

Reproductive Medicine & Infertility Associates
DONOR RECIPIENT INFORMATIONAL PACKET

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INTRODUCTION

Reproductive Medicine and Infertility Associates (RMIA) recognizes the fact that being faced with infertility can be an overwhelming experience. When donor oocytes (eggs) are recommended, those feelings are often magnified. We have included information on stress and infertility at the end of this section.

RMIA offers several donor oocyte programs for couples who are unable to utilize the female partner's own eggs to achieve a successful pregnancy. The information that follows is designed to help you understand our various donor egg programs and should serve as an excellent resource as you move forward through your individual program.

We feel strongly that, through proper education, you will be better able to make key decisions about your care which will, in turn, greatly reduce the stress and anxiety often felt by couples as they progress through this complex process.

We at RMIA wish you a successful outcome.

THIRD PARTY REPRODUCTION

“Donor eggs offer the possibility of childbearing to women whose ovaries are absent, or whose ovaries do not reliably produce eggs that can be fertilized. The first pregnancy achieved with the use of donor egg was reported in 1984. By using *in vitro* fertilization (IVF) techniques, eggs are obtained from the ovaries of another woman (donor), fertilized by sperm from the recipient’s partner, and the resulting embryos placed into the recipient’s uterus.” (American Society for Reproductive Medicine, *Third Party Reproduction, A guide for Patients*. 1996) Third party reproduction includes all procedures in which patients utilize donor sperm, donor eggs, and/or gestational carriers.

Third party reproduction is currently regulated by the Food and Drug Administration (FDA). On May 25, 2005 the FDA instituted stricter screening and testing requirements on all procedures utilizing human cells, tissues, and cellular and tissue-based products. This therefore includes all procedures categorized as third party reproduction. RMIA has expanded its screening and testing procedures to comply with these requirements, making its already careful screening process to determine donor eligibility even more thorough.

WHEN ARE DONOR OOCYTES RECOMMENDED?

There are many reasons why a physician may recommend *in vitro* fertilization with donor oocytes. The following list includes some, but certainly not all, of the reasons for considering the use of donor eggs:

- Advanced maternal age
- Premature ovarian failure
- Decreased ovarian reserve
- Surgical removal of ovaries
- Congenital absence of functioning ovaries
- History of chemotherapy or radiation treatments to abdominal/pelvic area
- Bypass risk of passing on a serious genetically linked disease/disorder to a child.

WHO ARE THE WOMEN THAT DONATE THEIR EGGS?

Many young women contact RMIA to inquire about becoming an egg donor. Although hundreds of women inquire, only a relatively few of them are accepted into the final screening process and even fewer pass through all phases of the intense screening and testing process. Ideal candidates must fit the following criteria:

- They must be between the ages of 20 and 31 years of age.
- Women who are 27 years old or older must have 'proven fertility' (at least one prior pregnancy and live birth).
- Body Mass Index (weight, measured in kilograms, divided by the square of height, measured in meters) can not be greater than 30.
- She must not smoke cigarettes for at least 30 days prior to starting treatment, and she must agree not to smoke during treatment.
- Her family history must be available for review by a physician and, in some cases, a genetic counselor. (Thus, adoptees with no access to genetic/birth parents are ineligible, except in uncommon circumstances and only with the consent of the recipient.)
- Potential donors must pass all screening and testing requirements. (See page 9).

Women contact RMIA to become an egg donor for a variety of reasons. Many women learn about egg donation via internet searches, the yellow pages, or from advertisements. A large number of our donors know a relative or acquaintance who experienced infertility and, for that reason, they have decided to take an active role in helping couples by donating their eggs. Although anonymous donors are monetarily compensated for their time and inconvenience, the majority of the donors are doing so primarily for altruistic reasons rather than for monetary compensation.

HOW DO I/WE FIND AN EGG DONOR?

The answer to this question depends upon the type of donor you are planning to use. Basically, there are two types of oocyte donors – known and anonymous. You may elect to use the oocytes of someone whom you know, such as a friend or relative, or you may elect to use an anonymous donor. All donors, regardless of familiarity, will be thoroughly screened and tested using the process outlined on page 9.

