Embryo and Pre-Embryo Cryopreservation Program Information
Participation Agreement and Informed Consent

- Freezing of viable embryos not transferred after the egg retrieval provides additional chances for pregnancy.
- Frozen embryos do not always survive the process of freezing and thawing.
- Freezing of eggs before fertilization is currently less successful than freezing of fertilized eggs (embryos).
- Ethical and legal dilemmas can arise when couples separate or divorce; disposition agreements are essential.
- It is the responsibility of each couple with frozen embryos to remain in contact with the clinic on an annual basis.

Understanding Cryopreservation:

Cryopreservation is a clinical procedure that is performed by the embryologists at Conceptions Reproductive Associates of Colorado (CRA).

The technology permits the storage of human tissue in a frozen state. Cryopreservation is the “freezing” or “vitrification” and storage of any suitable embryos or pre-embryos which are not transferred during the original assisted reproduction cycle. There are two methods of “cryopreservation”. In this consent, anywhere the word “freeze” is used, “vitrify” would also apply. Also, in this consent and agreement, anywhere the word “embryo” is used the word “pre-embryo” would also apply. Participation in this clinical procedure is voluntary. If patients elect not to participate in the “Cryo” program it will not affect their relations with Conceptions Reproductive Associates of Colorado or result in any penalty or loss of benefits to which they are otherwise entitled.

The “Cryo” Program may be used in the event that excess embryos are produced during an IVF treatment cycle. This program is designed so frozen embryos can be transferred to the female partner’s uterus in some later cycle for the purpose of establishing pregnancy. Freezing (or “cryopreservation”) of embryos is a common procedure. Since multiple eggs (oocytes) are often produced during ovarian stimulation, on occasion there are more embryos available than are considered appropriate for transfer to the uterus. These embryos, if viable, can be frozen for future use. In the cryopreservation form, such embryos are called “cryopreserved embryos” for purposes of this consent. Patient and partner acknowledge the “cryopreserved embryos” will have no capacity to produce human life until by proper thawing and ascertainment of survival an embryo has been produced and properly transferred into the patient’s uterus.
The “Cryo” Program may also be used to “freeze all” embryos produced during the IVF cycle. There are cases due to medical reasons that a fresh transfer is deemed unadvisable by the physicians. Examples would include but not be limited to: risk of severe hyperstimulation, inadequate uterine lining development, fluid seen by ultrasound within the uterine cavity, (both of which could compromise implantation), and/or if a couple were concerned that their future fertility potential might be reduced due to necessary medical treatment (e.g., cancer therapy or surgery).

Indications for Cryopreservation:

- To reduce the risks of multiple gestation
- To increase the chance of having one or more pregnancies from a single cycle of ovarian stimulation
- To minimize the medical risk and cost to the patient by decreasing the number of stimulated cycles and egg retrievals
- To temporarily delay pregnancy and decrease the risks of OHSS especially when this risk is high
- To temporarily delay pregnancy if the progesterone level or endometrial lining is poor

Not all embryos or blastocysts have the necessary properties to be frozen or cryopreserved. Only those embryos or blastocysts, as assessed by the embryologist, that have qualities that suggest that they will survive the cryopreservation process will be cryopreserved. This is a determination that can only be made by the embryologist as he/she monitors their growth and development. It is accepted that some or all of the embryos may not continue to grow in the laboratory and reach the stage of development where they can be cryopreserved. There is no guarantee that any or all of the embryos will survive the freezing and thawing process. Moreover, there is no guarantee that those embryos which thaw properly will continue to develop normally or result in a viable pregnancy, normal pregnancy, or pregnancy at all. All antenatal screening is highly recommended to screen for non-genetic structural defects for any fetus, even if the couple has elected to screen their embryos prior to transfer. Some abnormalities may be undetected by these methods.

Embryo cryopreservation is conducted as follows: on the days following the insemination of the oocytes (eggs), any excess embryos will be frozen. Embryos will be frozen either on day 5 or 6. In most situations embryos are frozen on day 5 or 6 when the embryos have reached the blastocyst stage. When “freezing” embryos, the CRA embryologists will transfer the embryos to a special solution containing a cryoprotectant compound. Embryos will be cooled to -350 C in a machine designed to carefully control the rate of freezing. When “vitrifying” embryos, the CRA embryologists will transfer the embryos to a special solution containing a cryoprotectant compound and then the
embryos are plunged directly into liquid nitrogen at \(-196\,^\circ\text{C} (-321\,^\circ\text{F})\). Embryos which undergo “freezing” and those which were “vitrified” are then transferred to storage containers and maintained at a temperature of \(-196\,^\circ\text{C} (-321\,^\circ\text{F})\) until they are thawed. Frozen embryos are thawed at a carefully controlled rewarming rate. After thawing, embryos are washed free of the freezing solutions and treated in a manner identical to that used in the IVF laboratory for non-frozen embryos. Any embryos believed to be abnormal will not be transferred, although this can not be completely determined by visualization alone. Any embryos deemed “non-viable” will not be transferred.

