



# Reproductive Technologies, Inc. THE SPERM BANK OF CALIFORNIA

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## INFORMED CONSENT FOR SEMEN RECIPIENT (5 pages)

Please read and then initial next to EACH statement.

(Electronic signatures/initials will not be accepted.)

This agreement is made between The Sperm Bank of California, a nonprofit California corporation (hereinafter "TSBC") and the undersigned, hereinafter referred to as "Recipient." TSBC is registered as a reproductive tissue bank with the FDA (U.S. Food and Drug Administration) and performs clinical screening of all its sperm donors in accordance with parameters required by the FDA and recommended by the American Society for Reproductive Medicine, the American Association of Tissue Banks, and the Centers for Disease Control and Prevention. TSBC is also licensed as a Reproductive Tissue Bank and/or Clinical Lab by the following states: California, New York, and Maryland.

**I attest that I am at least eighteen years old, that I am the recipient who will try to conceive using sperm samples purchased under my account, and that my initial of each paragraph and signature at the bottom of each page signify my understanding, acknowledgment, and acceptance of the terms of this agreement.**

\_\_\_ I understand that TSBC evaluates the fertility of every sperm donor and performs a pre-freeze and post-thaw analysis of every sperm sample that is released for insemination. TSBC guarantees a post-thaw minimum of 20 million motile sperm per cc and 15% motility in every regular, unwashed sample. TSBC guarantees a post-thaw minimum of 20 million motile sperm per cc and 20% motility in every washed, IUI-ready sample. As samples that have been washed for intrauterine insemination (IUI) are .5cc in volume, this guarantee translates to a minimum of 10 million motile sperm per IUI-ready vial.

\_\_\_ I understand that TSBC cannot guarantee that a viable pregnancy will occur as a result of donor insemination or other assisted reproductive procedure. I understand that thawed frozen sperm will not survive as long as fresh sperm, and that I should time insemination to take place as close to ovulation as possible.

\_\_\_ I understand that fertility clinics have different protocols regarding when to use traditional IVF or ICSI and that some clinics always recommend ICSI for donor sperm cycles. I further understand that TSBC does not provide a refund for vials that meet our guarantees for motile sperm count and motility solely because a clinic recommends or requires ICSI or other advanced assisted reproductive procedures.

\_\_\_ I understand that TSBC tests all sperm donors for the following sexually transmitted diseases (STDs): gonorrhea, chlamydia, syphilis, and antibodies to hepatitis B, hepatitis C, cytomegalovirus (CMV), Human T cell Lymphotropic Virus Types 1 and 2 (HTLV-1 and HTLV-2), and HIV-1/2/O. From 2017 forward, all donors are tested for West Nile Virus. All sperm samples are quarantined for a minimum of six months. Donors are repeatedly tested for the STDs mentioned above while active in the program and after quarantine period.

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Recipient's signature

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Recipient's printed name

\_\_\_\_\_  
Date

\_\_\_ I understand that although TSBC guarantees that the appropriate tests have been performed by its reference lab, laboratory tests are not 100% accurate, and TSBC cannot guarantee the absence of sexually transmitted diseases, inheritable illnesses, or inheritable birth defects resulting from insemination with donor sperm. I further understand that it is not possible to pre-test a donor for each and every disease, illness, condition, or birth defect that may potentially affect the health of a child born as a result of using the donor's sperm.

\_\_\_ I understand that policies involving emerging infections, such as the Zika virus, are subject to change as more information is learned. I understand that TSBC follows FDA and ASRM guidelines regarding Zika virus, and that potentially infected donors (i.e. donors who report travel in a region with an outbreak) are deferred from donation until they are believed to be no longer potentially infectious based on current knowledge. I understand that there is limited information with regard to risks from using sperm samples from an individual who is potentially infected with the Zika virus and has no symptoms and therefore guidelines are subject to change. I further understand that TSBC recommends that recipients who have traveled to a region with Zika virus transmission in the last 6 months consult the CDC website and their medical providers for guidelines regarding Zika virus testing and individuals trying to conceive.