If you plan to use an anonymous donor, your information will be added to the recipient waiting list on the day of your program start visit (see the *In Vitro* Fertilization section of the Patient Handbook for a detailed description of the program start visit). Due to the high intensity of the donor screening process, recipients may wait several months to a year before being matched with an appropriate donor. Some individuals or couples elect to run advertisements on their own to ‘recruit’ an anonymous donor. This is a relatively inexpensive option and, although there are no guarantees, this option may greatly reduce your waiting period. If you would like more information on this option, please contact RMIA; and we will be happy to assist you with this process.

If you know of someone who is interested in donating specifically for you, please let us know and we will initiate the eligibility determination process for that individual.

THE ANONYMOUS DONOR/RECIPIENT MATCHING PROCESS

Information, such as your name, physical characteristics, and specific program in which you have enrolled, is added to the bottom of the recipient waiting list upon completion of your program start visit. As recipients are matched with donors, you move up on the list. Thus, you are continuously moving closer to actually being matched with a donor. Once ready for matching, the donor coordinator will review the program in which the recipient is interested (refer to page 15).

If the recipient is enrolled in a shared donor program, the donor coordinator will locate an additional recipient who is also enrolled in the shared donor program and will then match, *as closely as possible*, the general physical characteristics of the recipients to that of the donor. (General physical characteristics consist of ethnicity, height, weight, and hair color). The donor coordinator will then contact the recipients in order to update any testing that may need to be done and to synchronize their menstrual cycles so that IVF dates can be reviewed and scheduled.

If the recipient elected to enroll in the choice shared or exclusive donor program (regular or FCWP), the donor coordinator will locate an available/suitable donor and will send a letter with the donor's characteristics (including: height, weight, hair and eye color, blood type, ethnic background, education, hobbies and interests) to the recipient. Upon receipt and review of the information provided, the recipient will have the option to accept or decline that particular donor. If the recipient elects to decline that donor, she would simply return the letter indicating the declination of the donor and would then wait to be contacted when the next suitable donor became available.

Please refer all questions related to the matching process to our donor coordinator.

CONFIDENTIALITY / DISCLOSURES

Anonymous donors understand and agree that they shall have no right to learn the identity of the recipient(s). The donor will not be given any information regarding fertilization, pregnancy, children, or cryopreservation of pre-embryos. The donor understands that the recipient(s) will similarly have no right to learn the identity of the donor. All donors must complete the screening process on page 9 of this packet. Any results that are deemed abnormal would disqualify the donor from our program, or, in special circumstances, be disclosed to the recipient(s) for acceptance prior to final matching. In addition, recipients will receive donor characteristics and genetic history following their second confirmation of pregnancy ultrasound. Such information supplied to the recipient(s) shall be without any identifying information. RMIA will exercise its best efforts to ensure the confidentiality of the donor and the recipients(s) and all identifying information to the full extent allowed and provided by law.

WHAT IS THE SCREENING/TESTING PROCESS FOR DONORS?

The eligibility determination process for all donor applicants is extensive. RMIA abides by standards set forth by the American Society for Reproductive Medicine (ASRM) as well as the rules instituted by the Food and Drug Administration (FDA).

If a potential donor meets all of the preliminary criteria, she will complete (usually orally) an initial screening questionnaire. All applicants passing the initial screening will then be sent a second, more extensive, medical/genetic history questionnaire. Information contained on this application is reviewed by the prescreening nurse, a physician and, if indicated, a genetic counselor. Upon approval of both the oral and the written applications, the applicant will be contacted to proceed with the donor eligibility determination process.

