

Recipient Consent to Use Ineligible or Quarantined Donor Specimen

Purpose of this waiver

Cryomate follows rigorous Food and Drug Administration (FDA) screening and testing protocols for all donors. Under FDA regulations, donors may be classified as **eligible** or **ineligible**.

Directed donors (those known to the recipient) may be either eligible or ineligible; the FDA does not prohibit use of reproductive cells or tissue from an *ineligible* directed donor.

This waiver applies when a recipient requests to use semen from a directed donor who has been determined ineligible or whose specimen is under quarantine. Examples of reasons a donor may be ineligible include engaging in high-risk behaviors, which disqualifies the donor under FDA rules or testing reactive for a relevant infectious disease. Under § 1271.65(b)(1)(ii), cells or tissues from an ineligible directed donor may be released provided that (1) the specimen is labeled with a biohazard legend and warnings, (2) the responsible physician is notified of the donor's ineligibility, and (3) the summary of records specifies the reason for ineligibility. Cryomate strongly recommends using eligible donor specimens when available; however, we will accommodate recipient requests to use an ineligible or quarantined donor specimen if the recipient acknowledges and accepts the additional risks.

Donor/Specimen Information

Donor's full name/FDA # _____
 Date(s) of donation _____
 Reason for ineligibility _____
 Infectious-disease testing date(s) _____

Recipient Information

Recipient's full name _____
 Recipient's Partner Full Name _____
 Address _____
 Telephone / email _____

Acknowledgment & Assumption of Risk

By initializing each statement and signing below, the recipient(s) certifies that they understand and accept the following:

1. **Reason for ineligibility-** I have been informed that the above-named donor is ineligible or that the specimen is quarantined, and I understand the reason for that determination (e.g., the donor engaged in high-risk behavior or had a reactive test result). I understand that ineligible donors may have a higher risk of harboring HIV, hepatitis B, hepatitis C or other relevant infectious diseases.

_____ [Recipient(s) initials]

2. **FDA requirements for ineligible donors-** I understand that, although use of cells or tissue from an ineligible directed donor is not prohibited, federal regulations require that the specimen be

labeled with a biohazard legend and warning statements, the responsible physician be notified of the donor's ineligibility, and the summary of records include the reason for ineligibility. I acknowledge that the donor's ineligibility will be documented in accordance with these requirements.

_____ [Recipient(s) initials]

3. **Testing and quarantine-** I understand that directed donors are not required by the FDA to undergo a six-month quarantine and repeat testing. Cryomate may elect to quarantine and retest the donor, but if quarantine is not performed, the donor must still undergo infectious-disease testing within seven (7) days of each collection. This waiver does not eliminate those testing requirements. I acknowledge that even with testing, there is a "window period" during which newly acquired infections may not be detected.

_____ [Recipient(s) initials]

4. **Increased risk and recommendation of eligible donors-** I acknowledge that using an ineligible or quarantined specimen may increase the risk of transmitting infectious diseases. Cryomate strongly recommends the use of eligible donor specimens whenever possible. I have been offered the option to select an eligible donor specimen and have chosen to proceed with the ineligible or quarantined specimen despite the increased risks.

_____ [Recipient(s) initials]

5. **Clinic and physician requirements-** I understand that many fertility clinics and physicians will not accept semen from an ineligible donor or a specimen that has not completed the recommended quarantine and repeat testing. If my clinic or physician refuses to use these specimens, I will not be entitled to a refund for storage or processing fees.

_____ [Recipient(s) initials]

6. **Right of Cryomate to decline release-** I understand that Cryomate reserves the right to refuse to release the specimen or to require a quarantine period if new medical information about the donor arises, if regulatory bodies mandate quarantine, or if Cryomate deems it necessary to protect the health and safety of the recipient or child. Cryomate also reserves the right to update or revoke this waiver to comply with changes in federal, state or local law.

_____ [Recipient(s) initials]

7. **Medical and legal consultation-** I certify that I have consulted, or had the opportunity to consult, with my physician regarding the risks of using an ineligible or quarantined specimen, and that I have or will seek independent legal advice about donor agreements and parental rights. I understand that this waiver is not a substitute for a legal contract between the donor and recipient.

_____ [Recipient(s) initials]

Agreement & Release of Liability

I, the undersigned recipient, understand and voluntarily accept all risks associated with the use of semen samples from the above-named donor, who has been determined ineligible or whose specimen is under quarantine. I hereby release Cryomate Donor Bank, its current and former employees, owners, directors, officers, attorneys, insurers, agents and representatives from any claims, liabilities, damages, expenses or causes of action, known or unknown, arising out of or relating to the use of these ineligible or quarantined specimens. I agree that this waiver is binding upon my heirs, executors, administrators and assigns.

I acknowledge that this waiver is subject to Cryomate's internal legal review and may be updated to comply with federal, state or local law. If any provision of this waiver is found unenforceable, the remaining provisions shall remain in full force and effect.

Signatures

Recipient Signature

Print Name

Date

Recipient Partner Signature

Print Name

Date

Physician Signature

Print Name & Title

Date