The pregnancy success rates for cryopreserved embryos transferred into the human uterus can vary from practice to practice. Overall pregnancy rates at the national level with frozen embryos are lower than with fresh embryos. This, at least in part, results from the routine selection of the best-looking embryos for fresh transfer, reserving the “second-best” for freezing. There is some evidence that pregnancy rates are similar when there is no such selection. Genetically tested embryos that have been frozen render pregnancy rates similar to fresh embryos.

The time an embryo can remain frozen and undamaged appears to be indefinite. Frozen embryos can be used for future transfer back to the patient’s uterus, discarded if no longer wanted or donated to: a) research, b) our anonymous embryo donation program, or c) CRA to be used at its discretion.

**Risks and Benefits:**

Cryopreservation is intended to benefit patients personally by reducing the risk of multiple births and their obstetric complications while at the same time creating additional opportunities for the initiation of pregnancy at a later date with the transfer of concepti developed from frozen/thawed embryos. This saves the expense and inconvenience of stimulation to obtain additional eggs in the future. Furthermore, the availability of cryopreservation permits patients to transfer fewer embryos during a fresh cycle, reducing the risk of high-order multiple gestations (triplets or greater). As an alternative, patients may elect to inseminate fewer eggs in the initial IVF cycle and donate or discard any excess eggs.

Laboratories worldwide now have the ability to cryopreserve human embryos and to establish pregnancy after transfer. Many babies have been born subsequent to the transfer of such frozen/thawed embryos. Studies of these human embryos, and extensive investigations of cryopreserved animal embryos, suggest no increase in the risk of abnormalities in offspring that had been cryopreserved beyond the risk of the IVF process itself. This does not mean that cryopreservation eliminates the normal risk of obstetric complications or fetal abnormalities but rather that cryopreservation does not appear to create an increased risk, although the possibility of a presently unforeseen risk cannot be completely eliminated. I/we also understand that the embryos are stored in liquid nitrogen and are not stored in a closed system, meaning they are stored with other patients who have tested negative for communicable diseases. Although unlikely, it is theoretically possible for your embryos to be exposed to an undetected virus from other patient’s embryos.
There are several techniques for embryo cryopreservation, and research is ongoing. Traditional methods include “slow”, graduated freezing in a computerized setting, and “rapid” freezing methods, called “vitrification”. Current techniques deliver a high percentage of viable embryos thawed after cryopreservation, but there can be no certainty that embryos will thaw normally, nor be viable enough to divide and eventually implant in the uterus. Cryopreservation techniques could theoretically injure the embryo. Extensive animal data (through several generations), and limited human data, do not indicate any likelihood that children born of embryos that have been cryopreserved and thawed will experience greater risk of abnormalities than those born of fresh embryos. However, until very large numbers of children have been born following freezing and thawing of embryos, it is not possible to be certain that the rate of abnormalities are no different from the normal rates.

It must be understood that with any technique necessitating mechanical support systems, equipment failure can occur. Neither Conceptions Reproductive Associates of Colorado, employees, or consultants are to be held liable for any destruction, damage, or improper freezing, maintenance storage, withdrawal, thawing, and/or delivery caused by or resulting from any malfunction of the storage tank, failure of utilities, strike, cessation of services or other labor disturbance, any fire, wind, earthquake, water, or other acts of God, or the failure of any other laboratory.

**Use of Cryopreserved Embryos and Pre-Embryos:**

Any cryopreserved embryos will remain frozen until such time that the IVF physician responsible for your care determines that the recipient is ready to receive the embryos into her uterus. To reach this stage, the recipient receives appropriate medications such as estrogen and progesterone preparations to prepare the uterus for receipt of the embryos which will be continued after the embryo transfer. The recipient may have to undergo suppression of her own menstrual cycle with gonadotropin releasing hormone agonists such as Lupron in order to prepare her uterus for embryo transfer. Some patients will receive no medications to prepare the uterus. The appropriate protocol will be determined by your CRA physician. Vaginal ultrasound examinations will be necessary to assess the development of the uterine lining, and blood studies will be required to monitor blood levels of hormones including estradiol and progesterone. When the physician feels that the uterus is ready and that the uterine lining is appropriate for embryo transfer, the appropriate number of embryos will be thawed. The embryos are periodically evaluated by the embryologist to assess development. If, after thawing, an embryo does not survive or develop normally after observation, that embryo will not be transferred into the intended mother’s uterus.