The donor, and significant other when applicable, will have two or more appointments at RMIA during which the following will be completed:

- Viewing of the informational donor video
- Signing of consent confirming the potential donor's wish to proceed with the donor eligibility determination process
- Hormonal testing to evaluate "ovarian reserve"
- Cystic Fibrosis screening
- Ethnically indicated screening (such as Tay-Sachs or sickle cell anemia)
- Completion of SLC-90-R psychological assessment tool
- Psychological review/appointment with psychologist
- Injection training
- Blood typing (ABO/Rh)
- Infectious Disease Screening (HIV 1 & 2 antibody, Hep B surface antigen, Hep B Core (total antibody), Hep C antibody, RPR (syphilis test), HIV 1 (nucleic acid testing), Hep B (nucleic acid testing), Hep C (nucleic acid testing), Chlamydia and Gonorrhea screening ***
- Physical Examination
- Signing of consent to participate as an oocyte donor

If the potential donor has a consort, s/he must be present for the following:

- Infectious Disease Testing (HIV 1 & 2, Hep B surface antigen, and Hep C antibody)
- Psychologist appointment (if married)
- Co-signing (if married) of consent to participate as an oocyte donor

After all of the above items have been completed, the chart will be reviewed once again by a physician. Upon approval, the chart will be forwarded on to the donor coordinator and she will begin the donor / recipient(s) matching process.

*** Additional testing may be performed if mandated by changes in FDA requirements



MY PHYSICIAN ORDERED A MOCK CYCLE. WHAT IS A MOCK CYCLE?

After meeting with the physician for your program start visit and consent signing, the physician will initiate orders for your IVF cycle. These orders will typically include what is referred to as a 'mock cycle' in preparation for the actual donated oocyte cycle. A mock cycle provides valuable information, as it gives your physician the opportunity to observe how your endometrial lining responds to hormonal medications. Individual responses can be somewhat variable. Mock cycles are typically done immediately after the program start visit.

If a mock cycle has been ordered you can anticipate the following protocol:

- Oral Contraceptive Pills (OCP's) utilized for a minimum of 14 days
- Expect some light spotting or bleeding following discontinuation of the birth control pill
- Oral or intravaginal estrogen as directed by the physician.
- After approximately 9 or 10 days of estrogen therapy, a vaginal ultrasound will be performed to measure your endometrial lining.
 - If your uterine lining is determined to be of adequate thickness ($\geq 8\text{mm}'\text{s}$), you will be given additional instructions to begin Provera in order to induce a period
 - If your lining is determined not to be of adequate thickness ($< 8\text{mm}'\text{s}$), your physician will gradually increase your estrogen dosage. This may be done by adding to the number of times you take the tablets each day and/or by utilizing an additional form (e.g., transdermal or intramuscular) of estrogen supplementation. Periodic measurements of your endometrial lining and adjustments of your estrogen therapy will continue to be made until your lining has reached the desired thickness.

Once the mock cycle has been completed, the physician knows what specific medication regimen you will need to prepare your endometrium for your embryo transfer. The actual transfer, of course, does not occur until after the matching process has been completed and the donor's oocytes have been retrieved and fertilized.

WHAT MEDICATIONS ARE PRESCRIBED FOR THE RECIPIENT COUPLE?

If using fresh sperm, the male partner will be required to take oral antibiotics, typically Doxycycline, twice a day through the morning of the donor's oocyte retrieval - as this is the same day the semen specimen will be collected.

The oocyte recipient's treatment plan will essentially be the same as it was during the mock cycle now that we know what amount of estrogen supplementation is needed in order for her endometrial lining to reach the desired thickness. The biggest difference between a mock cycle and the actual embryo transfer cycle is that the use of Lupron that will be given prior to starting to take estrogen and Provera will not be given as it was in the mock cycle. The recipient's schedule will be coordinated with the donor's cycle so that her endometrial lining is ready to receive the embryos three to five days after the oocytes have been retrieved.

