

MicroSort®

A Division of the Genetics & IVF Institute

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Patient Information Packet For Participation In MicroSort® Separation of X- and Y-Sperm

This packet of information will provide you more specific details regarding participation in the MicroSort clinical trial study for preconception gender selection, the use of MicroSort sperm separation with IUI (intrauterine insemination; placement of sperm directly into the uterus through the natural opening in the cervix using a catheter), and recommended plan of care. Please take the time to compile a list of any questions or concerns as you read through these materials. Once you have reviewed this packet of information, if you have additional questions please contact MicroSort to have your questions answered. If you feel you may need IVF, IVF with ICSI, PGD, or are uncertain, please contact MicroSort by e-mail (microsort@givf.com) or phone (800-277-6607).

If you decide you would like to participate in this clinical trial, please complete and submit the enclosed Medical History Form by fax (703-995-4928) or by mail. You may contact the MicroSort Clinic (703-289-1840) to schedule a consultation appointment with a clinician who will discuss your Medical History information with you during the consultation. Consultations may be either by phone or in-person.

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Attached Documents

Patient Registration Form
Medical History Form
Informed Consent to Test for HIV
Patient Consent

I. Instructions for Intrauterine Insemination (IUI) With MicroSort Sperm Separation

A. Consultation

The consultation is best completed with both husband and wife available and consists of a 30-60 minute telephone or in-person appointment. During this time the medical information provided on the Medical History Form will be reviewed to determine the most appropriate clinical procedure and preliminary testing for your care. You will also be given the opportunity to ask questions you may have regarding participation in the MicroSort gender selection clinical trial.

Minimum preliminary tests include:

<u>Female</u>	<u>Male</u>
HIV-1 antibody	HIV-1 antibody
Hepatitis B surface antigen	Hepatitis B surface antigen
Hepatitis C antibody	Hepatitis C antibody
	Semen Analysis

Additional preliminary tests required for IUI at the Laguna Hills, CA location include:

<u>Female</u>	<u>Male</u>
HIV- 2 antibody	HIV- 2 antibody
HTLV 1 & 2	HTLV 1 & 2

All test results must be current (at a minimum within the last 12 months) and a copy of the report must be available prior to scheduling an insemination cycle. During the consultation appointment, we will also discuss cycle management to determine how we can best meet your needs, whether you live out-of-town or in the local area.

Once the consultation is completed, the infectious disease tests and semen analysis should be completed and the results should be sent by FAX (703-995-4928) or mail to the MicroSort clinic. The informed consent and medical records release forms must be signed after the consultation and sent to the MicroSort clinic. Once these documents have been received, you may schedule an intrauterine insemination cycle. We recommend starting this consultation process at least 1-2 months prior to the desired treatment cycle date.

You will be instructed to call the MicroSort Clinic (703-289-1840) on the first day of your menstrual period in the month you have scheduled your cycle to take place.

B. Calendar of Events

The following calendar of events will help you plan for your upcoming cycle. Remember that this may be adapted for your personal situation, as discussed in your consultation. In addition, please review the "Fee Schedule" section of this packet.

Many patients coming to the MicroSort Clinic do not reside within the local area around the two current MicroSort laboratories; therefore, we have allowed for flexibility in the cycle monitoring process. You may choose to have a portion or all of your monitoring completed where you live or you may have all of your monitoring completed with us.

1. Cycle Day 1 (first day of full menstrual flow) :

Please call the MicroSort Clinic (703-289-1840) on cycle day 1 to inform us that your menstrual cycle has begun. This is extremely important, as it allows the clinicians time to review your chart, order the necessary medications, and plan your monitoring schedule; and it allows the lab to prepare for your upcoming sort. If it is a holiday or a weekend please leave a message and someone will contact you within 24-48 hours.

2. Cycle Days 3-7:

If the decision has been made to use clomiphene citrate (Clomid[®]) for follicular stimulation, you will be instructed during the Day 1 call when to begin the medication and the number of tablets to take each day. (see "Clomiphene Citrate Information" section) Typically between 1-3 tablets are taken for five consecutive days beginning on day 3 of your cycle.

My prescription is _____ tablets, days _____ to _____.

3. Cycle Day 3:

We strongly advise that, from cycle day 3 through the end of your treatment cycle (or until **at least** 7 days after the insemination), you and your partner use a barrier method of contraception (condom and/or diaphragm) when having intercourse.