The recipient of the thawed embryos will be monitored in a standard fashion following embryo transfer. In the event a pregnancy occurs as a result of thawed embryo transfer, observation by the staff at CRA will be necessary just as if the pregnancy had been achieved during an IVF procedure.
The Responsibilities of Patients Who Elect Cryopreservation:

It is imperative that all patients understand, and accept, that there are responsibilities that accompany the choice to cryopreserve embryos. Additionally, maintaining embryo(s) in a frozen state is labor intensive and expensive. There are fees associated with freezing and maintaining cryopreserved embryo(s). A yearly storage fee shall be charged starting the following calendar year after the initial cryopreservation procedure. Storage fees are subject to change each year in order to cover maintenance costs. Patients/couples who have frozen embryo(s) must remain in contact with the clinic on an annual basis in order to inform CRA of their wishes as well as to pay fees associated with the storage of their embryo(s). In situations where there is no contact with CRA for a period of four years or fees associated with embryo storage have not been paid for a period of four years and CRA is unable to contact the patient after reasonable efforts have been made, the embryo(s) will be considered to be abandoned and may be destroyed by the clinic in accordance with normal laboratory procedures and applicable law.

All patients must provide CRA with any change in address, so that we may contact you with respect to changes and billing. If you fail to keep us apprised of your location in writing upon each change of address or a prolonged absence from the last address which is on file, we shall endeavor to contact you by a letter sent by certified mail to the last address on file and by phone to the last number on file.

Your current address and phone number on file:

_______________________________________                    Phone Number: ________________

If you elect to cryopreserve embryos you will be asked to sign a disposition plan for any embryos that you cryopreserve.

Time-Limited Storage of Embryos:

The clinic will only maintain your cryopreserved embryos for a period of 4 years. After that time, your embryos will be automatically transferred to ReproTech, a company specializing in the long-term storage of frozen embryos. Before your embryos can be cryopreserved (frozen) at our center, paperwork including payment arrangements and preparation for the seamless and automatic long-term storage of your embryos must be completed.

Default Disposition: I/We understand and agree that in the event that provisions are not made for the long-term storage or disposition of our embryos, the clinic is authorized, without further notice to us, to destroy and discard our frozen embryos.
Ownership of Cryopreserved Embryos and Pre-Embryos and the Need for a Disposition Plan

Embryos are a unique form of “property”, and the law is still developing as to the rules which govern them. Since CRA cannot predict the changes in the law (or medicine) that will ultimately have effect on the disposition of embryos, we can only offer you a policy based on our best medical judgment and the advice of attorneys who are knowledgeable in the field.

Because of the possibility of you and/or your partner's separation, death or incapacitation, it is important to decide on the disposition of any embryo(s), fresh or cryopreserved that remain in the laboratory. Since this is a rapidly evolving field, both medically and legally, CRA cannot guarantee what the available or acceptable avenues for disposition will be at any future date. At the present time, the alternatives are:

1) Discarding the cryopreserved embryo(s)
2) Donating the cryopreserved embryo(s) for approved research studies
3) Donating the cryopreserved embryos to another couple (married or unmarried), individual or a custodial agency in order to attempt pregnancy. (In this case, you may be required to undergo additional infectious disease testing and screening due to Federal or State requirements and complete additional necessary paperwork required by the designated recipient).
4) Use by one partner with the contemporaneous permission of the other for that use

This agreement provides several choices for disposition of embryos in these circumstances (death of the patient or the patient’s spouse or partner, separation or divorce of the patient and her spouse/partner, successful completion of IVF treatment, decision to discontinue IVF treatment, and by failure to pay fees for frozen storage).

CRA treats all cryopreserved embryos as the joint property of the patient and partner and will not participate in any use of such embryos without the consent of both. However, all parties must recognize that there may be embryos that will not be utilized by the patients and which must be stored and ultimately removed from storage.

CRA recommends that, in the usual case, cryopreservation be continued for no more than four (4) years. CRA will only maintain cryopreserved embryos for a period of four (4) years. After that time, any cryopreserved embryos must be: 1) thawed and transferred; 2) donated to another couple; 3) donated to research; 4) discarded or 5) transferred to a long-term storage facility.

CRA’s policy regarding cryopreservation and the need for a disposition plan has been developed to clarify issues for patients choosing cryopreservation and to aid in a thoughtful solution to the disposition of possibly unused or abandoned embryos.
Patients electing to cryopreserve embryos must sign a disposition plan which will govern the future of the embryos in the event that there is a change in the relationship of the patients. CRA’s consent form asks the patients to elect who will have the right to embryos in the event of death of one of the patients or in the case of divorce.