On the following two pages you will find a complete listing of all medications that are currently (as of September 2008) prescribed for oocyte recipients. You may or may not be prescribed any medication on this list. **YOUR INDIVIDUALIZED MEDICATION REGIMEN WILL BE DISCUSSED WITH YOU, IN DETAIL, AS YOU PROGRESS THROUGH THE IVF CYCLE.**

RECIPIENT MEDICATION LIST

- ***Prenatal or multivitamin*** – This supplement will help to assure you have the necessary vitamins and minerals needed for a healthy pregnancy. Either is fine as long as it contains at least 400 mcg of folic acid. This can be started immediately.
- ***81mg (baby) aspirin*** – This has been shown to enhance the blood flow to the uterus thus increasing implantation rates.
- ***Birth Control Pills (OCP's)*** – These are used to both regulate reproductive hormones and to help coordinate scheduling with the donor.
- ***Lupron Depot*** – A one-time intramuscular injection that will suppress the reproductive hormones (FSH and LH), produced in your pituitary gland that stimulate the development of ovarian follicles (fluid-filled sacs containing the oocytes) and trigger ovulation. The effects of this medication last approximately four weeks.
- ***Luprolide Acetate*** – A daily subcutaneous injection that will suppress the reproductive hormones (FSH and LH), produced in your pituitary gland that stimulate the development of ovarian follicles (fluid-filled sacs containing the oocytes) and trigger ovulation. The effects of this medication last approximately four weeks.
- ***Doxycycline*** – A synthetic tetracycline derivative that will help prevent the transmission of bacterial infections between partners.
- ***Flagyl*** – This is used for treatment of bacterial vaginosis and also in combination with Doxycycline to treat endometritis (a uterine infection).
- ***Endometrin*** – A tablet form of progesterone that is inserted vaginally. Usually in conjunction with intra-muscular progesterone.
- ***Estrace/Femtrace*** – These are estrogen tablets that are taken 2 – 4 times daily to help thicken your endometrial lining.
- ***Estraderm/Vivelle (estrogen patch)*** – This patch may be used in conjunction with Estrace tablets to thicken your endometrial lining.
- ***Estradiol valerate*** – An injectable form of estrogen that may be used in conjunction with Estrace to help thicken your endometrial lining.

- ***Progesterone*** – This medication is used to help prepare your uterine lining for the implantation of the embryo. Progesterone is required to maintain the pregnancy also. It is typically administered by intramuscular injections 1 – 2 times daily.
- ***Prometrium*** – This is a tablet form of progesterone and can be administered either orally or intravaginally, usually in conjunction with intramuscular progesterone.
- ***Heparin/Lovenox*** – These are anticoagulants that are given as subcutaneous injections once or twice a day. They are used in some women who have had repeated spontaneous abortions or who may have an underlying clotting disorder. Only one of these medications is used at any given time.
- ***Valium (Diazepam)*** – This medication is given to decrease anxiety and to relax your muscles prior to the embryo transfer.
- ***Medrol (Methylprednisolone)*** – This steroid is prescribed to prevent inflammation of the uterine lining to assist with pre-embryo implantation.
- ***Viagra suppositories (Sildenafil Citrate)*** – These may increase the blood flow to the uterus helping with uterine growth and overall embryo implantation.

WHAT IS THE DONOR'S CYCLE LIKE?

Once the donor has been determined to be eligible and has been matched with a recipient, she will undergo another complete set of infectious disease testing at the start of the actual oocyte donation cycle to ensure that all infectious disease test results are current, within 30 days of the oocyte retrieval.

All donors are started on a course of hormonal contraception (e.g., OCP's or Nuvaring) in order to coordinate the timing of the donor's cycle with that of the recipient(s). Donors also take an oral antibiotic to decrease the risk of infection at the time of oocyte retrieval. The donor will be on daily subcutaneous Lupron injections and will eventually be placed on a course of injectable fertility drugs to stimulate the development of her ovarian follicles. These medications (Bravelle, Gonal-F, Follistim, Repronex, and/or Menopur) are referred to as gonadatropins. Typically, donors take stimulation medications for approximately 10 \pm 2 days. When the follicles reach a predetermined size, near the end of the stimulation cycle, donors may begin taking another injectable medication (Ganirelix Acetate or Cetrotide), which is taken to prevent ovulation during the final stages of maturation.

Throughout the course of treatment the donor will make multiple trips to RMIA in order to have blood hormone levels tested and to assess the size of her follicles via vaginal ultrasound examination. When it has been determined that the maximum number of mature follicles has been reached, an injection of hCG will be given to trigger the final maturation process in preparation for the egg retrieval. You and your partner will be notified with additional instructions regarding medications and necessary appointment scheduling.

