



Alabama
Fertility
Specialists

DONOR OOCYTE PROGRAM

Patient Information

Approved

INTRODUCTION

The Alabama Fertility Specialists (AFS) Donor Oocyte program was designed to assist women in becoming pregnant who would otherwise be infertile due to certain medical conditions, but are able to carry a pregnancy. These conditions include premature menopause, genetic disorders, and failure to produce adequate numbers of normal eggs. Oocytes (eggs) are retrieved from the donor, fertilized in the laboratory, and resulting embryos are transferred to the recipient.

Potential recipients will be included on a waiting list, matched with an oocyte donor, and enrolled into the program. This information was designed to assist you in completing your donor oocyte recipient cycle and to answer some of the questions that may arise during the process. We encourage you to keep these instructions with you for reference.

WHO'S WHO

Oocyte donors are consenting healthy women between 21 and 34 years of age who ovulate normally and have had either had a prior successful donation cycle or at least one biological child. Women approved for being an oocyte donor in our program have a normal health history, no family history of significant genetic disorders, and a normal physical examination. Laboratory screening for sexually transmitted diseases must all be negative.

Oocyte recipients are women who will receive eggs from the oocyte donor. These women have medical conditions which prevent normal conception, but are otherwise able to carry a pregnancy.

The IVF Team is comprised of the Program Director (Dr. Michael P. Steinkampf), the Nurse Coordinator (Karen R. Hammond, MSN, CRNP), additional nursing personnel, and laboratory technicians. The team works closely together to match the donor and recipient, monitor the stimulated cycles of the donor and recipient, retrieve the oocytes from the donor, fertilize the oocytes in the laboratory, and transfer the embryos to the recipient. The Program Director directly supervises all members of the IVF Team.

BEFORE YOU START YOUR OOCYTE RECIPIENT CYCLE

All patients interested in the Oocyte Donation Program at AFS must first make an appointment to see Dr. Michael P. Steinkampf, the Program Director. At that time, he will review the details of the program with you, and we will schedule any tests that need to be performed before the start of the process. All oocyte recipients must have the following tests performed:

1. Hysterosalpingogram (HSG), sonohysterogram (SHG) or hysteroscopy
2. Recent semen analysis on husband (within 12 months)
3. Baseline ultrasound
4. Uterine sounding
5. Rubella titer
6. Blood type and RH
7. HIV (AIDS) testing (husband and wife)
8. Hepatitis-B surface antigen (husband and wife)
9. Hepatitis-C (husband and wife)
10. Cytomegalovirus serum titer
11. Serum RPR (Syphilis) (husband and wife)
12. Chlamydia screen of the cervix
13. Gonorrhea culture of the cervix

In addition, hormonal evaluation may be necessary. The costs of these tests are **not** included in the treatment cycle charges.

After the results of all screening tests are received, all potential oocyte recipients must make a follow-up appointment with Dr. Steinkampf. At this visit, we will discuss all test results. In addition, the medications you will need to take to prepare your endometrium (uterine lining) for pregnancy will be reviewed, and financial arrangements finalized.

RECIPIENT MEDICATIONS

All oocyte recipients will take hormones (estrogen and progesterone) to simulate the normal hormonal changes that occur with ovulation and early pregnancy. Most patients are prescribed estradiol valerate (taken intramuscularly twice a week), and later, Progesterone in Oil (taken intramuscularly each day). Recipient who have any residual ovarian function will also take daily Lupron injections to suppress her own hormone production. You will be given specific instructions about the medications that are best for you. All of these medications are daily injections that we will be happy to teach you or your husband how to give. If your pregnancy test is positive, you will continue one of these medications for about the first 10-12 weeks of pregnancy. You will be instructed before your cycle exactly what medications to take and when.

"PREP" CYCLE

In order to maximize the chance for pregnancy, all oocyte recipients must first undergo a preparation ("prep") cycle. In this cycle, the oocyte recipient will take the prescribed medications and undergo monitoring to make sure the endometrium is prepared appropriately for a pregnancy to implant. The monitoring includes transvaginal sonography, blood tests (serum estradiol and progesterone levels) and an endometrial biopsy. Each of these tests must be performed at a specific time in your medication cycle.