4. Cycle Days 7-9:

You will be instructed during the Day 1 call when to begin monitoring. For out of town patients, the first day of monitoring usually consists of a blood test for evaluation of estradiol (E₂), progesterone (P₄), and luteinizing hormone (LH) levels. This information gives us an indication of your body's anticipated response to medications (if used) and your readiness to cycle. You may have your blood drawn at the facility of your choice. The laboratory or physician's office should FAX (703-995-4928) us the results that day before 2 pm EST. Once we receive the results, we will contact and advise you regarding the next necessary monitoring date. Please call our office if we have not contacted you by 4:30 pm EST.

To optimize sperm number and quality, it is recommended (unless otherwise instructed) that your partner have an ejaculation on **cycle day 10** and then abstain until the specimen for sorting and insemination is given. Please remember to use a barrier contraceptive if the ejaculation on day 9 is with intercourse.

5. Cycle Day 12:

Most of our patients arrive at the MicroSort Clinic for monitoring on day 12. This day may vary based on your cycle length. If monitoring is done at our facility, you will be instructed regarding the appropriate day and time designated by our clinicians.

6. Cycle Monitoring from Day 12 to hCG injection:

Monitoring at the MicroSort Clinic is available 7 days a week. Monitoring appointments are usually 20-60 minutes in length. Monitoring includes blood testing for the hormones estradiol (E₂), progesterone (P₄), and luteinizing hormone (LH); and transvaginal ultrasound to evaluate follicle development and endometrial thickness.

If monitoring takes place at another facility, the results should be sent by FAX to us before 2 pm EST.

FAX monitoring results to: 703-995-4928

Once we receive the results, we will contact and advise you regarding the results. Please call our office if we have not contacted you by 4:30 pm EST. Monitoring is normally done on a daily basis until you are near ovulation, but occasionally, if indicated, you may be allowed to skip a day or two.

Please Be Advised that most monitoring ultrasounds are vaginal and are best accomplished when the patient has an **empty** bladder.

7. Day of hCG/Ovidrel Injection:

When it is determined that you are close to ovulation you will usually be instructed to administer an injection of hCG. hCG assists in completion of egg maturation and induces ovulation. It is important that you receive the injection at the instructed time. Please refer to the "hCG or Ovidrel Injection Instructions" sections.

You will also be given instructions for Doxycycline use. Doxycycline is an oral antibiotic given to prevent infection. Usually you will take one capsule every 12 hours starting the evening prior to insemination and continue until the day after insemination (6 capsules). If you have an allergy to Doxycycline, it is important to inform the clinician and an alternate antibiotic can be prescribed. You will also be given the time to arrive at the MicroSort Clinic for both providing the semen specimen and the subsequent insemination.

8. Day of Insemination:

Your partner will be instructed to arrive at the MicroSort Clinic at a specific time on the morning of insemination to provide a semen specimen. You are welcome to accompany your partner if desired. MicroSort does not have child care. Please arrange day care for your children.

You will most likely be requested to arrive at the MicroSort Clinic for the insemination at 3:45 PM. This time may vary depending upon the lab schedule and clinic requirements. It is advantageous to perform the insemination when the patient has a full or partially full bladder. Please drink plenty of fluids throughout the day and regularly empty your bladder so that you are well hydrated when you arrive at the clinic. The insemination procedure will typically occur sometime between 1:30 and 5:00 PM. After the procedure you will be required to lie down for 15 minutes, after which you are free to leave.

9. Pregnancy Testing:

If you have not started menstruating 16 days after the insemination, a pregnancy test should be completed. The first pregnancy test may be either a home pregnancy test or a quantitative serum beta hCG determination. A positive test result on a home pregnancy test should be confirmed by a quantitative serum beta hCG determination (blood test).

10. Pregnancy Follow-up

You will be required to contact us at least every three months during the course of your pregnancy. After your baby is born, we will request birth records from the facility where you delivered your baby. We will also request Pediatric records from the Pediatrician when your baby reaches 1 year of age. This follow-up is important for clinical trial purposes and all information we obtain will remain strictly confidential.