The TVOR (Trans-Vaginal Oocyte Retrieval) is the procedure performed to obtain/retrieve oocytes from the donor. This is done under anesthesia. Your partner will need to be available on that morning to provide our laboratory with a semen specimen for fertilization.

DONOR OOCYTE PROGRAMS***

FCWP Known Donor Program – With this program, the recipient/recipient couple provides their known donor for incorporation into the program. If the known donor meets the age and prescreening qualifications, then the recipient may opt to do a warranty program using their known donor. In this case, we would base the cost of the FCWP on the age of the donor and all eggs would go to that recipient.

FCWP Shared Anonymous Donor Oocyte Program – In this program, the recipient will share the eggs obtained from the donor with a second recipient and the cost of the program is divided equally between both recipients. The eggs obtained from the donor are also shared equally between both recipients.

FCWP Exclusive Anonymous Donor Oocyte Program – In August of 2000 RMIA launched its second FCWP donor oocyte program with the intention of providing patients the opportunity to utilize a given donor's services exclusively. In this program, the entire cost of the donor's services is fully absorbed by the recipient and, in return, the recipient receives all of the eggs obtained from that particular donor.

FCWP Shared Choice Anonymous Donor Program – This program is a combination of the shared program in that you split the eggs with another recipient and the exclusive program in that you get information on the donor in advance to either accept or decline that donor.

Regular Known Donor Program – The recipient/recipient couple provides their known donor for incorporation into the program. Certain criteria used for an anonymous donor may be modified for a known donor in this program; however all requirements mandated by the FDA must be met. The program consists of one fresh IVF cycle. All costs associated with the donor are borne by the recipient, and the recipient therefore receives all of the eggs obtained from the donor.

Regular Anonymous Donor Program – This program offers the recipient one fresh IVF cycle. In this case, the services of the anonymous donor are exclusive to the recipient meaning that the recipient will bear all costs associated with the donor and, in turn, will receive all eggs obtained from the donor.

All programs are only available to women <51 years of age. In addition, women between the ages of 45 and 50 must have clearance from a perinatologist before proceeding with prescreening.

Note: Under the FCWP Donor Programs, if you wish to opt for a single embryo transfer and are approved by an RMIA physician, then an additional cost of 10% will be added to the program cost.

*** For a detailed description of the FCWP (Fertility Cost Warranty Program) and Regular IVF programs, please see the Financial Matters section of our website (www.rmia.com) and/or attend one of our monthly evening IVF seminars. Also, our business office staff is available to answer any questions about our various programs.

WHAT INFORMATION WILL WE RECEIVE ABOUT OUR DONOR?

FCWP Shared Anonymous Donor Oocyte Program – Our donor coordinator matches basic characteristics (ethnicity, height, weight, and hair color) *as closely as possible* to two recipients. Keep in mind, however, that these basic characteristic requirements may not all match. With that in mind, RMIA can not guarantee each recipient's request for a particular characteristic. Once a confirmed pregnancy is achieved, written information regarding the donor's characteristics, medical history, and past 3 generation family medical history is shared with the recipient(s).

FCWP Exclusive or Choice Shared Anonymous Donor Oocyte Program – With this program the recipient is permitted to select one donor whose eggs she will utilize exclusively. Physical characteristics of a donor, along with blood type, ethnic background, education, interests, and hobbies are shared with the potential recipient. The recipient has the option of accepting or declining that particular donor. If the recipient chooses to decline the donor selected by the donor coordinator, she would then wait for another potential donor.

Regular Anonymous Donor Program – Please see FCWP Exclusive Anonymous Donor Oocyte Program above. These two programs differ in the financial aspect, but the information provided to the recipient about the donor and the ability of the recipient to accept or decline a particular donor are the same.