If the test results from the "prep" cycle are normal, the same medication protocol will be repeated for the actual treatment cycle. If the test results are abnormal, the medication protocol will be adjusted, and a repeat "prep" cycle will be performed. The charges incurred during the "prep" cycle are **not** included in the treatment cycle charges.

SCREENING FOR THE OOCYTE DONOR

The process of screening for oocyte donors involves the following:

1. A Telephone Interview is conducted by one of the IVF nurses. The interview form is then sent to the Program Director. If approved, further information and a more detailed questionnaire are mailed to the potential oocyte donor.
2. The Oocyte Donor Questionnaire asks in-depth questions related to the personal, medical, social and family history of the potential oocyte donor. This form is completed by the potential donor and returned by mail to the IVF Team. Once reviewed by the Program Director, an interview will be scheduled.
3. The Interview with the Program Director provides an opportunity for Dr. Steinkampf and the potential oocyte donor to meet face to face. The interview includes confirmation and clarification of the information from the telephone interview and questionnaire. Other aspects of oocyte donation and the exact procedures involved will also be discussed. A thorough medical examination and transvaginal ultrasound will be performed at this visit.
4. Intelligence testing is performed on all prospective oocyte donors. Only women scoring a minimum of 100 are allowed to continue in the oocyte donation program.

5. Laboratory evaluation includes the following tests:

1. Blood type and Rh
2. HIV (AIDS) testing
3. Hepatitis-B
4. Hepatitis-C
5. Serum RPR (Syphilis)
6. Chlamydia screen of the cervix
7. Gonorrhea culture of the cervix

Additional tests may include hormonal testing and other indicated tests, such as screening for sickle cell, cystic fibrosis, thalassemia, and Tay-Sachs traits.

5. Consent to anonymous oocyte donation will be signed by each potential oocyte donor accepted into the program.

MATCHING OF RECIPIENT AND DONOR

Donor and recipient will be matched by race. Any requests for cross-racial matching will be handled on an individual basis. The respective phenotypes (physical characteristics) of the donor and recipient will be matched as much as possible within the constraints of the number of donors and recipients in the program. No guarantees or details of phenotypic matching can be made. Matching with respect to blood type and Rh status will be done in a manner to maximize blood type matching and minimize the risk of Rh disease. The entire matching process is strictly confidential. You will be provided with basic non-identifying information about the donor. Of course, you have the right to reject the donor, and your name will be placed on the waiting list for the next appropriate match.

THE OOCYTE DONATION CYCLE

Donor Procedures

Once screened and matched with the recipient, the oocyte donation process will be initiated based on the menstrual cycle of the oocyte donor. Because there is evidence that the success rate is improved when more than one egg is obtained per cycle, medications are used to stimulate the growth of more than one follicle. Each follicle contains one egg. By using the injectable medications Lupron, Follistim, and Menopur, multiple follicles, and therefore, multiple eggs, develop.

Since the medications will cause several follicles to grow at the same time, the development must be monitored with sonography and hormone testing. Donors must be frequently monitored in our office with blood tests and ultrasound examinations.

The actual retrieval is performed in our office. The procedure is guided by transvaginal ultrasound. A needle is advanced through the vagina and into each ovarian follicle. All mature follicles will be aspirated. The eggs retrieved will be inseminated with the sperm of the recipient's husband (or a sperm donor, if warranted).

Recipient Procedures

A member of the IVF Team will contact the oocyte recipient to instruct her exactly when to begin taking the prescribed medications. If the recipient is taking Lupron, a transvaginal ultrasound and estradiol level will be obtained prior to beginning the estradiol valerate. When the date of the oocyte retrieval is determined, you will be notified when to begin progesterone injections. We will also make arrangements for your husband to provide a semen sample for insemination of the eggs. We will contact you following the donor's retrieval to let you know how many eggs were retrieved. All eggs retrieved will be inseminated with the sperm of the recipient's husband. We will again contact you the day after the egg retrieval to let you know how many eggs fertilized and schedule the time of your embryo transfer. Generally, two or three embryos are transferred.