C. Ovulation Predictor Kit (OPK) Instructions

1. Patients doing a natural cycle, meaning they are NOT using Clomid, should begin OPK testing starting on day 10 of the cycle, unless otherwise informed by a clinician. If you are using Clomid, please start your OPK testing on day 11, not on day 10. All other information regarding OPK use is the same regardless if you are taking Clomid or not.
2. A MicroSort clinician will inform you of your husband's last day of ejaculation based on his semen analysis results and the information you have provided regarding previous OPK cycles and Basal Body Temperature (BBT) charts. You should be informed of the recommended ejaculation and abstinence status when you call on "Day 1" of your cycle. If you have questions regarding this, please call the MicroSort clinic (703-289-1840) and a clinician will discuss it with you.
3. Patients should complete the OPK testing at 6 AM, 2 PM, and 10 PM and chart the results on the worksheet provided.
4. If you obtain a positive result on your 6 AM OPK test, call the MicroSort clinic after 7:30 AM EST to schedule an appointment for insemination (usually the next day). If you obtain a positive result on your 2 PM test please call that clinic that afternoon. If the test is positive at 10 PM, please call the clinic the next morning after 7:30 AM EST to schedule insemination (usually the following day). You will usually be instructed to administer HCG or Ovidrel after the OPK test turns positive. This is an *overview* of the schedule, please keep in mind that every person is different and that it may be clinically necessary to deviate from this plan to obtain a better outcome. The clinicians will inform you of the best plan of care based on your individual needs.

II. Semen Analysis and Collection for MicroSort Sperm Separation

Semen Analysis

Prior to initiating a MicroSort cycle, you will be required to have a basic semen analysis test performed and the result sent to MicroSort.

Purpose of the Semen Analysis

The primary purposes of the semen analysis are to determine the specific characteristics (cell number, motion characteristics, and morphology) of your sperm sample and the appropriate method of processing the semen for the MicroSort procedure.

How to provide the best semen sample

The interval between ejaculations (abstinence), as well as the general frequency of sexual intercourse (coitus), influence the sperm count and semen quality. As the abstinence interval lengthens, the sperm count rises and the motility (ability of the sperm to move spontaneously) falls. Therefore, we ask you be prepared to produce a semen sample at the correct abstinence interval on the designated day for the MicroSort procedure.

Instructions for collecting semen

Please try to have intercourse or ejaculate 2-3 times per week for two weeks prior to the semen collection. Then abstain for approximately 3 days before providing the semen specimen.

Based on the semen analysis, you will be instructed by the MicroSort clinical staff regarding the length of the abstinence period for producing the actual semen specimen for MicroSort separation and insemination. Generally, we recommend that men with a normal sperm count have an abstinence of 3-5 days before the day of the semen collection for MicroSort processing and insemination.

Method for semen specimen collection

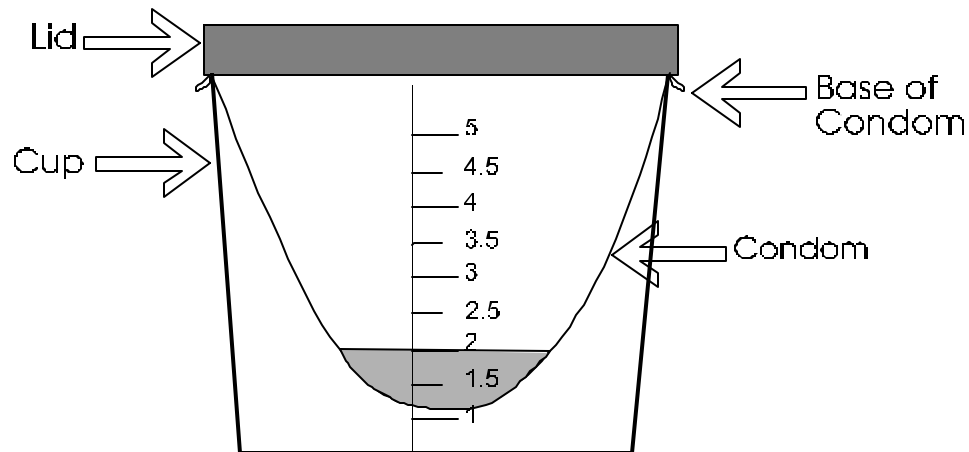
The technique used in collecting semen is very important. The best way to obtain a semen sample is by masturbation, as this makes it easier to collect the entire ejaculate in an appropriate specimen container. Please be especially careful to collect all of the first portion of the ejaculate since this part contains most of the sperm. Avoid using any type of lubricant, gel, powder, or soap other than what we provide while collecting a specimen. These items will alter semen quality and give misleading information. Only sterile, non-toxic semen specimen containers should be used for collecting the semen sample. Specimen collection rooms and containers are provided at the lab facility or MicroSort Clinic.