**Informed Consent**

A. We are advised that Conceptions Reproductive Associates of Colorado provides no insurance, compensation plan, or free medical care plan to compensate us if we or our embryos are harmed in any way by this cryopreservation procedure. If we believe that we have been harmed, we may contact CRA, who will be glad to review the matter with us.

B. It is intended that the “Cryo” Program operate indefinitely. However, CRA reserves the right to discontinue the operations of the “Cryo” Program upon reasonable notice in the event that scientific, financial, or other considerations lead it to do so. If CRA discontinues the “Cryo” Program for any reason while the patient and her partner have embryos in storage at the Laboratory, the Laboratory shall give written notice of the discontinuance to the patient and her partner by United States Mail sent to their latest address on file at the Laboratory. If the notice is returned for insufficient address or similar reason, or if no written response is received within 90 days after mailing, it is agreed that the Laboratory may discard the embryos in accordance with laboratory procedures. However, if patient and her partner do respond to such notice in writing signed by both of them and received at the Laboratory within 90 days after mailing of the notice, the Laboratory will, if so requested in the response, release to patient and her partner jointly their frozen embryos for transport elsewhere to a physician or clinic of their choice via approved portable cryopreservation container. All risks, costs, arrangements, and expenses for such transport and for the subsequent fate of the Cryopreserved Embryos shall be the sole responsibility of patient and her partner. Embryos will be discarded, if after 90 days from the agreed date the patient and her partner do not carry out their transfer arrangements.

C. As the patient and her partner enter into the Cryopreservation Program they waive, to the maximum extent permitted by law, any and all claims which they or either of them may be entitled to assert to recover damages from CRA, or any personnel thereof, for mental suffering, emotional distress, failure to achieve pregnancy, representation as to the likelihood or rate of success in achieving pregnancy, or any related cause of action or basis for liability. No assurance has been, or can be, given as to achieving a pregnancy in the patient.

D. If patient and her partner or both of them shall make CRA or any of its officers a party to any litigation arising from any disagreement between patient and her partner as to the rights of either of them hereunder as to each other or as to CRA, patient and her partner shall be liable for the reasonable attorney’s fees and other costs to CRA in such litigation unless CRA
is found to have: (i) breached this agreement; (ii) acted arbitrarily and capriciously so as to justify being made a party to the legal proceedings or (iii) committed a tort (wrong) against patient and her partner.

E. Patient and her partner acknowledge that the Laboratory, for medical reasons, recommends against the transporting of the Cryopreserved Material of patient and her partner to any other facility or location (except as may be necessary in the event the Laboratory discontinues its “Cryo” Program). The parties agree that the Laboratory need only permit such transfers when the patient and her partner (i) assume all risk and expenses, (ii) agree in writing to indemnify the Laboratory from all costs, expenses and liability associated therewith, (iii) pay the current fee for administrative and other costs and (iv) comply with such other conditions as the Laboratory may, in its reasonable discretion, impose.

F. Any information obtained during these procedures that can identified with us will remain confidential and will be described to individuals not connected with this IVF cycle only with our written permission. We understand that photographs or videotapes may be taken of the embryos during the cryopreservation procedures as a permanent record and for possible use at medical meetings or with the lay public for educational purposes. We understand that confidentiality will be maintained.

G. Data from your ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC) and the Society for Assisted Reproductive Technology (SART). The 1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. In order to maintain compliant with the law, CRA will contact you to provide information regarding the outcome of your pregnancy should you become pregnant. Due to the sensitive information reported, the CDC applied for and received an “assurance of confidentiality” for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that the CDC has that identifies you will not be disclosed to anyone else without your consent.

H. We have read this document carefully and know we should ask questions about anything, which is unclear, before we decide whether to be participants in this procedure.

Patient’s Signature _______________________________ Date __________________

Partner’s Signature _______________________________ Date __________________

Notary Signature: _________________________________ Date __________________

City/State: _________________________________

Commission Expires: _________________________________

CONCEPTIONS REPRODUCTIVE ASSOCIATES OF COLORADO
www.conceptionsrepro.com
Pre-Implantation Genetic Diagnosis (PGD)/Comprehensive Chromosome Screening (CCS) Informed Consent

Purpose:
PGD/CCS is a technique used in conjunction with in vitro fertilization (IVF) to detect embryos with extra or missing chromosomes (aneuploidy) or for conditions caused by single gene defects. Embryos that are affected by certain chromosomal conditions can lead to failure of implantation, pregnancy loss, or result in the birth of a child with physical and/or mental defects. The purpose of PGD/CCS is to help prevent adverse outcomes by identifying affected embryos in the laboratory and preventing them from being transferred into the uterus. PGD/CCS can help in the selection of chromosomally normal embryos for transfer in order to increase the chance of pregnancy, reduce the chance of miscarriage, and reduce the chance of children born with medical conditions or genetic disorders.