EMBRYO TRANSFER

The embryo transfer is usually performed three to five days after the egg retrieval. This procedure involves placing the embryo up through the cervix into uterus using a thin plastic catheter. Prior to this day, you will be given a prescription for an antibiotic (Doxycycline). Please let your doctor and nurse know if you have any allergies to antibiotics. You will take one capsule the morning of the embryo transfer and the other one before you go to bed that night.

Your nurse will tell you what time to arrive for your embryo transfer. The egg retrieval and does not require any anesthesia. At AFS, most embryo transfers are performed under ultrasound guidance; therefore, please arrive at our office with a full bladder. A speculum will be inserted into your vagina and your cervix cleaned with a sterile solution. A "practice" embryo transfer with an empty catheter will be performed first. Then, the catheter with the embryos will be inserted into your uterus, and the embryos deposited. This procedure usually takes about 5-10 minutes and is very similar to having an intrauterine insemination. Any discomfort from the transfer is minimal. Following the procedure, you will be taken to the recovery room to lie down for 30 minutes before being discharged home.

Extra Embryos

You have the option of cryopreserving (freezing) extra embryos that are not transferred during the cycle in which these embryos are created. The AFS laboratory will determine which extra embryos are suitable for freezing. A separate consent form for embryo cryopreservation must be signed by the recipient and her husband and payment must be made prior to beginning the treatment cycle. If no embryos are frozen, the fee for cryopreservation will be refunded.

ACTIVITY

Following the embryo transfer, we recommend that you relax for the remainder of the day as if you are recovering from a minor surgical procedure. We also recommend that you abstain from intercourse for at least one week after the transfer. You may otherwise resume any normal activity except excessive physical exertion.

CYCLE CANCELLATION

An oocyte donation cycle may be cancelled for any of the following reasons:

- development of only one or two follicles by the donor
- premature LH surge by the donor
- premature ovulation by the donor
- inadequate follicle growth/poor response by the donor
- failure of sperm to fertilize eggs
- inadequate endometrial growth or estrogen level by the recipient

If the oocyte donation cycle is cancelled because of a poor response by the recipient, the oocytes will be retrieved from the donor, fertilized with the sperm of the recipient's husband, and cryopreserved for embryo transfer in a subsequent cycle.

FINANCIAL AGREEMENT

A deposit of \$1000 must be paid prior to being included on the oocyte donation waiting list. This fee is non-refundable, but will be applied to the total charges for the cycle. Once a donor is matched, all remaining fees for the oocyte donation cycle must be paid before a donor begins any treatment medications. Once the cycle has begun, these fees are non-refundable. Charges for a cancelled cycle will be prorated. A detailed description of the charges is attached.

CONFIDENTIALITY

The identity of the donor and recipient, as well as all other information obtained in the oocyte donor screening process will be kept strictly confidential. The identity of the donor will not be made know to the recipient, nor will the recipient be identified to the donor.

QUESTIONS

Any questions may be directed to Karen Hammond, MSN, CRNP or to Dr. Steinkampf at (205)874-0000.

Oocyte Recipient Fees

Please note that all fees are subject to change without notice.

The following fees must be paid in advance of beginning an IVF treatment cycle:

Description	CPT Code	Fee
Transvaginal Oocyte Retrieval	58970	1,650
Ultrasound Guidance for Oocyte Retrieval	76948	400
Complete Semen Analysis	89320	40
Complex Sperm Prep for IVF	89261	200
Oocyte Identification	89254	650
Insemination of Oocytes	89268	200
Culture of Oocyte/Embryos < 4 days	89250	2,300
Preparation of Embryos for Transfer	89255	250
Practice Transfer Catheter	99070	60
Embryo Transfer	58974	300
Ultrasound Guidance for Embryo Transfer	76942	250
TOTAL		6,300

The following fees are based upon one recipient versus two recipients for a single donor:

Description	One Recipient	Two Recipients
Administrative Fee *	\$ 1,000	\$ 1,200
Donor Screening (including laboratory screening)	2,500	1,250
Donor Medications	3,000	2,000
Donor Monitoring	1,450	750
Donor Compensation	3,000	1,500
TOTAL DUE AT START OF CYCLE	\$17,250	\$13,000

The following fees must be paid in advance of beginning an IVF treatment cycle, if recommended by the physician:

Description	CPT Code	Fee
Intracytoplasmic Sperm Injection, ≤ 10 eggs	89280	1,000
Intracytoplasmic Sperm Injection, > 10 eggs	89281	1,000
Assisted Embryo Hatching	89253	750
Extended Embryo Culture	89272	200
Embryo Cryopreservation (includes one year storage)	89258	750
Annual Embryo Storage Fee (per year)	89342	300
Thaw/Prepare Frozen Embryos for Transfer	89352	800
Sperm Cryopreservation	89259	300
Thawing of Cryopreserved Sperm/Semen	89352	150
Annual Sperm Storage Fee (per year)	89343	300

* Administrative Fee includes donor evaluation and screening and donor/recipient matching, donor/recipient medical/nursing management.

Consent to Receive Embryos Obtained from Oocyte Donation

Alabama Fertility Specialists

We voluntarily authorize and direct Dr. Michael P. Steinkampf or his associates or assistants to perform procedures necessary for the transfer of embryos obtained from oocyte (egg) donation to the wife.

1. Explanation of Procedure

Both husband and wife understand that donor oocytes are used to achieve a pregnancy in a woman who is infertile due to certain medical conditions, but otherwise able to carry a pregnancy. In this procedure, oocytes obtained from another woman will be mixed with the sperm of _____ (husband) and the fertilized eggs will be transferred to _____ (wife), who has been treated with hormones to prepare her uterus to implant and maintain a pregnancy.

2. Selection of Oocyte Donor

Both the husband and wife consent and authorize Dr. Michael P. Steinkampf or his associates or assistants to select an appropriate oocyte donor. I understand that basic, non-identifying characteristics of the oocyte donor will be provided, and we have the right to decline to use a particular donor prior to beginning the treatment cycle.

3. Risks and Discomforts

Discomfort: Mild discomfort may result from blood drawing, medicine injections, ultrasound examinations, and the embryo transfer.

Reaction to Medication(s): Adverse reactions may result from the prescribed medications. We understand that any drug can cause side effects. In rare cases, treatment with estrogen or progesterone may result in blood clots in the legs, heart, lung or brain. We understand that there is also a risk of liver disease, gallstones, high blood pressure, and minor side effects such as abdominal bloating or breast tenderness. The most common side effects of leuprolide are hot flashes and vaginal dryness. We understand that other risks, not reasonably identifiable by the physician, may exist.

Pregnancy Complications and Birth Defects: The risk of birth defects from pregnancy arising as a result from oocyte donation is not known to be greater than that in spontaneously (naturally) occurring pregnancies. We understand, however, that any pregnancy may result in a child with birth defects. In addition, not all congenital defects are known at birth, and some physical and mental disorders present in adolescence or adulthood. Since more than one embryo may be transferred, the potential for multiple pregnancy exists. We understand that, if pregnancy does occur, there is a possibility of complications during the pregnancy and childbirth and that, despite screening of oocyte donors for genetic disorders, there is a possibility of the birth of an infant who is abnormal or who has undesirable hereditary tendencies.

Sexually Transmitted Diseases: We understand that although oocyte donors are screened for sexually transmitted diseases, including HIV (AIDS), gonorrhea, syphilis, chlamydia, and hepatitis, there is no way to protect the oocyte recipient completely or guarantee that the oocyte and infant are free from such disease.

Other Complications: We understand that other problems may prevent successful completion of the treatment cycle, such as ovulation occurring before the egg retrieval procedure is performed, medical emergencies which may make the egg retrieval facility unavailable, inability to retrieve an egg, failure of the eggs to fertilize, or an accident resulting in the loss or damage of the egg(s) and/or embryo(s). Additionally, implantation (pregnancy) may not occur.