\_\_\_ I understand that policies involving emerging infections, such as the SARS-CoV-2 virus (also known as Coronavirus) which causes COVID-19, are subject to change as more information is learned. I understand that TSBC follows FDA and ASRM guidelines regarding SARS-CoV-2 virus, and that potentially infected donors (i.e. donors who report symptoms, diagnosis or suspected diagnosis) are deferred from donation until they are believed to be no longer potentially infectious based on current knowledge. I understand that there is limited information with regard to risks from using sperm samples from an individual who is potentially infected with the SARS-CoV-2 virus as the virus is new and transmission via semen is unknown, and therefore guidelines are subject to change. I further understand that TSBC recommends that all recipients (and especially those who have had a positive test for SARS-CoV-2 or diagnosis with COVID-19) consult their medical providers for guidelines regarding SARS-CoV-2 virus and individuals trying to conceive.

\_\_\_ I understand that TSBC performs genetic testing on all donors. I understand that genetic testing technology and genetic testing recommendations continue to evolve and, therefore, donors screened at different times may have been tested with different screening panels. I understand that each donor's profile will list the testing performed and the results of that testing, and that TSBC makes the details of each donor's genetic testing available for free through links on TSBC's donor catalog.

\_\_\_ I understand that TSBC performs the following genetic testing: All donors are screened for Cystic Fibrosis carrier status and are tested by Hemoglobin Electrophoresis to screen for Sickle-cell and Thalassemia carrier status and to identify other hemoglobin-related blood disorders. All donors are screened for spinal muscular atrophy (SMA) carrier status (starting in 2013). Donors reporting Ashkenazi Jewish, French-Canadian, or Cajun descent also receive genetic carrier screening for Tay Sachs carrier trait. All donors reporting Ashkenazi Jewish ancestry have been tested for a panel of conditions more common in their ethnic group. Starting in June 2021, all new donors are tested using an Expanded Carrier Screening panel which includes the above recessive conditions.

\_\_\_ I understand donors screened through Expanded Carrier Screening may be positive as a carrier for one of the 260+ autosomal recessive conditions tested. TSBC requires all recipients choosing a donor with positive carrier screening results to complete an acknowledgement that they are aware of the test results. TSBC strongly recommends that recipients using a donor with one or more positive carrier results (1) receive genetic counseling and (2) consider carrier testing for themselves to reduce the risk of having an affected child.

\_\_\_ I understand that genetic testing technology and recommendations continue to evolve and that donors screened under one protocol may have additional genetic screening performed at a subsequent time. Additional genetic screening may be performed at the discretion of TSBC (1) as recommendations or regulations change, (2) on advice of TSBC's medical advisors based on new medical information or genetic testing results received from a donor or from a recipient (regarding a pregnancy or child), or (3) for other medical or business reasons as determined by TSBC's Medical Director, Executive Director, and other advisors. Also, additional genetic screening may be performed on behalf of a recipient who reports they are a recessive carrier, such testing is performed at the recipient's expense. If a donor is positive for any additional genetic screening, TSBC will make efforts to notify recipients who have children, may be pregnant, or are trying to conceive with the donor. Depending on the results, TSBC may require recipients to complete an acknowledgement that they are aware of the test results (see paragraph above).

\_\_\_ I understand that genetic testing analysis continues to evolve, and that genetic test reports may be amended in the future to include additional positive carrier screening results. This occurs at the discretion of the testing company, as research reveals stronger evidence linking a variant to a disease. I understand that TSBC will make updated genetic test reports available to recipients and will require me to sign an acknowledgement of the most up-to-date Expanded Carrier Screening report that we have available, prior to retrieving vials of a donor with positive results.

\_\_\_ I understand that TSBC asks each donor to provide a three or four-generation, self-reported health history on the donor and their family and that this self-reported history is reviewed collaboratively by our Genetic Counselor, Medical Director, Executive Director, and LCSW. I understand that while TSBC does not conduct a formal/diagnostic mental health evaluation on donors, our LCSW and Donor Program Team meet with donors over the course of a 2-3 month long screening process. Our LCSW follows-up on self-reported mental health issues as well as any unreported but observable causes for concern regarding the mental health of prospective donors. We work with each donor to obtain as complete and accurate information as possible, but we are unable to completely rule out the existence of other health information that is not known, or that remains unreported to us.

