

PATIENT NAME: _____

RECORD #: _____



THE CENTER FOR HUMAN REPRODUCTION (CHR)

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INFORMED CONSENT FOR RECIPIENTS OF ANONYMOUSLY DONATED FROZEN OOCYTES

REVISED: January 18, 2017

(Since oocyte donations at CHR in a large majority are anonymous, this consent form addresses the receipt of anonymously donated frozen oocytes *a.k.a, American Infertility of New York, doing business in New York as Medical Offices for Human Reproduction)

EXPLANATIONS & AFFIRMATIONS

I/We are desirous of going through an in vitro fertilization (IVF) cycle, with the use of donated oocytes/eggs from a third party female. I/We reached this conclusion after I/we received detailed advice about alternatives. In this process I/we were given the opportunity to ask all of my/our questions and I/we received satisfactory answers to all of them from CHR staff.

After deciding that I/we wish to go as recipients through an anonymous egg donation cycle, I/we were explained in detailed that CHR offers two methods of anonymous egg donation. The first is considered the standard egg donation cycle (SEDC), which has been offered at CHR for many years. In SEDC, one egg donor is matched with one recipient who has first rights on all of the donor's eggs. Moreover, in an SEDC, the recipient receives the donor's eggs fresh. They, therefore, are fertilized with sperm fresh and without prior cryopreservation (freezing). SEDC is, therefore, currently considered the "standard" method of egg donation and is not considered an experimental procedure.

Since October 2011, CHR also offers a so-called Eco-Donor Egg Cycle (EcoDEC). CHR introduced this method of egg donation in an attempt to offer patients a less costly egg donation alternative to SEDC. I/We were in detail explained the differences between SEDC and EcoDEC, including, though not exclusively, the following:

- EcoDEC, in contrast to SEDC, uses cryopreserved (frozen) eggs.
- While experience with egg freezing has greatly improved in recent years, it still is NOT on par with the experience of embryo freezing.
- Professional organizations, therefore, currently consider egg freezing under certain circumstances still an EXPERIMENTAL PROCEDURE.

- SUCH A DESIGNATION MEANS THAT NEITHER CHR, NOR THE PROFESSION IN TOTAL, HAVE ADEQUATELY LARGE EXPERIENCE TO OFFER EGG FREEZING AS A STANDARD NON-EXPERIMENTAL ROUTINE CLINICAL PROCEDURE.
- In practical terms, it means that CHR cannot make accurate representations as to what expected outcomes may be with EcoDEC.
- Specifically, CHR cannot predict what pregnancy chances will be from an EcoDEC, while, in contrast, pregnancy chances from an SEDC have been recorded for decades and, therefore, are well established.
- Since live births experiences after EcoDEC (and any use of frozen eggs) are worldwide still inadequately small, no statements can be made whether EcoDEC, in comparison to SEDC, results in more birth abnormalities. While available experience does not suggest an increase in birth defects, currently available outcome data are too small to reach final conclusions.
- It is estimated that so far a few thousand babies have been born worldwide from use of frozen eggs.
- A small number of babies from frozen eggs have also been born after egg freezing at CHR. Most egg freezing at CHR has, however, been in the past performed for fertility preservation purposes and patients have not yet returned to claim their frozen eggs. Numbers, therefore, have remained very small.
- By establishing the ECO-DONOR EGG PROGRAM at CHR, prospective data will, therefore, have to be accumulated to establish expected pregnancy rates for the first time.
- In the last several years, several research teams have reported positive experiences using the so-called vitrification method for egg freezing, with good results for egg fertilization, embryo development and pregnancy rates. This method of egg freezing is utilized at CHR. Although the efficiency of egg freezing appears greatly improved, more information is needed.
- As such information is developed at CHR, it will be published on CHR's website and, likely, in peer review medical publications, and therefore, available to all patients.
- There are no additional risk know to recipients of EcoDECs, but the following potential risks may affect the eggs:
 - The egg may not survive the thawing process;
 - Fertilization of the egg may not occur;
 - Once fertilized, the egg may not undergo cell division;
 - The egg may fertilize abnormal;
 - A resultant embryo may develop abnormally;
 - A resulting fetus and/or pregnancy may develop abnormally;

- All of these risks also exist when fresh eggs are used, but it is unknown at the present time whether any of these risks is increased if frozen eggs are used. At least one report, offering information on 120 live births, reported similar outcomes to cycles generated with fresh eggs. While such results are encouraging, available information is still too limited to reach valid final conclusions. It, therefore, is important to continue monitoring outcomes of pregnancies resulting from previously frozen eggs.