Alternative methods for semen collection

Sometimes, because of ethical, religious, or personal reasons, collecting a sample by masturbation may not be preferred. If this is the case, a sample can be collected away from the facility with both partners participating. When collecting in the privacy of your own room, the male can withdraw just before ejaculation and collect the sample in the container provided by the facility. It is very important that the first portion of the ejaculate be collected. The specimen must be kept at room temperature and promptly brought to the facility within 30 minutes of collection. Sperm quality is altered when exposed to temperatures well above or below body level (*i.e.*, car heaters, air-conditioners, extreme winter or summer temperatures). If samples are collected outside the lab facility or MicroSort Clinic, the specimen container with the sample should be placed in a transport box (may be provided by the facility) to protect the specimen against temperature fluctuations during transit.

Another alternative method is to collect a sample using a “non-toxic” condom during coitus. When you use a condom to collect a semen sample, the following points need to be remembered:

1. Use a plain Milex-brand condom without lubricant or spermicide.
2. The condom must be slipped off carefully so that the semen stays in the condom.
3. The condom should then be placed into the specimen container as shown below:



4. Stretch the top of the condom over the cup and cover the specimen container tightly.
5. Place the specimen container in the transport box and return the sample to the facility.

III. Human Immunodeficiency Virus Testing (AIDS Testing) Patient Information

Statement

The Genetics & IVF Institute requires that all MicroSort patients be tested for the presence of antibodies to HIV.

Purpose

The Genetics & IVF Institute is aware that there are potential adverse consequences for an individual being tested for the presence of antibodies for the human immunodeficiency virus (HIV), the virus which causes Acquired Immunodeficiency Syndrome (AIDS). There are, however, health-related imperatives for determining whether an individual is HIV positive, particularly since recent research indicates that early intervention in the progress of the disease can prolong the asymptomatic stage of the illness and assist the individual to avoid opportunistic infections and HIV-associated illness.

A woman who is positive for AIDS carries a high risk of infecting her fetus with this disease. For this reason, the Institute will not provide MicroSort sperm separation services to patients with positive HIV tests. We also will not perform MicroSort sperm separation involving the husband's sperm if the husband is HIV positive.

Patient Procedures

1. Prior to performing any test to determine exposure to HIV, the patient will be provided with an oral or written explanation of the meaning of the test.
2. Prior to performing any test to determine exposure to HIV, the patient or a legally authorized representative must voluntarily sign a consent form which shall be included in the patient's medical record. The consent form is attached to this statement.
3. Testing protocol currently recommended by the Centers for Disease Control shall be followed.
4. Test results, if positive, will be provided to the patient, or the legally authorized representative, by a physician.

IV. Clomiphene Citrate Information

What is clomiphene citrate?

Clomiphene citrate is a drug that has been on the market for over 25 years. Research has shown that clomiphene citrate can increase the likelihood of pregnancy in some women by stimulating or enhancing ovulation.

How does it work?

Clomiphene citrate (Clomid[®], Serophene[®]) is an oral medication with anti-estrogenic properties. It is thought to increase output of follicle stimulating hormone (FSH) and luteinizing hormone (LH) from the pituitary gland. The increased level of FSH encourages development of one or more ovarian follicles and the eggs within them.

How is it taken?

The most common dosage of this medication used in the MicroSort clinic is two 50 mg tablets on days 3, 4, 5, 6 and 7 of your menstrual cycle. The time and dosage may be different if your medical history indicates that this is appropriate.

What are the side effects?

Temporary hot flashes, due to hormone changes, are the most common side effect. Transient ovarian enlargement may cause abdominal discomfort. Less frequent symptoms include breast tenderness, headache, irritability, dizziness, nausea and vomiting, fatigue and temporary visual disturbances. About 10% of women experience side effects, usually mild, from clomiphene citrate.

What are the chances of multiple births?

Approximately 95% of all pregnancies resulting from a clomiphene cycle are singleton births. Twin pregnancies occur in approximately 5-12% with less than 1% resulting in triplets.

Does clomiphene citrate cause birth defects?

There is no increased incidence of congenital malformations in children conceived in clomiphene-stimulated cycles.

V. hCG Injection Instructions

Important Information

hCG (human chorionic gonadotropin) is a medication which assists in maturation of the egg and stimulation of ovulation. HCG will be given as a subcutaneous injection (directly under the skin).