Aneuploidy:
Chromosomes are the elements within every cell of the body that contain genetic information. Normal human cells contain 46 chromosomes in 23 pairs. Embryos receive 23 chromosomes from the sperm and 23 chromosomes from the egg. The first 22 pairs of chromosomes are the same for the male and the female. The 23rd chromosome pair determines the gender and is called the sex chromosomes. A female has two “X” chromosomes and a male has an “X” and a “Y” chromosome. The eggs only have “X” chromosomes and the sperm contains either an “X” or a “Y”, therefore determining the sex of the child. If the egg or the sperm have an extra or missing chromosome then the resulting embryo is said to be aneuploidy. An extra chromosome is known as a trisomy and a missing chromosome is known as monosomy. The most well known is trisomy 21, also known as Down syndrome. Most aneuploidies will fail to implant or end in early miscarriage but if they do develop successfully, the resulting child can have physical differences, genetic disorders and/or mental retardation.

Indications:
PGD/CCS for aneuploidy is beneficial for couples over the age of 35 due to increased risk of miscarriage or birth defects from chromosomal abnormalities. It may also benefit couples who have previously failed IVF cycles, recurrent pregnancy loss, or have had chromosomally abnormal pregnancies in the past.
Single Gene:
PGD/CCS techniques can be used to detect embryos that may be affected by a genetic disease known to be present in your family. Couples who are carriers for a specific genetic disorder are at risk for transmitting the disorder to their child. Some examples of this are Cystic Fibrosis, Tay Sachs, Fragile X, or Huntington’s disease. The genetic material removed from the embryo is limited in these cases so prior knowledge of the genetic mutation carried by the genetic parents and family members may be necessary for the testing to be performed. PGD/CCS can also detect translocations, inversions or other structural chromosomal rearrangement. This is done using specific probes made for the loci of interest that is selected for individual patients based on their unique abnormality.

Biopsy and Analysis:
Conceptions performs embryo biopsy at the day 5 or day 6 stage (blastocyst). A small opening is created in the outer shell of the embryo using a laser. The cells are extracted using a laser and an aspiration pipette. There is risk of damage to the embryo during the biopsy procedure. This risk is relatively low and influenced by the quality of the embryo and the experience of the embryologist.

Biopsied cells are sent to Natera or IviGen for analysis. The cells are analyzed using microarray with parental support. For more information on how this technology is utilized please visit the Natera website (www.Natera.com) or call Natera directly (1-650-249-9090) or visit the IviGen website (www.ivigen.com) or call IviGen directly (1-305-501-4948).

Risks and Limitations:
PGD/CCS carries a set of risks and limitations that need to be considered. There is a chance of misdiagnosis due to test error or mosaicism. Mosaicism is when there is more than one chromosomally distinct cell line in the same embryo. This occurs by chance during embryo development and can cause a misdiagnosis if the cells tested are not representative of the entire embryo. This can result in a false negative or a false positive result for the embryo being tested. For this reason, we recommend patients undergo antenatal screening and possible testing by chorionic villus sampling (CVS) or amniocentesis.

Other risks associated with PGD/CCS include no normal embryos or no genetic result. There is a chance that all embryos that are tested may come back aneuploidy and will not be suitable for a transfer. In these cases, an embryo transfer will not be performed. There is also a chance during preparation, transportation, or analysis of the cells that a result cannot be obtained for a particular embryo or for all the embryos.

The actual biopsy of an embryo can carry a risk. This procedure has only been evaluated in a limited number of studies and the negative effects are unknown. There may be a risk of decreased viability of the embryo from the biopsy procedure as well as a potential for unknown consequences to a live born child.
Not all chromosome abnormalities can be detected and not every specific gene is analyzed. Therefore, PGD/CCS does not guarantee the birth of a chromosomally normal child. Ongoing pregnancies resulting from PGD/CCS should always be followed by prenatal testing by CVS or amniocentesis and these options should be discussed with your obstetrician.

There will not be any additional physical discomfort other than what you would experience during a regular IVF cycle with the PGD/CCS procedure.