\_\_\_ I understand that all donors meet with an LCSW to discuss the implications of being a donor and participating in our Identity-Release® Program. Donors are encouraged to consider the impact of sperm donation on their own lives and assessed for their understanding of the parameters of the Identity-Release® Program.

\_\_\_ I understand that sperm samples released to me by TSBC are intended for my personal use and not for sale, or other commercial purposes, or for genetic testing. I understand that any additional genetic testing of sperm samples must be coordinated by and/or authorized by TSBC prior to testing and that such testing will only be performed after the donor has been informed and provides consent for the testing of their DNA.

\_\_\_ I forever release and absolve TSBC, including any of its staff, consultants, board members, or other representatives, from any and all responsibility or liability whatsoever for the outcomes as a result of inseminating with, or other assisted reproductive procedure using, TSBC donor sperm, including but not limited to (1) any resulting infectious disease in the recipient or in any fetus/child conceived, (2) any birth defect or serious illness in a child conceived, (3) any genetic defect leading to any tendency towards illness or genetic carrier status for any illness in a child conceived.

\_\_\_ I understand that TSBC is not responsible for any damage to sperm samples that may occur during the transport or shipping process, or due to subsequent storage at another facility. I understand that samples should be used, transferred to another facility for storage, or returned to TSBC as follows: (1) within 7 days of the scheduled arrival date of a shipped tank, or (2) within 7 days of picking up in a tank.

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 Recipient's signature

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 Recipient's printed name

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 Date

\_\_\_ I understand that I am fully responsible for the liquid nitrogen vapor tank from the time it is picked up by me, delivered to me, or delivered to my medical provider's office until it is returned to TSBC, and that if the tank is returned to TSBC late or in damaged condition, I will be held financially responsible. I understand that a daily tank rental fee applies to all tanks picked up at TSBC and to shipped tanks returned after the guarantee period.

\_\_\_ I understand that donor sperm samples are purchased on a nonrefundable basis, and that if I have not retrieved samples purchased from general inventory within three months of purchase, storage fees will be due. I further understand that storage fees for "sibling inventory" (sperm samples allocated for recipients and/or their partners who have had at least one live birth and wish to conceive another child using the same donor) are due at the time of purchase.

\_\_\_ I understand that storage fees are automatically charged (quarterly for general inventory or annually for sibling inventory) using the credit card on file until all vials have been retrieved, and that storage fees are not prorated or refundable. I understand that I am responsible for providing valid and up to date credit card information. I further understand that nonpayment of storage fees cancels the storage agreement and releases ownership of the vials back to TSBC.

\_\_\_ I understand that TSBC has final responsibility for all donor sperm samples that are collected, screened and stored at its facility. I understand that TSBC reserves the right to retain any samples that I have purchased should the donor retire or meet family limit. I also understand that TSBC reserves the right to retain any samples that I have purchased if an unforeseen situation arises where, in the discretion of TSBC, it is necessary to do so and that TSBC will not reveal the reason for retaining the samples if issues of donor confidentiality or other privacy issues are involved. In the event that TSBC retains any sperm samples that I have purchased for any of the reasons listed above, TSBC will refund the cost of the samples, but will not refund any storage or shipping fees I may have paid.

\_\_\_ I understand that TSBC serves recipients of all ethnicities, races, sexual orientations, genders, and relationship statuses. To help achieve more equitable access, TSBC may reserve vials from some donors for recipients with more limited options.

\_\_\_ I understand that for the purpose of family limits, sibling inventory, and equity, TSBC defines "a family" as one or more parents and the child(ren) they parent. This includes new partners of anyone already parenting a child conceived with a TSBC donor.