The following supplies are necessary for the hCG injection:

- One box of hCG (10,000 USP) containing a vial of liquid and a vial of powder
- One 3 cc syringes with a 23-gauge 1½-inch needle to reconstitute with
- One 26 or 27-gauge 3/8, ½, or 5/8 inch needle to inject with
- Alcohol swabs and Band-Aid® brand adhesive bandages
- Body map of injection sites

Instructions:

1. Wash your hands and assemble the equipment listed above.
2. Flip caps off the vials and wipe the rubber tops with an alcohol swab.
3. Put the needle on the syringe with a clockwise twisting motion.
4. Draw back one cc of air into the syringe, push the needle through the rubber top of the vial containing liquid, and push all of the air into the vial. Turn the vial upside-down, draw back one cc of water and pull the needle out of the vial. (The remainder of the water in the vial is not used.)
5. Push the needle through the rubber top of the vial containing powder, push all of the liquid into the vial, remove the needle, and carefully recap the needle. Gently roll the vial between your palms for a few seconds until all of the powder dissolves. Again, draw back one cc of air into the syringe, push the needle through the rubber top, and push all of the air into the vial. Turn the vial upside-down and draw back the solution. Make sure to maintain the tip of the needle below the liquid line to avoid drawing up air into the syringe. It will be necessary to slowly withdraw the needle from the vial as it empties in order to obtain all of the solution. Withdraw the needle from the bottle.
6. Change the needle to the 26 gauge 5/8 inch needle.
7. Make yourself comfortable by sitting down.
8. Choose an injection site (abdomen, thigh, or upper arm).
9. Cleanse the injection site with an alcohol swab. Clean from the intended site outward in a circular pattern.
10. Hold the syringe at eye level with the needle pointing up. Tap the barrel of the syringe to get the air bubbles to the end of the syringe and slightly depress the plunger to remove bubbles.
11. Place your free hand at the perimeter of the site for injection so that the forefinger and the thumb frame the site. Draw the forefinger and thumb together so that a fold of skin is grasped between them.
12. With a quick, firm motion (similar to that of throwing a dart) insert the needle into the site at a 90-degree angle to the skin. Most of the needle should penetrate the skin to ensure that the medication is injected correctly.
13. Depress the plunger with even moderate pressure until all the medication is injected, then withdraw the needle in one quick, smooth motion. Then release the skin.
14. Gently rub the injection site with an alcohol swab in a circular motion to facilitate dissemination of the fluid.
15. Dispose of the needles, syringe and medication vials in a safe manner. An old coffee can or plastic milk carton taped closed after use makes a good receptacle. You may return these used supplies to MicroSort for proper disposal.

VI. Ovidrel® (Registered trademark Serono, Inc).Administration and Storage Instructions:

1. Please allow the pre-filled syringe to adjust to room temperature before you administer your injection
2. Wash your hands thoroughly
3. With the needle pointing upwards, carefully remove the needle cap from the syringe. Do not touch the needle or allow it to touch any surface.
4. To remove any air bubbles, point the needle up and gently tap on the syringe until all the bubbles rise to the top.
5. Push the plunger carefully until a small drip of liquid begins to appear from the tip of the needle.
6. Choose an injection site in the lower abdominal area, preferably around the belly button but at least one inch away.
7. Carefully clean the injection site on the stomach with an alcohol swab and allow it to air-dry.
8. Holding the syringe with one hand the way you hold a pencil, pinch the skin on the chosen injection site with the other hand and hold firmly.
9. Insert the entire length of the needle into the skin at an upward angle of about 45 to 90 degrees. (This is a subcutaneous, not intramuscular injection).
10. Release the skin and push the plunger in a slow, steady motion until all the medication is injected.
11. After injecting all the contents, gently withdraw the needle.
12. Apply pressure to the injection site with a gauze pad. If the bleeding does not stop within a few minutes, place a piece of clean gauze over the injection site and cover it with a bandaid.
13. Discard the syringe in your sharps-disposal container.

Storage:

Ovidrel® pre-filled syringe should be stored refrigerated (36 – 46 degrees Fahrenheit) to allow the product to be used until the expired date shown on the syringe or carton. Alternatively, the Ovidrel® pre-filled syringe may be stored by the patient for no more than 30 days at room temperature and in this case must be used within those 30 days. Protect from light. Do not freeze.

