Donation of Embryos

**These template documents were revised before the US Supreme Court decision in *Dobbs v. Jackson* (which repealed Roe v. Wade), and therefore, SART has not reviewed the template documents and did not make any changes based on the *Dobbs* decision. SART strongly recommends that before any SART template document is put into use in a Member's practice, the document should be reviewed by the Member's local legal counsel to ensure that the language conforms to current federal, state and local laws as these may have recently changed or are in the process of being changed.**

DESCRIPTION

This document informs the Embryo Donor about donating embryos, and includes an instruction for use.

TARGET

* All individuals planning to donate their stored embryos.

RELEASE NOTES

* This is the 2nd version of this document
* Signature page allows for Witness (in office option) and Notary verification (require if offsite)

TO DO

* Modify this document according to local needs and preferences.
* Get legal review to assure conformance with State and local laws and regulations
	+ State law may, among other things, define, characterize, or govern:
		- A pre-implantation IVF embryo; and
		- When legal control over IVF embryos may transfer
		- If and when any such transfer may be withdrawn

***DISCLAIMER.***

*SART and ASRM make this template available to their member clinics (Clinics) for use as a starting point to design their own patient forms and agreements. The template and all intellectual property rights in the template are owned exclusively by SART and ASRM, and Clinics receive only a right to use the template for their own internal business purposes.* ***This template may not be shared with any non-member organizations****.*

*Neither SART nor ASRM represent or warrant that the template will meet a particular Clinic's needs or objectives or that the template with comply with all the laws, rules or regulations applicable to a particular Clinic.* ***Before using this template you should conduct a legal review to ensure the resulting document complies with all of your responsibilities; meets all applicable legal requirements; and meets all of your program's specific considerations****.*

*Neither SART nor ASRM nor any of their respective administrators, executives, employees, committees or agents make any representations or warranties with respect to the template and disclaim any and all warranties, express or implied, including, without limitation, warranties of merchantability, fitness for a particular purpose, compliance with laws, non-infringement or accuracy with respect to the template. Neither SART nor ASRM will be liable for any incidental, consequential, special, indirect, direct, business interruption, regulatory or punitive damages incurred in connection with or as a result of any claim arising out of use of or reliance on the template or the Clinic's resulting document, even if such consequences or damages were foreseeable.*

*[Without limiting the foregoing, use of the template is subject to the ASRM Website Terms and Conditions of Use and by using the template, you consent to those terms.]*

Embryo Donation for Procreation

Consent, Authorization & Instructions for Disposition

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Embryo Donor A:** Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Cell phone: (\_\_\_) \_\_\_\_\_\_\_\_ - \_\_\_\_\_\_\_\_\_\_\_\_\_

**Embryo Donor B:**

 Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Cell phone: (\_\_\_) \_\_\_\_\_\_\_\_ - \_\_\_\_\_\_\_\_\_\_\_\_\_

This “Embryo Donation for Procreation: Consent, Authorization and Instructions for Disposition” (“Authorization”) addresses donation for procreation of embryos stored on-site at the Clinic.

The embryo(s) to be donated were created and frozen on or about: \_\_\_\_\_\_\_\_\_\_\_(date) (the “Embryos”).

□ The Embryos were created using gametes from Embryo Donor A and Embryo Donor B; or

□ The Embryos were created with □ donor oocytes and/or □ donor sperm, and the gamete donor has consented to the proposed donation. Appropriate documentation has been submitted to and approved by the Clinic.

 \_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_ (initial)

You, as the Embryo Donor(s) named above (collectively “Donors”) hereby consent and authorize donation of your Embryos for purposes of procreation by another individual or couple in accordance with this Authorization.

If you have embryos in storage that were created during a previous IVF cycle that you no longer wish to use yourself to have a child (and the embryos meet certain minimum criteria for donation), you may donate them for an individual or couple to try to have a child. Before you can donate, psychological counseling and additional blood tests may be required. This Authorization addresses donation for procreation only through the Clinic.