\_\_\_ I understand that TSBC will only release sperm samples if they meet current FDA and Tissue Bank licensing protocol at the time of release. If TSBC determines that the samples I have purchased do not meet current medical protocol, TSBC will make reasonable efforts to bring the samples up to current medical protocol, but there is no guarantee this can be accomplished. I understand that if the samples do not meet current medical protocol, TSBC will not release these samples to me. In this event, TSBC will refund the cost of the samples, but will not refund any storage fees I may have paid.

\_\_\_ I understand that when I am ready to retrieve sperm samples for insemination, I must call TSBC to schedule a pick-up appointment or to request a shipment, and that a completed and signed Shipping/Pick-up Order Confirmation Form is required with each pick-up or shipment.

\_\_\_ I understand that sperm samples released to me are intended for my use only. I agree not to give and/or sell vials to my medical provider or another person for insemination that were released for my use, except as follows. I agree to notify TSBC before giving TSBC sperm samples to any other individual and I understand that the other individual will be required to register with TSBC *prior* to using the samples. I understand that this registration is required regardless of my relationship with the individual receiving the vials. I further understand that the same registration is required for embryo donation.

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 Recipient's signature

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 Recipient's printed name

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 Date

\_\_\_ I understand that TSBC collects information on pregnancies and pregnancy outcomes, and I agree to notify TSBC of each and every pregnancy, birth, stored embryos, miscarriage or other outcome within 30 days of occurrence. I understand that my medical provider may also provide this information directly to TSBC and that if this occurs TSBC may contact me to obtain additional information. I also understand that TSBC conducts audits to obtain this information and I agree to provide pregnancy and outcome information if requested by TSBC.

\_\_\_ I understand that TSBC works to limit each donor to 10 families and depends on recipient participation to maintain these limits. I understand that reporting (a) my pregnancy, (b) any embryos or vials stored off-site, if applicable, and (c) pregnancy outcome in a timely manner will assist TSBC in maintaining my donor's 10 family limit. I further understand that factors outside of TSBC's control may result in more than 10 families from a donor. These factors include, but are not limited to, multiple families conceiving in the same month, late reporting of pregnancies or births, recipients storing sperm vials or embryos at fertility clinics for future use, and recipients sharing vials or embryos with others who do not already have a child from the donor.

\_\_\_ I understand that TSBC cannot guarantee that sibling inventory (sperm samples allocated for recipients and/or their partners who have had at least one live birth and wish to conceive another child using the same donor) will be available for any donor. I understand that TSBC makes every effort to set aside inventory for families choosing to have multiple children and that the availability of sibling inventory is subject to change without notice.

\_\_\_ I understand that TSBC will release identifying information on donors participating in the Identity-Release® Program only to offspring who are at least 18 years old and that TSBC will not under any circumstances release identifying information on our donors to any other party, including the parents of individuals conceived using TSBC donor sperm.

\_\_\_ I understand that TSBC requests that families who are curious about genetic relations seek information through mutual consent options (such as TSBC's Identity-Release® Program and Family Contact List) and not search for or try to contact the donor or other families who share the donor without their consent.

\_\_\_ I understand that TSBC provides educational articles, research-based information, and other resources on their website to assist parents in discussing donor origins with their children. I understand that TSBC advises all parents that telling their donor-conceived child at an early age, in an age-appropriate manner, that the child is donor-conceived is associated with improved family functioning and welfare of the donor-conceived child.

\_\_\_ I understand that TSBC uses unencrypted email to communicate with recipients. TSBC follows industry standards to maintain recipient confidentiality, but as commonly used email servers have been breached in the past, I recognize that no electronic communications are completely secure.

\_\_\_ I understand that any and all questions as to the legal interpretation, validity or any other aspect of this agreement as it relates to the purchase of and insemination with sperm samples shall be determined by the laws of the State of California, regardless of the location or residence of any of the parties, including any offspring conceived as a result of insemination with TSBC sperm samples. I further understand that any child conceived with sperm purchased or stored at TSBC is explicitly and categorically not intended to be a third-party beneficiary to any contract or agreement with TSBC.

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 Recipient's signature

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 Recipient's printed name

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 Date