For further information on Ovidrel® pre-filled injection and instructions, go to http://www.fertilitylifelines.com/assets/pdfs/products/ovidrel/ovidrel_printableinstructions.pdf

VII. Patient Record Keeping Calendar

Consultation Appointment: Date _____ Time _____
Month of Scheduled Cycle: Month _____ Year _____
Cycle Day One: Date _____
Clomid Dosage: _____ # of Tablets Days _____ to _____

Monitoring Information

Event	Date	Time	Results	Questions
1st Monitoring Day				
2nd Monitoring Day				
3rd Monitoring Day				
4th Monitoring Day				

hCG/ Ovidrel Instructions

Give injection on: _____ (Date) _____ (Time)

Doxycycline Instructions

Take one capsule by mouth every 12 hours for a total of 6 doses. Start the medication the day before the scheduled IUI procedure. (Avoid taking with milk or antacids.)

Begin: _____ (Date) _____ (Time)

Day of Insemination

Date _____

Husband to arrive at the MicroSort Clinic to give sample: Time _____

Couple to Arrive for Insemination: Time _____

Additional Questions to Ask the Clinician:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

GENETICS & IVF INSTITUTE

MicroSort Division

3015 Williams Dr., Suite 101

Fairfax, VA 22031

PATIENT REGISTRATION FORM

PATIENT NUMBER: _____

Please PRINT all Information

PATIENT					SPOUSE/PARTNER				
Name (last, first, middle initial)					Name (last, first, middle initial)				
Address					Address				
City/State/Zip					City/State/Zip				
Home phone	Work phone	Social Security #			Home phone	Work phone	Social Security #		
email address:					email address:				
Date of Birth	Age	Sex	Driver License No. & State		Date of Birth	Age	Sex	Driver License No. & State	
Race(optional)	Religion(optional)	Married	Divorced	Single	Race(optional)	Religion(optional)	Married	Divorced	Single
PATIENT EMPLOYMENT					SPOUSE/PARTNER EMPLOYMENT				
Company Name:			Your Occupation:		Company Name:			Your Occupation:	
Address:					Address:				
City/State/Zip:					City/State/Zip:				
PRIMARY OR PATIENT'S INSURANCE					SECONDARY/PARTNER INSURANCE				
Insurance Company Name:					Insurance Company Name:				
P.O. Box/Address:					P.O. Box/Address:				
City/State/Zip:					City/State/Zip:				
Group Name:			Group No.:		Group Name:			Group No.:	
Policy No.:		Subscriber Name:			Policy No.:		Subscriber Name:		
REFERRING PHYSICIAN					OBSTETRICIAN (IF DIFFERENT FROM REFERRING PHYSICIAN)				
Name:					Name:				
Address:					Address:				
City/State/Zip:					City/State/Zip:				
Phone:		Practice Name:			Phone:		Practice Name:		

Emergency Contact:	Day Phone:	Night Phone:	Relationship:
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In consideration for services provided to me, I acknowledge responsibility for payment for services rendered to me or my dependents at the Genetics & IVF Institute. If such services are covered under a contract between the Institute and my insurer, I acknowledge responsibility for any deductibles, co-payments, and non-covered services. I understand that I must obtain any exception from standard Genetics & IVF Institute payment or billing policy in writing or it will not be considered binding. If my account becomes delinquent, I agree to pay all costs the Institute may incur in collecting its fees including collection agency and attorney's fees (25%). If charges on my account are not fully paid within 180 days of the date of service, I also agree to pay interest from that date at a rate of 1.5% per month. Unless full payment is made on the date of service, I authorize my insurer to pay my medical benefits directly to the Genetics & IVF Institute. I agree that any possible dispute or claim in relation to services which I/we received from the Institute shall be settled solely by arbitration by the American Arbitration Association (using its health care claim settlement arbitration rules). The locale will be Fairfax County, Virginia, and the arbitrators' judgement may be entered in any appropriate court and shall be binding and enforceable. I authorize the release of any medical information necessary to permit processing of claims made to insurance for services performed by the Genetics & IVF Institute.

_____ PATIENT'S SIGNATURE	_____ DATE	_____ SPOUSE/PARTNER SIGNATURE (required)	_____ DATE
_____ AUTHORIZED GIVF REPRESENTATIVE	_____ DATE		

MicroSort

Division of the Genetics & IVF Institute

Medical History Form

Date completed _____

Please complete all sections of this questionnaire to the best of your ability. Your confidential answers will be reviewed by a clinician and will help to give you the best possible care. Mail or fax (703-698-7293) the completed form to MicroSort, 3015 Williams Dr., Suite 101, Fairfax, VA 22031.

