened and tested once while he is participating in the program. Recipient may request additional genetic screening and testing on the donor and Cryobio will attempt to comply with this request if the donor and Cryobio's genetic counselor agree to it.

**e. Health Risks of Pregnancy and Birth when Using Donor Sperm.**

Recipient's use of donor sperm does not eliminate any of the common risks of pregnancy and birth, such as miscarriage, stillbirth, and injury during birth.

**f. Health Risks to Offspring.** Recipient's use of donor sperm does not eliminate the risk of having children with birth defects, physical and mental health conditions, intellectual disabilities, autism spectrum disorders, or any condition caused by environmental or unknown factors. Recipient's use of donor sperm does not eliminate any risk to any resulting children associated with Recipient's age, health, or genetic background.

**4. Alternatives to Using Donor Sperm.** Recipient does not have to attempt to have and raise a child, but if Recipient chooses to do so there are several alternatives to using Cryobio's services. For example, Recipient could use another FDA registered sperm bank, attempt a pregnancy without using donor sperm, or pursue adoption.

**5. Recommendations to Consult with Various Professionals.**

**a. Mental Health Professional.** Recipient should consider consulting a mental health professional before and while using Cryobio's services.

**b. Attorney.** Recipient should consult an attorney before using donor sperm because the law in this area is unsettled and may change. Cryobio is not giving legal advice to Recipient.

**c. Genetic Counselor.** Recipient should consult a genetic counselor if Recipient has a personal or family history of disease, is at an age, or is part of an ethnic group that is at greater risk of disease. If Recipient has specific concerns about her own and any potential children's genetic risk, these concerns should be discussed with a genetic counselor before selecting a sperm donor. All genetic testing results are available on the website in each donor's profile.

**d. Physician.** Recipient should be cleared by a physician prior to attempting a pregnancy and should be under a physician's care when using donor sperm. A physician should go over the Recipient's individual health history addressing any concerns and the risks, benefits, and alternatives to using donor sperm. The American Society for Reproductive Medicine suggests that Recipient should consider blood type and Rh-factor when selecting a donor, and review this with a physician.

## **6. Program Policies.**

**a. Payment.** Recipient is obligated to pay Cryobio for their services before Cryobio will ship any vial. Cryobio may change the price of their services from time to time and will give notice on the website that pricing is changing before it goes into effect.

**b. Ordering.** Recipient should check the physician's policy on accepting shipments. Recipient is obligated to place the order with Cryobio on the website or by phone with enough time so that all required forms are complete and the sperm will arrive at Recipient's physician's office in time for the procedure. Recipient is responsible for ordering the correct donor selected.

**c. Shipping Methods and Risks.** Cryobio uses independent delivery services for shipping. *Cryobio is not responsible for shipping problems that are beyond Cryobio's control and Cryobio does not control the tanks once they leave the sperm bank.* There are always risks associated with shipping, for example, weather related delays or tank mishandling may affect delivery; a tank may get lost; or not maintain proper temperature resulting in compromised quality of the sperm. Recipient can choose to arrange and pay for alternate shipping methods, for example, shipping sperm in multiple tanks, using her own tanks, or contracting with a shipping company of her own selection.

**d. Shipping Confirmation.** Recipient is obligated to confirm or have her physician's office confirm that the sperm has arrived without damage. Recipient is obligated to confirm that the donor number that Recipient ordered is the donor number that was received. Recipient or her physician's office is obligated to do this when the sperm arrives and again right before the procedure.

**e. Sperm Storage.** Cryobio also provides storage for donor sperm. If Recipient stores donor sperm with Cryobio, Recipient is obligated to enter into a storage agreement with Cryobio and pay storage fees when they are due. Cryobio is not obligated to keep Recipient's selected donor sperm in stock if Recipient has not purchased extra vials of selected donor and stored them with Cryobio.

**f. Contact Information.** Recipient is obligated to provide current and accurate contact information to Cryobio when creating an account. If Recipient orders sperm from Cryobio, Recipient is obligated to update this information as it changes. Cryobio uses Recipient's contact information to send receipts or notices about payment; and to inform Recipient if there is a recall of the sperm, or a health problem with the donor or any other children from the same donor. If Recipient does not update Recipient's contact information with Cryobio and verify that Cryobio has received the updated information, then Cryobio is not responsible for any harm that occurs because Cryobio was unable to contact Recipient. Recipient should provide contact information where Recipient can receive potentially confidential or sensitive information.

**g. Outcome of Sperm Use.** Recipient is obligated to update Cryobio about pregnancy and birth outcomes. Cryobio is not obligated to notify Recipient about any health recall issues with the sperm if they are unaware that Recipient has used the sperm to become pregnant and have children. Recipient can update Cryobio through the provided shipping inserts or through the website.

**h. Confidentiality Concerns.** Cryobio keeps all information Recipient provides to Cryobio in the course of this relationship confidential, except, any information that is shared with Recipient's physician on record, to comply with any federal and state regulations, and to arrange open donor contact when it was agreed to.

**i. Retention of Donor Records.** Cryobio keeps all records about the donors as required by law, industry standard, and internal policy.

**j. Cryobio's Transfer of Vials and Records.** If Cryobio decides to no longer provide the services under this agreement, they may transfer any remaining vials and records to their successor. Cryobio will provide notice of this transfer to any Recipient who reported successful pregnancy and birth information and updated her contact information. Cryobio's obligations to Recipient and any of Recipient's representatives will end at this transfer.

**k. Sperm is Intended for Recipient's Use.** Recipient intends to use the sperm herself or with a gestational carrier to attempt a pregnancy and have children. Recipient will not provide Cryobio donor sperm to anyone else to use without notifying Cryobio. If Recipient does this without notifying Cryobio, then Cryobio will be unable to notify any unknown users about health recall issues.