**Possible Benefits of PGD/CCS:**
Genetic diagnosis of your embryos may increase the possibility of becoming pregnant with a healthy child. PGD/CCS may improve the ability to recognize possible abnormalities in embryos before placement into the uterus which may increase implantation rates. This may also help to reduce the miscarriage rate and reduce the chance of having a child with abnormalities. Information obtained from PGD/CCS may also be beneficial for pregnancy attempts in the future.

**Alternatives to PGD/CCS:**
Standard antenatal testing once you are pregnant such as CVS, amniocentesis, blood tests, and ultrasound are alternatives to PGD/CCS. These options should be discussed thoroughly with your obstetrician or with the person who would be performing or ordering the tests. You may also discuss your options with a genetic counselor. These tests may serve as alternatives to PGD/CCS however; PGD/CCS is not a substitute for routine prenatal testing. You should undergo recommended prenatal testing based on your age and medical history even if PGD/CCS has been performed.

**CONSENT FOR PGD/CCS**

We have read the entire consent form, or it has been read to us. We understand that PGD/CCS has benefits and risks, some of which may be unknown at this time. We would like to proceed with PGD/CCS testing.

We know that participation in PGD/CCS incurs extra cost in addition to those related to normal IVF procedures.

We understand that PGD/CCS cannot detect all chromosomal abnormalities and that it does not eliminate the need for standard prenatal testing such as chorionic villus sampling or amniocentesis. If pregnancy is achieved it should be followed by antenatal screening and diagnosis. We understand if we have questions about prenatal testing we may ask our obstetrician or a genetic counselor.
CONSEN TO DISCARD ABNORMAL EMBRYOS

We understand that by doing genetic testing some or all of our embryos may come back genetically abnormal and cannot be used for transfer. Abnormal embryos include aneuploidy or those with a single gene defect.

We agree to give Conceptions permission to discard any genetically abnormal embryos on our behalf.

INITIAL REQUIRED /________/

We have been given the opportunity to ask questions about PGD/CCS and the contents of this consent form. If we have any additional questions we may contact our physician. We understand that we may discontinue PGD/CCS at anytime.

_________________________________________  __________________________________________
Printed Name of Patient  Printed Name of Partner

_________________________________________  __________________________________________
Signature of Patient  Date  Signature of Partner  Date

STATE OF COLORADO  )
COUNTY OF ________________  )

The foregoing instrument was acknowledged before me this ________ day of ____________________
20__, by ________________________________.

(Signature of Notary)

My Commission Expires: ________________
Embryo and Pre-Embryo Cryopreservation Storage Consent

Patient: ______________________________ Partner: ______________________________
DOB: ________ SSN: ____________ DOB: ________ SSN: ____________

We understand that this agreement is a contract made and to be performed between the above patient and her partner and Conceptions Reproductive Associates of Colorado (CRA).

1. We understand that as a result of our participation in the In Vitro Fertilization (IVF) program, more fertilized eggs may form than the physicians at CRA recommend be transferred in the IVF cycle. We wish these fertilized eggs to be frozen so they can be transferred to the female partner’s uterus in some later cycle for the purpose of establishing pregnancy. We understand there is no guarantee the fertilized eggs will survive the freezing process, or that a pregnancy will occur. Patient and partner agree that prior to CRA thawing Cryopreserved Material, both must sign a separate, notarized consent expressly requesting and authorizing the thawing and transfer of each attempt to achieving pregnancy.

2. Neither the patient, partner, nor CRA shall have any rights or obligations, concerning the Cryopreserved Material except as expressly created by the options below. We understand that patient and her partner can jointly change the directions for future disposition contained in this form at any time by signing a new consent form incorporating any new disposition allowed within the limitations of CRA policies.

3. CRA will maintain and utilize or dispose of the Cryopreserved Material strictly as follows:
   A. So long as a patient and her partner continue participation in the “Cryo” Program, the Cryopreserved Material shall be stored exclusively to preserve the opportunity of thawing it for potential transfer into the patient’s uterus during a later cycle. A gestational carrier may be used on approval by a CRA physician and both the patient and her partner. CRA shall continue to store Cryopreserved Material for a period of four (4) years (after this time period the Cryopreserved Material will be sent to long term storage) so long as patient and her partner continue to pay, in a timely manner, the Laboratory’s yearly prevailing storage fees and keep CRA appraised of any changes in address and other contact information. CRA reserves the right to thaw and dispose cryopreserved embryos if payment is not received within 90 days of billing.