**You understand that embryo donation involves many considerations, and you specifically authorize the Clinic to discard your embryos if the donation process cannot be completed for any reason.**

Special Considerations

Donating embryos for procreation, whether to someone you know like a close friend or relative, or to someone who is not known to you, may carry some risks. There may be emotional and psychological risks to the donors, recipients, and/or resulting child(ren), including potential issues that may arise from genetically related offspring being reared in different families, who may or may not be known to one another. In addition, while you may not be given any information about the individual(s) to whom your embryos are being donated, given rapidly expanding genetic testing availability, social media, and the potential for changes in law and regulations, there can be no guarantees of anonymity over time between donor linked individuals and/or donor conceived offspring. Medical information updates as well as the possibility of future contact for other reasons should be considered and addressed in any legal agreement entered into for embryo donation.

Embryos created with donor sperm or donor eggs are subject to additional FDA screening and testing requirements and any gamete donors must also have consented to any future embryo donation.

Subject to the above limitations, please indicate below whether you would like to choose the person(s) to receive your donated Embryo(s), or whether you would like to have the Clinic determine a recipient(s) of the Embryo(s).

Please check and initial the appropriate choice, A or B [both Donors must sign the same choice]:

A. □ **“Non-Identified Donation”:** You authorizethe Clinic to choose who will receive the Embryos.

Donor A Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Donor B Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

B. □ **“Directed Donation”:** You wish to choose the individual or couple as the recipient(s) of the Embryos (“Recipient(s)”). Please be aware that your Recipient(s) may decide NOT to accept the Embryo(s). You should also be aware that the Clinic may refuse to transfer Embryos to any potential recipient based on Clinic policy in accordance with legal and ethical standards, and require you consult with separate, independent legal counsel and a legal agreement be executed between Donors and their Recipient(s).

Recipient(s):

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Cell phone number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Donor A Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Donor B Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If your Recipient(s) above does NOT wish to accept the Embryos, you then authorize the Clinic to: (choose one disposition)

* Discard the Embryos:

 Donor A Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Donor B Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Authorize the Clinic to choose a Recipient or a 3rd party entity who may select a Recipient for the Embryo(s):

 Donor A Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Donor B Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Donor Requests

Unless you have identified a specific Recipient(s) above, you understand the Clinic will select a Recipient(s) for your Embryos. You may request the Clinic take into consideration any preferences you have regarding a recipient, but acknowledge it is not required to do so. If you have any such requests, they must be noted here:

# Screening

Prior to May 25th, 2005, embryos could only be donated if federally mandated infectious disease testing was performed at the time of embryo creation (within 30 days of egg retrieval and 7 days of sperm acquisition). Subsequently, FDA guidelines were updated to allow donation of embryos if the person who provided the egg and sperm undergoes testing and screening at the time of donation if it was not done at time of embryo creation. If feasible, this includes infectious disease screening, medical screening, and genetic screening. If you are not tested at the time the Embryos were created, the Recipients must be given a clear warning of potential infectious disease risks, and the Embryos(s) and the medical record must be labelled appropriately, advising that screening and testing of donors was not performed at time of freezing.

All screening and testing expenses will be paid in full by the Recipient(s).

# *Infectious Disease Screening*

These tests will look for infections that could endanger the Recipients or their pregnancy or contaminate the embryology laboratory and endanger other embryos. Tests will be done for infectious diseases. A separate consent may be required for HIV screening. If there is evidence of any type of infection, the results of your test will be discussed with you; and if needed, you will be treated or referred for treatment. [TO BE COMBINED]

# *Genetic Screening*

The Recipients who will use your Embryo(s) in an attempt to have children will rely on the information that you provide to the Clinic to decide if they wish to use your Embryos. It is important that this information is complete and accurate to the best of your knowledge. If either of you suspect that you may have a family history of an inheritable disease or disorder, please inform the Clinic as the Clinic may consider performing further testing to determine if you carry that condition.