I/we was/were also explained details of the upcoming IVF cycle, summarized by the following steps:

- A determination via standard infertility testing methods that I/we, indeed, am/are medically suitable as oocyte recipient(s).
- If the female recipient is above age 45 years, a determination that she is medically and psychologically able to tolerate pregnancy.
- The utilization of various fertility enhancing medications, including (but not limited to) medications called LUPRON, ESTRACE and PROGESTERONE, and the utilization of other medications, routinely used in IVF cycles at CHR.
- Vaginal ultrasound examinations, and blood tests, to evaluate the uterine lining for suitability to accept the transfer of embryos.
- Collection and preparation of sperm for fertilization of donated eggs.
- I have agreed to purchase _____(number) of frozen eggs from anonymous egg donor #_____, which shall become my/our legal property upon receipt by CHR of my/our appropriate payment for these eggs. On a day, determined by CHR staff based on preparation of your uterus to receive embryos, your eggs will be thawed by the embryology staff of CHR and will be fertilized, utilizing a procedure called intracytoplasmic sperm injection (ICSI). ICSI is essential when fertilizing frozen eggs.
- Utilizing frozen eggs, CHR also automatically applies assisted zona hatching (AZH) to all embryos.
- Should your five (5) eggs after fertilization result in more embryos than will be transferred into uterus, these additional embryos can be frozen and will be your property. Should such a circumstance arise, you will be asked to give consent to the freezing of your embryos.
- If fertilization occurs, the developing embryos are usually observed until day 3 after fertilization, when in most cases embryo transfer into the uterus takes place. In selected cases embryos are cultured in the lab till day 5 or 6, and embryo transfer then takes place on those days. A micromanipulation technique, called assisted zona hatching (AZH), will be applied to the embryos prior to their transfer into the uterus.
- The embryo transfer is painless and occurs via the insertion of a small catheter into the uterus.
- Following embryo transfer, multiple blood draws and ultrasound examinations are required to check for pregnancy, and, if pregnancy is established, to follow it.

I/We confirm that we have entered this process of being recipient(s) of egg donation based on the representation of all parties that this process is anonymous. This means that I/we don't know, or wish to know the identity of the egg donor, nor will the egg donor, as assured by CHR, become aware of my/our identity.

I/We affirm that, in selecting our egg donor, we were given all the information about our egg donor we requested and required to make such a choice/ The choice of my/our egg donor was exclusively mine/ours and was reached after all our questions about our egg donor were answered by CHR staff to my/our fullest satisfaction. I/We also affirm my/our understanding that even the most complete medical testing cannot predict the performance of an egg donor with 100 percent accuracy. Indeed, the literature suggests that approximately 5 percent of even carefully selected egg donors will show disappointing results.

ADVERSE OUTCOMES

While pregnancy rates from egg donation cycles at CHR have historically been high, neither pregnancy, nor a successful delivery, in case of pregnancy, can be assured. Moreover, historical pregnancy rates do not necessarily reflect on future pregnancy rates, since pregnancy rates are dependent on multiple factors, which can change over time, not the least patient characteristics.

CHR and its staff, therefore, can make no guarantees whatsoever in regards to the outcome of egg donation cycles.

Amongst many potential adverse outcomes, any of the following alone, or in combination, may adversely affect egg donation IVF cycle outcome:

- The partner's sperm may not be collectable in time and/or donor semen may not arrive in time.
- The laboratory for technical reasons may not be able to process sperm in timely fashion.
- Fertilization of donor eggs may fail partially or completely.
- Embryo transfer into the recipient's uterus may be technically difficult, impossible, or medically contraindicated.
- A majority of transferred embryos will not implant in the uterus and/or continue to develop as a normal pregnancy.
- If a pregnancy occurs, it may not lead to a normal delivery. Pregnancies can be miscarried, can be outside the uterus (ectopic) or can die in utero prior to delivery. **A normal pregnancy can, therefore, never be guaranteed.** Moreover, pregnancy complications can occur like in any other, spontaneously conceived, pregnancy.
- Since egg donors in CHR's anonymous egg donation program are young, CHR in frozen egg cycle recommends the transfer of only 2 to 3 embryos. Twin pregnancies, and in very rare cases higher pregnancies can still occur. CHR perceives multiple pregnancies beyond twins, after fertility treatment, as potential complications of the IVF process.
- The IVF process, especially if not successful, may lead to psychological stress, anxieties and disappointment.
- Unforeseen circumstances may make laboratories or other medical facilities unavailable, or make physicians unavailable.