**7. Miscellaneous.**

**a. Waiver.** If either party does not enforce a term of this agreement that does not mean that it has been waived and they may enforce it in the future.

**b. Entire Agreement in Writing.** This agreement sets forth all obligations between the parties, unless an additional genetic testing consent is required. There are no other agreements, oral or written, between the parties. The only exception is if the parties have entered into a separate written agreement for Cryobio to provide additional services beyond those described in this agreement.

**c. No Reliance on Statements or Communications Beyond this Agreement.**

Recipient is not relying on any other statements or communications made by Cryobio or its representatives related to the services provided by Cryobio that are described in this agreement, unless these statements or communications have been put into writing and included in this agreement or in a separate agreement between the parties.

**d. Incorporated Terms of this Agreement.** The price list on Cryobio’s website is incorporated as a term of this agreement. If an additional genetic testing consent is required, it is incorporated as a term of this agreement.

**e. Severability.** If any part of this agreement is found to be unenforceable, the rest of the agreement remains in effect, to the extent that it can be enforced.

**f. Governing law and Consent to Jurisdiction in Ohio Courts.** The laws of the state of Ohio govern any proceedings between the parties and their representatives arising out of this agreement and the screening, testing, and selection of donors, and the collecting, processing, freezing, storing, shipping, and use of donor sperm. Only the federal and state courts of Franklin County, Ohio, have jurisdiction over these proceedings.

**g. Changing the Agreement.** Cryobio and Recipient may change the terms of this agreement, but only if the changes are in writing and both parties have agreed to the changes.

**8. Cryobio’s Standard of Care.** Cryobio provides services under this agreement using a standard of care that incorporates guidelines of the following professional groups into setting internal policies and procedures: American Society for Reproductive Medicine, American Association of Tissue Banks, American College of Obstetrics and Gynecologists, and American College of Medical Genetics. Cryobio’s standard of care also incorporates Cryobio’s professional knowledge, skill, quality control practices and procedures; and various federal and state laws and regulations.

**9. No Warranties or Guarantees.** *Cryobio is providing a service, they are not selling a product, and so Cryobio makes no warranties, express or implied, as to the donor sperm’s fitness for a particular purpose or merchantability. Cryobio does not guarantee a pregnancy from use of the donor sperm. Cryobio does not guarantee that the donor sperm provided will create a child without disease or health conditions or a child with the traits of the donor.*

**Initials:** \_\_\_\_\_ **Initials:** \_\_\_\_\_

**10. No Obligations to Children.** Neither Cryobio nor any donor has any parental, social, or financial obligations to any resulting children without making a separate agreement beyond the terms of this agreement.

**Initials:** \_\_\_\_\_ **Initials:** \_\_\_\_\_

**11. Changes in Laws, Regulations or Industry Standards.** Cryobio is not responsible for any changes in laws, regulations, and industry standard that prevent them from fulfilling their obligations under this contract.

**Initials:** \_\_\_\_\_ **Initials:** \_\_\_\_\_

**12. Assumption of Risk, Waiver of Negligence, and Limitation of Liability.**  
**a. Viral and Sexually Transmitted Diseases.** There is always a risk that viral and sexually transmitted diseases may be transmitted when using donor sperm.

**Initials:** \_\_\_\_\_ **Initials:** \_\_\_\_\_

**b. Genetic Diseases and Conditions.** There is always a risk that genetic diseases and conditions may be transmitted when using donor sperm. I have reviewed the donor’s genetic test results in his profile and I am aware of his genetic carrier status. I have reviewed and completed any additional consents that are required for a donor who is a carrier for a recessive genetic disease.

**Initials:** \_\_\_\_\_ **Initials:** \_\_\_\_\_

**c. Spontaneous Birth Defects.** Many birth defects, diseases, and disorders are spontaneous. This means they can occur without inherited transmission and without any way to screen or test donors to detect them.

**Initials:** \_\_\_\_\_ **Initials:** \_\_\_\_\_

**d. Screening and Testing.** Cryobio screens and tests donors to help prevent transmission of genetic, viral, and sexually transmitted disease, but no screening and testing procedures are completely accurate all of the time.

**Initials:** \_\_\_\_\_ **Initials:** \_\_\_\_\_

**e. Other Testing.** Recipient’s use of donor sperm does not eliminate the need for prenatal and in utero testing.

**Initials:** \_\_\_\_\_ **Initials:** \_\_\_\_\_

**f. Shipping Issues.** Cryobio is not responsible for shipping issues beyond Cryobio’s control.

**Initials:** \_\_\_\_\_ **Initials:** \_\_\_\_\_

*By signing this agreement and ordering and using the donor sperm, Recipient accepts the risks of using Cryobio's services. Recipient agrees that Cryobio and any of its agents, employees, directors, officers, consultants and assignees will not be liable for negligence in providing these services, except where damage is caused by or is the result of willful, wanton, or reckless behavior. If, despite the waiver of negligence above, Cryobio is found liable in a proceeding under a theory based in contract, tort, or otherwise, damages will be capped at the cost of a replacement vial and shipping fees.*

**Initials:** \_\_\_\_\_ **Initials:** \_\_\_\_\_

**SIGNING**

The parties signing below have read this agreement. They have had an opportunity to consult with the various recommended professionals. They have had a chance to ask questions and these questions have been answered satisfactorily. They understand and accept the terms of this agreement.

\_\_\_\_\_  
Recipient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Partner

\_\_\_\_\_  
Date

\_\_\_\_\_  
Cryobio

\_\_\_\_\_  
Date