   B. Should patient and her partner elect to terminate their participation in the “Cryo” Program, all future charges for storage of the Cryopreserved Material shall cease and CRA agrees to be governed, to the extent feasible, by any one of the following four options selected by patient and her partner in writing signed by both of them in the presence of a notarized representative.
(i) CRA may use the Cryopreserved Material for the benefit of another infertile couple, to be selected at the couple’s discretion, whose identity is to remain undisclosed to the patient and her partner. No information will be released by the Laboratory and its staff. The patient and her partner shall respect all affected individuals’ rights to privacy and confidentiality and shall not seek future information regarding the identities of donors, recipients, or child(ren) born through this donation. Criteria for donation of embryos to another couple will be discussed with the Donor Gamete Program Director and/or nursing staff.

(ii) For use in research conducted at Conceptions Reproductive Associates of Colorado.

(iii) For use at the discretion of Conceptions Reproductive Associates of Colorado.

(iv) For thawing and subsequent discarding per CRA protocol without undergoing any further development or utilization for any purpose.

4. Termination of patient and her partner’s participation shall occur upon:

A. Receipt of CRA’s election for disposition form, signed by both patient and her partner in the presence of a notarized representative, requesting termination of participation by selection of options (i) – (iv) above.

B. Receipt of CRA’s election for disposition form signed by both patient and her partner in the presence of a notarized representative together with a certified copy of an order entered by a court of law, binding on both spouses, and authorizing the requesting spouse or either spouse to terminate participation.

C. Change in the physical condition of the female patient rendering her incapable of receiving a transfer or of carrying a pregnancy to term, in the opinion of the CRA physicians. A gestational carrier may be used at the approval of a CRA physician.

D. Death of patient and her partner – unless both have signed the disposition form stating the remaining spouse may remain in the program.

E. Failure to pay prevailing charges for Cryopreservation storage ninety (90) days past the billing date. All correspondence shall be mailed to the last address shown on file at the Laboratory.

F. Patient and her partner electing to transfer Cryopreserved Material to another site. Appropriate agreement forms will be signed at the time of the transfer.
G. I/We understand that before I (the patient) reach 50 years of age (DATE ____/____/____), the cryopreserved embryo(s) must be:
   1) Thawed and transferred
   2) Donated to another couple
   3) Donated to research
   4) Discarded
   5) Transferred to another storage facility
   6) Transferred into the uterus of a gestational carrier – This option only applies if either the patient or partner is less than 50 years of age at the time of embryo transfer.

If no disposition has occurred by the above date, I/We hereby waive any and all interest in said cryopreserved embryo(s) and the cryopreserved embryo(s) shall become the sole and exclusive property of the clinic. In this event, I/We elect to: (please initial your choice)

1. Discard the cryopreserved embryo(s)  _______  _______
2. Donate the cryopreserved embryo(s) for research  _______  _______

Disposition Plan

In the event we elect to terminate our participation in the Cryopreservation Program at CRA, we request that any remaining cryopreserved embryos be disposed of in accordance with subparagraph ____ below. In certain situations, donating embryo(s) for research or to another couple may not be possible or may be restricted by law. While efforts will be made to abide by your wishes, no guarantees can be given that embryo(s) will be donated to another couple. In these instances, if after five years no recipient can be found, or your embryos are not eligible, your embryo(s) will be discarded by the lab in accordance with laboratory procedures and applicable laws. If we do not meet the criteria for embryo donation and/or we do not comply with all the requirements of embryo donation, then we wish to have our embryos disposed of in accordance with subparagraph ____ below (if (i) is not an option here).

(i) CRA may use the Cryopreserved Material for the benefit of another infertile couple. To be selected by the couple, their identity is to remain undisclosed to patient and her partner, if requested. No information will be released by the Laboratory and its staff. The patient and her partner shall respect all affected individuals’ rights to privacy and confidentiality and shall not seek future information regarding the identities of donors, recipients, or child(ren) born through this donation. Criteria for donation of embryos may be discussed with the Donor Gamete Program Director and/or nursing staff.

(ii) For use in research conducted at Conceptions Reproductive Associates of Colorado.
(iii) For use at the discretion of Conceptions Reproductive Associates of Colorado.

(iv) For thawing and discarding without undergoing any further development or utilization for any purpose.

Printed Name of Patient

Printed Name of Partner

Signature of Patient
Date

Signature of Partner
Date

STATE OF COLORADO
COUNTY OF ________________

The foregoing instrument was acknowledged before me this _______ day of ________________
20___, by ________________________________

(Signature of Notary)

My Commission Expires: ________________
I/We agree that in the absence of a more recent written and witnessed consent form, the Clinic is authorized to act on our choices indicated below, so far as it is practical.

I/We also agree that in the event that either our chosen dispositional choices are not available or we fail to preserve any choices made herein, whether through nonpayment of storage fees or otherwise, the clinic is authorized, after 30 days written notice to us, to discard and destroy our embryos.