- Thawed eggs may not look normal and/or degenerate during culture.
- Equipment failure, infection of cultures, human errors and other unforeseen circumstances may result in loss or damage to eggs, sperm or embryos.
- Fertility medications are universally considered safe and are not considered to increase the risk of any medical disorders, including cancer. Longer term effect of fertility drugs are, however, still being evaluated, including breast and ovarian cancer risks.

I/We acknowledge all of these adverse outcomes and indemnify CHR, all of its associated corporate entities, its physicians and staff members from any liability should any of these adverse outcomes, indeed, occur.

It is CHR policy, whenever possible, to bring egg donors back for infectious retesting six months after their donation. You, therefore, have the option to choose below whether, under all circumstances, you want to wait until the donor has been retested or whether you want to go ahead with embryo transfer even if such testing has not yet been performed.

Even if you choose to go ahead independent of repeat infectious testing of the donor, you at the time of transfer will be one more time formally asked to reaffirm your choice, should by that point the donor not have been retested already.

WAIVER OF DONOR’S INFECTIOUS RETESTING (If this waiver is not signed, embryo transfer can only be performed after egg donor has undergone infectious retesting, at least six months after her egg donation.)

I/We have been advised of the following options: (i) an embryo transfer, using our donor’s eggs, only after the donor has been retested for infectious risks, including HIV, at least six (6) months after her donation; (ii) voiding the requirement of retesting, and proceeding with embryo transfer before the donor is retested. Choosing this second option, we have been advised that, even though egg donors are carefully screened under FDA guidelines before donation, such screening takes place a few weeks before their donation. Therefore, at least theoretically, they could have gotten infected between testing and egg donation, which would be detected in a six-month post-retrieval screening.

Having read above, I/we have decided to waive the requirement to have the donor retested for infectious diseases, six months after her donation, before I/we receive embryos, generated from her eggs.

Recipient Name	Recipient Signature	Date
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Partner Name (where applicable)	Partner Signature	Date
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FURTHER RECITATIONS

If CHR staff determines in the exercise of reasonable medical judgment that eggs, sperm or embryos are not viable, or otherwise medically suitable for use in embryo transfer or cryopreservation, such eggs, sperm and/or embryos will not be utilized by CHR and will be discarded.

IVF is considered a safe procedure (over 3 million children have so far been born worldwide after IVF), though IVF has been associated with a small increase in pregnancy complications and birth defects. The long-term effects of IVF are still largely unknown.

In addition to routine IVF, frozen egg cycle require the utilization of AZH and ICSI. The long-term effects of AZH and ICSI have so far not been determined. From available data, both procedures appear safe to offspring, though some data suggest that especially ICSI may be associated with an increase in some congenital abnormalities, and especially amongst male offspring. The use of ICSI cannot completely eliminate the risk of fertilization failure. AZH can damage the integrity of the embryo.

OWNERSHIP

Purchased frozen eggs from my/our egg donor and all embryos produced by CHR from these eggs are my/our property. Consequently, I/we reaffirm my/our parenthood of all children born to me/us from these embryos. I/We also reaffirm that the principle purpose for the creation of these embryos is my/our establishment of a pregnancy that will give me/us parenthood.

I/We have received assurances from CHR that, concomitantly, CHR has received a signed consent from the egg donor, in which she irrevocably gives all rights to her eggs and to any offspring thereof.

Since these embryos are my/our property, I/we have the right to determine their fate. Options are transfer into my (symbolically) our uterus; cryopreservation at CHR for future use; transfer into the uterus of another woman of my/our choice (a gestational carrier); "open-donation" to a third party; anonymous donation to a third party by donating the embryos to CHR for such a purpose, donation to CHR for research purposes; transfer of embryos to another IVF center and/or embryo bank. I/We also can at any given point ask for the ethical destruction of my/our embryos. CHR will follow my/our instructions based on written instruction forms, available at CHR. I/We hereby reaffirm that it is unethical to assign commercial value to embryos.

PAYMENTS

All predictable payments are to be made to CHR prior to the start of the egg donation cycle.

I/we are purchasing a total of _____ frozen eggs from my/our selected Donor # _____

Initials

Initials