What is the primary reason for your consultation (circle)? **Family Balancing**, **Genetic Disease Prevention** or **Other** (list) _____

Desired Gender: Female [] Male []

Please list other physicians or practices that you have consulted. _____

Comments: _____

(To be completed by **both** partners)

Wife

(Print Name)

(date of birth) (age)

Address _____

City/State/Zip _____

Occupation _____

Preferred Pharmacy _____

Tel #: _____

Phone (day) _____

(eve) _____

(cellular) _____

(e-mail) _____

(voice mail) _____

(pager) _____

(FAX) _____

Primary Care Physician or GYN

Print Name _____

(address) _____

(city) _____

(state, zip code) _____

(phone) _____

(FAX) _____

(medical specialty) _____

Husband

(Print Name)

(date of birth) (age)

Address _____

City/State/Zip _____

Occupation _____

Preferred Pharmacy _____

Tel #: _____

(day) _____

(eve) _____

(cellular) _____

(e-mail) _____

(voice mail) _____

(pager) _____

(FAX) _____

Primary Care Physician

Print Name _____

(address) _____

(city) _____

(state, zip code) _____

(phone) _____

(FAX) _____

(medical specialty) _____

Who should we send a summary letter to? [] Primary Care Physician [] OB/GYN

Date of Marriage: _____

Contraceptive practices:	(yes)	(no)	(dates)
Condoms/Diaphragm	_____	_____	_____
Depo-Provera	_____	_____	_____
Norplant	_____	_____	_____
Intrauterine device (IUD)	_____	_____	_____
Oral contraceptives	_____	_____	_____
Rhythm/withdrawal	_____	_____	_____
Other methods	_____	_____	_____

Pregnancies (Wife):

Pregnancy (include all pregnancies)	When? (Year)	How long to conceive?	Gender	Is current husband the father? (Yes/No)	Health of Child	Outcome (miscarriage, termination, ectopic, vaginal delivery, Cesarean section, or stillbirth)	Complications (high blood pressure, eclampsia, preeclampsia, diabetes, small for dates, placenta previa, infection, excessive blood loss, preterm labor, premature membrane rupture, early or late delivery, transfusion, Rh sensitization, multiples, etc.)
First							
Second							
Third							
Fourth							
Fifth							

Husband: Pregnancies from previous marriage(s) or partner(s), if any

Pregnancy (include all)	When? (Year)	How long to conceive?	Gender	Date of Birth	Health of Child	Outcome (miscarriage, termination, ectopic, vaginal delivery, Cesarean section, or stillbirth) and list complications, if any
First						
Second						
Third						

Husband and Wife: All Adopted Children

Adopted Children	Gender of Child	Date of Birth of Child	Health of Child
First			
Second			

Male History

Erectile function difficulties:

(yes)

(no)

collecting semen for testing

Growth and development:

undescended testicles

delayed puberty

breast enlargement

Testicular injury:

(date)

torsion (twisted)

painful swelling

severe trauma

Toxicant exposure:

alcohol

_____ drinks/week

recreation drugs

smoking

_____ packs/day

pesticides

other chemicals

radiation

Varicocele:

Sexually transmitted infections:

chlamydia

genital warts (HPV)

gonorrhea

herpes

_____ episodes/year

HIV

syphilis

Urinary tract infections:

bladder infection

kidney infection

prostatitis

Recent high fever:

Hot tub use:

_____ times/week

Male History (cont.)

List all medication you take now (prescription, vitamin and over the counter preparations):

(drug)

(date)

(dose)

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

List all allergic reactions you have had:

(drug or allergen)

(date)

_____	_____
_____	_____
_____	_____

List all surgery you have had:

(type of surgery)

(date)

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

List all other serious illnesses for which you have been under the care of a physician:

(illness)

(date)

_____	_____
_____	_____
_____	_____

List all blood transfusions you have had:

(number of units)

(date)

_____	_____
_____	_____

Male Family History

Country of origin: Mother _____ Father _____

Ethnic background (circle): African-American Asian Asian-Indian Caucasian Hispanic Jewish American-Indian
Mediterranean Middle East Other _____

Ethnic group (Check all that apply)	Have you been tested for?	Yes	No	Date	Result
African, African/American	sickle cell trait				
Asian, Mediterranean or Hispanic	thalassemia				
Caucasian, Jewish	cystic fibrosis				
Jewish	Tay Sachs				
Jewish	Canavan				
Jewish	Gaucher				

Are you related to your current partner (consanguinity)? _____

Is there anyone in the family who has had any of the following illnesses?