If either of you has one of many different congenital (present from birth) disorders or disabilities, the Clinic may not be able to accept your Embryo(s) for donation. Examples include cleft palate, spina bifida, significant congenital heart malformation, or congenital hip dislocation, albinism, hemophilia, hemoglobin disorder, hereditary hypercholesterolemia, neurofibromatosis, or tuberous sclerosis. If any member of your family has any of the above conditions or has a disorder such as asthma, diabetes, epilepsy, psychosis, or rheumatoid arthritis you may have to undergo further screening to determine if you are eligible to donate embryos for procreation. You may be screened by blood testing for certain genetic abnormalities including cystic fibrosis, spinal muscular atrophy, and hemoglobinopathies. Because of the importance of genetic background, if this information is not available for either the sperm provider or the egg provider, the Embryos may not be able to be donated for procreative use. The decision to accept the Embryos for donation is solely at the discretion of the Clinic.

# Psychological Assessment and Consultation

Guidelines from the American Society for Reproductive Medicine (ASRM) include a strong recommendation that any person or couple donating embryo(s) for procreation, and any designated embryo recipients, undergo psychological evaluation and counselling. ASRM also strongly recommends all embryo recipients participate in a psychological consultation.

For directed donations, ASRM Guidelines strongly recommend both separate and joint counseling to discuss “expectations, communications and future relationships,” including: the impact of possible treatment failure; disposition of any remaining embryos; the future implications for any offspring of having full genetic siblings in different families; the challenges of “anonymity”, and an exploration of future contact and roles between and among the donor and recipient families.

Deciding whether to donate embryos for procreation can be complex, and participation as an embryo donor can be time consuming. If the counselor feels that you need further support, you may be referred for additional assessment, continued counseling and/or psychological testing before our Clinic will proceed with donation. After any embryo donation, you may also choose to have a counseling session with the counselor.

# No Financial Cost or Compensation for Donation of Your Embryos

The Recipient(s) will assume full financial responsibility for all the screening and testing of the Donor(s) associated with the Embryo donation. You will not assume any expenses or receive any financial payment for donating your Embryos.

# Cancelled Cycles

An embryo donation cycle may be cancelled if the Embryos do not survive the thaw, or if a Recipient develops a medical issue (such as a thin uterine lining) that makes pregnancy unlikely or medically inadvisable. Even if the cycle is cancelled, there will still be no cost to you for any screening and testing related to the donation process.

# Informed Consent for Release and Donation of Embryos

If you choose to donate Embryos to a Recipient, either in a non-directed or a directed donation, you acknowledge that you have read, understand, and accept the information written in this Authorization, including:

**1. Informed Consent**

You acknowledge that you have read the entire Authorization and have had the opportunity to ask your physician any questions you may have about participation. Your consent to embryo donation is purely voluntary. You acknowledge that your doctor has provided you with alternatives to embryo donation for procreation, including continued storage options, donation for clinical research or training, discard, or using the embryos for our own procreation; as well as the risks of inadvertent loss or damage to the Embryo(s) at any time. You have specifically declined to accept these options.

**You hereby legally relinquish all control, possession, and rights to the Embryo(s) or to any child or children that may result from any embryo transfer of such Embryo(s) into a recipient, to the fullest extent allowable by applicable law. Subject to applicable law and the payment of any previously waived storage fees in accordance with the Clinic’s policies, once you have relinquished your control, possession and rights to the embryos, any right to withdraw your consent and authorization is governed by the legal agreement entered into between you and your Recipient, the Clinic and/or a 3rd party entity.**

**2. Risks and Benefits**

You acknowledge that you have been advised of the risks and benefits of undergoing the procedures involved in becoming an embryo donor and the possible alternatives thereto; and have undergone or will undergo psychological counseling regarding the process. You also confirm that you have reviewed this Authorization with your physician or designated Clinic staff and have had an opportunity to have your questions answered