4. Confidentiality

We understand that the medical records pertaining to the oocyte recipient shall be kept confidential and shall be subject to inspection only upon an order from the court for good and just cause shown. In the case of anonymous egg donation, both husband and wife understand and agree not to seek the identify of the donor(s) and that the oocyte donor has been advised and has agreed not to seek the identity of the oocyte recipient(s).

Data from your ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, 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 CDC has that identifies you will not be disclosed to anyone else without your consent.

5. Rights and Responsibilities of the Oocyte Recipient and Spouse

Cryopreservation: We understand that any embryo that is not transferred, but continues to develop normally, may be cryopreserved (frozen) for future attempts to achieve pregnancy in accordance with the policies and procedures of the In Vitro Fertilization (IVF) Program at Alabama Fertility Specialists. A separate consent form must be signed by both the husband and wife to allow this procedure. We agree that if we do not consent to cryopreserve any extra embryos, then the control and direction of these embryos will be relinquished to Alabama Fertility Specialists.

Legitimate Children and Heirs: We understand and agree that any children conceived or born as a result of this treatment shall be considered as naturally conceived and born of their union and confers on both parents and child all the rights, privileges, duties and obligations thereto.

Financial Responsibility: We understand that Dr. Michael P. Steinkampf and Alabama Fertility Specialists, Inc. have made no provision for monetary compensation in the event of physical injury from the procedure and, in the event of such injury to the wife, medical treatment shall be provided, but shall be the financial responsibility of the husband and wife.

6. Authorization for Successive Procedures

We understand that it may be necessary to undergo the procedures more than once, and hereby consent to each successive procedure until such time as consent is withdrawn by written notification of Dr. Michael Steinkampf. Consent is given for the performance of the procedures, and to operations and procedures in addition to or different from those now contemplated, whether or not arising from presently unforeseen conditions, which Dr. Steinkampf or his associates or assistants may consider necessary or advisable in the course of treatment.

7. Acknowledgment and Understanding

We acknowledge that we have received full explanation of the procedures and risks described herein, and that they are understood. We acknowledge that no warranty or guarantee has been made as to the results of these procedures. We acknowledge that we have had a full opportunity to discuss and ask questions about the procedures, their purposes, and nature, as well as reasonably foreseeable risks, and that all questions have been answered to our satisfaction. We have read this consent and fully understand the contents. We execute this consent of our own free will and accord.

_____/_____/_____
Signature of Wife

_____/_____/_____
Signature of Husband

_____/_____/_____
Signature of Witness

**Consent to Shared Anonymous Egg Donor In Vitro Fertilization Cycle
ALABAMA FERTILITY SEPECIALISTS**

By signing this consent form, you agree to undergo a Shared Anonymous Egg Donor In Vitro Fertilization (IVF) cycle at Alabama Fertility Specialists (AFS). In this treatment cycle, an anonymous egg donor will have her eggs retrieved, and the eggs will be shared among two infertile patients, who will attempt to get pregnant using the donated eggs. You understand and agree to the following aspects of this treatment cycle:

The number of eggs will be split fairly and equitably by AFS between the two infertile patients. Only anonymous donors who have previously produced and donated good quality eggs, and whose donation cycle has resulted in a successful pregnancy, will be used for this treatment cycle. However, due to variations in number of eggs obtained and differences in fertilization rates among patients, it is possible that one infertile patient may receive more eggs or embryos than the other patient.

AFS makes no guarantee that either patient will receive eggs or embryos during this treatment cycle.

If this treatment cycle is canceled before completion, your account will be credited for any services not performed.

You will be informed of the number of eggs obtained from the anonymous egg donor in this treatment cycle, but you will not be informed of whether the eggs used by the other infertile patient sharing the eggs in this cycle fertilized, whether the other infertile patient in this treatment cycle got pregnant, or any other information about the anonymous egg donor or the other infertile patient involved in this treatment cycle except as specified in the AFS IVF Patient Information Brochure, or as deemed medically necessary by the IVF Program Director.

You are not waiving any of your legal rights by signing this consent form. Your signature below indicates that you agree to undergo this treatment. You will receive a copy of this informed consent.