**Note:**

- Embryos cannot be used to produce pregnancy against the wishes of the partner. For example, in the event of a separation or divorce, embryos cannot be used to create a pregnancy without the express, written consent of both spouses or partners even if donor gametes were used to create the embryos.
- Embryo donation to achieve a pregnancy is regulated by the FDA (U.S. Food and Drug Administration) as well as state laws as donated tissue; certain screening and testing of the persons providing the sperm and eggs are required before donation can occur.
- You are free to revise the choices you indicate here at any time by completing another form and having it notarized.

In the event of the death of one or both of the patients or in the case of divorce, we agree on the following choices:

(i) In the event of the death of the male partner/significant other, we wish the cryopreserved embryos to be: **(Please Both Initial Option)**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Transferred to the care of the female partner if she wishes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Used in research</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Used at the discretion of CRA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Donation to another couple</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thawed and discarded without undergoing any further development or utilization for any purpose</td>
</tr>
</tbody>
</table>

(ii) In the event of the death of the female partner/significant other, we wish the cryopreserved embryos to be: **(Please Both Initial Option)**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Transferred to the care of the male partner/significant other if he wishes understanding that the embryos could be implanted into the male partner's new spouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Used in research</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Used at the discretion of CRA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Donation to another couple</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thawed and discarded without undergoing any further development or utilization for any purpose</td>
</tr>
</tbody>
</table>
(iii) In the event of both of our deaths, we understand that the cryopreserved embryos would be otherwise discarded.

_________________________  ____________________________
Printed Name of Patient                                   Printed Name of Partner

_________________________  ____________________________
Signature of Patient                                           Date                                  Signature of Partner                                           Date

(iv) In the event of Divorce or Dissolution of our marriage, or if we consider ourselves not legally married – then upon dissolution of our relationship we elect the following: (Please Both Initial Option)

______  _______ The female patient may have the embryos and may use them for any purpose, including attempting to establish pregnancy

______  _______ The male partner/significant other may have the embryos and may use them for any purpose, including attempting to establish a pregnancy in another woman or surrogate

______  _______ Used in research

______  _______ Used at the discretion of CRA

______  _______ Donation to another couple

______  _______ Thawed and discarded without undergoing any further development or utilization for any purpose

_________________________  ____________________________
Printed Name of Patient                                   Printed Name of Partner

_________________________  ____________________________
Signature of Patient                                           Date                                  Signature of Partner                                           Date

We understand that if we are not legally married and thus a legal divorce is not applicable, it may be difficult to prove that both parties consider the relationship no longer existing. Thus, both patient and partner will have to sign a separate notarized consent expressly requesting and authorizing the thawing and transfer of each attempt to achieve a pregnancy without a legal divorce decree.

For married couples it is understood that if any court of competent jurisdiction award to either Husband or Wife all rights with respect to the Cryopreserved embryos to the exclusion of the other spouse, by an order or decree which is final and binding to them, CRA shall have the right to deal exclusively with him or her to whom such rights were awarded, (the prevailing party) without liability or other accountability to the other party. CRA may:

CONCEPTIONS REPRODUCTIVE ASSOCIATES OF COLORADO
www.conceptionsrepro.com

INITIAL  ________/_________
1) Release their Cryopreserved embryos to the prevailing party if the prevailing party fulfills all conditions of transferring the embryos to another facility.

2) Agree with the prevailing party for termination of participation in the Cryopreservation Program at CRA.

3) Proceed with the prevailing party’s plan to continue participation in the Cryopreservation Program or attempts to establish a pregnancy conforming with the protocols and policies then in effect at CRA.

4) Comply in any other way with such decree.

__________________________  __________________________
Printed Name of Patient  Printed Name of Partner
__________________________  __________________________
Signature of Patient  Date  Signature of Partner  Date

Legal Considerations and Legal Counsel

The law regarding embryo cryopreservation, subsequent thaw and use, and parent-child status of any resulting child(ren) is, or may be, unsettled in the state in which either the patient, spouse, partner, or any donor currently or in the future lives, or the state in which the ART Program is located.

We acknowledge that the ART Program has not given us legal advice, that we are not relying on the ART Program to give us any legal advice, and that we have been informed that we may wish to consult a lawyer who is experienced in the areas of reproductive law and embryo cryopreservation and disposition if we have any questions or concerns about the present or future status of our embryos, our individual or joint access to them, our individual or joint parental status as to any resulting child, or about any other aspect of this consent and agreement.

__________________________  __________________________
Printed Name of Patient  Printed Name of Partner
__________________________  __________________________
Signature of Patient  Date  Signature of Partner  Date

INITIAL  ________/_________