FREQUENTLY ASKED QUESTIONS

- **If I become pregnant and deliver, would it be possible to use the same donor in the future?** Yes, if the donor is willing to participate and there are no health risks to the donor with doing additional stimulation and the donor meets all screening criteria.
- **Can I check in occasionally to see where we are at on the waiting list?** Yes, I would encourage this on occasion.
- **Can I see a picture of the donor?** No, the program is totally anonymous.
- **If I am doing the shared donor program, when do I receive information about the donor used?** You will receive the donor characteristics and medical history after an ongoing pregnancy has been confirmed by two ultrasounds, usually around 6 ½ weeks and 8 ½ weeks.
- **If there is something in my medical history that we want to avoid in my donor, can I make that request?** Yes, in making specific requests you need to realize this could delay the process of being matched with an available donor.
- **What happens if I have a failed cycle?** After meeting with the physician for a “Post-IVF Consult” and if you have frozen embryos available, the physician will initiate orders for a frozen embryo transfer. If you do not have any frozen embryos available, you will be added to the repeat cycle recipient list (this is included in the FCWP, however financial arrangements must be made for another cycle in the Regular program). This list is treated with priority for matching up with the next available/suitable donor.
- **Do I get matched up with the same donor for each cycle attempted?** No, a donor needs to wait three months after her retrieval before she is able to be stimulated again for an additional cycle. You, as the recipient, do not have such a requirement.

WHOM DO WE CALL WITH QUESTIONS?

If you have questions and would like to speak with someone at RMIA, please feel free to call us at 651-222-6050. You may find the following departments helpful as you proceed through the process of IVF using donor eggs.

- Donor Prescreening Coordinator
 - Questions about response to an advertisement.
 - Questions about the donor screening process.

- Donor Program Coordinator
 - Questions regarding the donor recipient waiting list.
 - Questions about the donor/recipient matching process.
 - Questions about the donor information letter you received.
 - Questions about response to an advertisement.
 - Questions about how to run your own advertisement.
 - All cycle scheduling questions.

- Business Office
 - Insurance questions.
 - Financial questions.
 - Questions about the various programs available.

- Level III Scheduler
 - Appointment Scheduling.

All other calls will be routed via Medical Records to the appropriate department.

STRESS AND INFERTILITY FACT SHEET

Infertility and stress often go hand and hand. The following information was excerpted from the “Stress and Infertility Fact Sheet” published by the *American Society for Reproductive Medicine*, Birmingham, Alabama (9/96).

“Stress is defined as any event that a person perceives as threatening or harmful. Stress can result in heightened activity of many body organs. This increased activity is offset by hormones secreted by the adrenal glands and through the nervous system. Acute stress can result in increased heart rate, blood pressure and respiration, as well as sweaty palms and cool, clammy skin. Chronic stress can also cause depression and result in changes in the immune system and sleep patterns.”

“Although infertility is a highly stressful experience, there is very little evidence that infertility can be caused by stress.”

“Research has shown that women undergoing treatment for infertility have a similar, and often higher, level of ‘stress’ as women dealing with life-threatening illnesses such as cancer and heart disease.”

“When diagnosed with infertility, many couples may no longer feel in control of their bodies or their life plan. Infertility can be a major crisis because the important life goal of parenthood is threatened. Most couples are accustomed to planning their lives. Experience has shown them that if they work hard at something, they can achieve it. With infertility, this may not be the case. Infertility testing and treatments can be physically, emotionally, and financially stressful. A couples’ intimacy is often reduced by the infertility experience, which further contributes to increased stress levels. Trying to coordinate medical appointments with career responsibilities can also increase pressures on infertile couples.”

TIPS FOR STRESS REDUCTION

- Keep the lines of communication open with your partner.
- Get emotional support so that you don’t feel isolated. Individual or couple counseling or support groups can help you cope. RESOLVE is a national support organization for couples with infertility. For information call Resolve National Helpline at 888-623-0744 or email info@resolve.org.
- Learn stress reduction techniques such as meditation or yoga.
- Avoid excessive intake of caffeine and other stimulants.
- Exercise regularly to release physical and emotional tension.
- Have a medical treatment plan that both you and your partner are comfortable with.

If you feel overwhelmed, please contact RMIA. Our licensed Psychologist would be happy to meet with you.