**3. Confidentiality and Future Communication**

You understand that all information about you obtained during the embryo donation process will be handled confidentially and, unless you have consented to donating to a specific, named Recipient(s) and thereby consented to sharing identifying information, the Clinic will not intentionally reveal either Donor’s identity, or your specific medical or psychological details which are unnecessary to the donation process without your consent. You have been informed that your name and address will be kept on file by the Clinic. You have been told that your name(s), address(es), or any other information which would directly or indirectly identify you will not be disclosed or released to any person or entity without your written informed consent, except to authorized employees of this state’s Department of Health or as permitted by law. You agree that specific medical details may be revealed in professional publications if your identity is concealed. Reproductive tissue bank records shall be open to inspection by the Department of Health and shall be kept in accordance with the regulations of the state in which the donation occurred.

You certify that the genetic and medical history forms you filled out are complete and accurate to the best of your knowledge. You authorize the Clinic to disclose your medical history information and relevant background information to potential donor embryo recipients and their physicians, consistent with statutory requirements and Clinic policies for the disclosure of genetic and other medical information.

The Clinic may or may not inform you (the embryo donor(s)) if a pregnancy results from the Embryo donation.

Unless you have designated your Recipient(s), you also understand that the Clinic will make reasonable efforts to protect your identity except as agreed to between Donors and Recipients, as set forth in a legal agreement, or if required by law or a court order.

You understand that if a child born from a Non-Directed donation has a medical or psychological need that might be met by you, the Recipient(s) or a child who reaches the age of legal majority may contact the Clinic and ask that their request be relayed to you; or, the child upon reaching the age of legal majority may contact the Clinic to request your identities be shared with them, and the Clinic may contact you for that or other purposes. You understand that you are not obligated by this Authorization to honor any such requests.

You also acknowledge and agree that if you enter into and provide the Clinic with a valid legal agreement entered into between you and any Recipient(s) or any off-site storage facility, those terms will prevail and supersede any contradictory instructions provided here.

You understand and agree that, if you have specified a Recipient(s) for the Embryos, that aspects of your medical care and conditions, and that of the Recipient(s) may be revealed and/or discovered as part of the donation or treatment process.

**4. Legal Concerns**

You understand that the legal status of embryo donation and the legal child-parent status as to any resulting child may be uncertain, vary by state, and that there may be future changes in the law, especially regarding identity disclosure. You have been advised, and have had the opportunity to, consult with your own legal counsel who is experienced in Assisted Reproductive Technology law. For a donation with a specified Recipient(s) you have entered into a separate/additional legal agreement after you and your Recipient(s) have each been represented by separate legal counsel. You have considered all the information provided to you, from various sources and knowingly relinquish, to the fullest extent allowed by law, all rights of any kind to the Embryos and any resulting child(ren).

[***Clinics should insert, according to the Practice Guidelines, a Jurisdictional statement that addresses, “jurisdiction and process for medical/legal procedures and/or dispute resolution.”***

**By signing your name below,** you acknowledge and agree that you read this Embryo Donation for Procreation: Consent, Authorization and Instructions for Disposition, and that you fully understand what is written here, including the benefits and risks explained. You also agree that you have had an opportunity to discuss all treatment and procedures discussed in this document, including any alternatives that may be available to you, that you have had an opportunity to have your questions answered, and confirm that you are voluntarily giving your consent and authorization to donate embryos. You also understand that you may receive a copy of this signed document for your personal records.

*If signed out of the office:*

X

Embryo Donor A Signature Date

Embryo Donor A Name Date of Birth

**Notary Public**

Sworn and subscribed before me on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_.

Notary Signature Date

-------------------------------------------------------------------------------------------------------------------------

X

Embryo Donor B Signature Date

Embryo Donor B Name Date of Birth

**Notary Public**

Sworn and subscribed before me on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_.

Notary Signature Date

======================================================================================

*If signed in the office:*

**Statement by Witness (must be employee of Clinic and at least 18 years of age)**

I declare that the person who signed this document is personally known to me and appears to be of sound mind and acting of his or her own free will. He or she signed (or asked another to sign for him or her) this document in my presence.

Witness Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_