Signature of Woman (wife)	Date
Signature of Husband (if applicable)	Date
Signature of Witness	Date

CONSENT TO CRYOPRESERVATION OF EMBRYOS ALABAMA FERTILITY SPECIALISTS

We, the undersigned, who are husband and wife, authorize the cryopreservation of embryos resulting from in vitro fertilization (IVF), subject to the guidelines and restrictions listed in this consent form. The following aspects of this process have been explained to us.

Purpose

Embryo cryopreservation (cooling and storage at very low temperatures) is a method of prolonging viability of embryos for later transfer and pregnancy.

Procedures

Embryos obtained by in vitro fertilization in excess of the number deemed optimal for transfer into the wife's uterus during the menstrual cycle in which they are obtained will be cryopreserved and stored at very low temperatures. The time limit of storage of cryopreserved embryos is unknown, but probably exceeds three years. These "extra" embryos may be thawed and transferred into the wife's uterus during a subsequent menstrual cycle for the purpose of establishing pregnancy. Monitoring and storage of the embryos, as well as establishing the timing for embryo transfer during a subsequent cycle, is the responsibility of the members of the IVF program. The control, direction and final disposition of the frozen embryos is the responsibility of the husband and wife, subject to the guidelines and restrictions listed in this Consent Form.

Benefits

The cryopreservation of embryos allows an attempt to establish pregnancy without the expense and risks of another IVF cycle. In addition, limiting the number of embryos transferred during the initial IVF procedure decreased the risk of multiple pregnancy in that cycle.

Risks

The major risk from cryopreservation of embryos is the failure to establish pregnancy. Extensive experience with animals and the initial human experience have not demonstrated any increase in birth defects in pregnancies using cryopreserved embryos beyond that seen in natural conceptions. Since storage of cryopreserved embryos requires mechanical support, it is possible that equipment failure could result in loss of embryos. Although freezer systems are available to decrease the likelihood of malfunction, unforeseen situations could occur which are beyond the control of the IVF program.

Alternative Procedures

1. The number of oocytes that are inseminated may be restricted, i.e., fewer embryos could be obtained if not all the eggs are mixed with sperm.
2. Excess embryos may be transferred into the wife's uterus in the cycle in which they are obtained (increasing the risk of multiple pregnancy).
3. Control of disposition of the embryos may be transferred (in writing) to the physicians of the IVF program for use according to medical and ethical guidelines approved by Alabama Fertility Specialists.
4. The husband and wife may elect to discard the embryos.

Guidelines and Restrictions for the Storage and Disposition of Cryopreserved Embryos

Alabama Fertility Specialists agrees to be responsible for the storage of cryopreserved embryos for a period of three (3) years from the time of the egg retrieval that resulted in the production of the embryos. During that period, the responsibility for control and direction for alternate disposition of these tissues rests with the undersigned wife and husband provided that the only options for disposition of these embryos are as listed below:

1. The couple may request the transfer of one or more of the embryos to the wife's uterus.
2. The couple may elect to discard the embryos.
3. The couple may request (in writing) that the embryos be released from the custody of Alabama Fertility Specialists and transferred to the custody of a physician, hospital, laboratory, clinic, or health care facility. This request will be complied with provided that the proposed disposition of the tissues is approved by Dr. Steinkampf and Alabama Fertility Specialists is released from all responsibility for the disposition of the embryos.

Control and direction of cryopreserved embryos will be relinquished to Alabama Fertility Specialists under any of the following conditions:

1. Dissolution of the marriage of the undersigned wife and husband by court decree (divorce), or
2. In the event of the death of one or both of the undersigned wife and husband, or
3. In the event both the husband and wife should become mentally and physically incapacitated, or
4. After three (3) years have elapsed from the time of the egg retrieval that resulted in the production of the embryos.

We the undersigned husband and wife have read and understand the information provided in this form, consent to the procedures or treatment described above, and agree to abide by the guidelines and restrictions for the storage and disposition of cryopreserved embryos.

(Signature of wife)

_____/_____/_____
(Date)

(Signature of husband)

_____/_____/_____
(Date)

(Signature of witness)

_____/_____/_____
(Date)