	Yes	Relationship		Yes	Relationship
abnormal breasts			learning problems		
abnormal genitals			mental retardation		
birth defects			metabolic disorder		
chromosomal disorders			miscarriages (2 or more)		
delayed development			short stature		
early puberty			testicular cancer		
hormone disorders			undescended testicles		
pituitary tumor			infertility		
lack of sense of smell			genetic (inherited) disorders		

Comments: _____

Female History

Menstrual History

Age at first menstrual period _____ Date of last menstrual period _____

of days from the beginning of one period to the beginning of the next: average _____ shortest _____ longest _____

If your cycles are irregular, how many cycles do you usually have in a year? _____

Average duration of your menstrual flow (days)? _____

	Mild/Light	Moderate	Severe/Heavy
Severity of menstrual cramps	_____	_____	_____

Amount of menstrual flow	_____	_____	_____
--------------------------	-------	-------	-------

Medication taken for cramps:	drug _____	amount _____	frequency _____
------------------------------	------------	--------------	-----------------

Do you have midcycle:	(yes)	(no)
spotting	_____	_____
pain	_____	_____
cervical mucus	_____	_____

Does the cramping or bleeding prevent you from:	(yes)	(no)
going to work	_____	_____
participating in fun activities	_____	_____

When was your last Pap smear? _____ Result _____

When was your last mammogram? _____ Result _____

Do you have or have you ever had (check all that apply):

Infectious Problems		Medical Problems	
positive HIV test	contact with cats or mice	anemia	kidney disease
chicken pox (varicella)	chlamydia	bleeding disorders	kidney infection
chicken pox immunization	gonorrhea	blood clots	liver problems
hepatitis A, B or C	syphilis (RPR)	blood transfusion	lost 15 lbs last year
hepatitis A vaccination	pelvic infection (PID)	diabetes	gained 15 lbs last year
hepatitis B vaccination	nongonococcal urethritis	cancer	lung disease
German measles (rubella)	condyloma (venereal warts)	appendicitis	asthma
Rubella immunization	herpes: genital	heart disease	recurrent urinary infections
rheumatic fever	herpes: oral	high blood pressure	thyroid problems
chronic bronchitis	trichomoniasis	mitral valve prolapse	arthritis
Neurological Problems	Gynecologic Problems		
severe headaches	abnormal mammogram	endometriosis	breast discharge
seizures (epilepsy)	abnormal pap smear	uterine anomalies	excess hair growth
	blocked fallopian tubes	cervical stenosis	hot flashes or night sweats
	pelvic adhesions	DES exposure	Rh sensitized

Comments: _____

Female History (cont.)

Weight _____ Height _____

Particular food diet or any special dietary habits? _____

How much do you exercise? _____

Toxicant exposure:	(yes)	(no)	(date last exposed)
alcohol	_____ drinks/week	_____	_____
recreation drugs	_____	_____	_____
smoking	_____ packs/day	_____	_____
pesticides	_____	_____	_____
other chemicals	_____	_____	_____
radiation	_____	_____	_____

List all medication you take now (prescription, vitamins and over the counter preparations):

(drug)	(date)	(dose)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Are you taking prenatal vitamins? _____

List all allergic reactions you have had:

(drug or allergen)	(date)
_____	_____
_____	_____

Are you allergic to egg yolk? _____

Do you have a known allergy to Hoechst 33342 dye? Yes [] No []

List all surgery you have had (cervix, uterus, ovarian cysts, tubes, endometriosis, appendix, etc.):

(type of surgery)	(date)
_____	_____
_____	_____
_____	_____
_____	_____

List all other serious illnesses for which you have been under the care of a physician:

(illness)	(date)
_____	_____
_____	_____

Family History of Female

Country of origin: Mother _____ Father _____

Ethnic background (circle): African/American Asian Asian Indian Caucasian Hispanic Jewish Indian Mediterranean Middle East Other _____

Ethnic group (Check all that apply)	Have you been tested for?	Yes	No	Date	Result
African, African/American	sickle cell trait				
Asian, Mediterranean or Hispanic	thalassemia				
Caucasian, Jewish	cystic fibrosis				
Jewish	Tay Sachs				
Jewish	Canavan				
Jewish	Gaucher				

Are you related to your current partner (consanguinity)? _____

Is there anyone in the family who has had any of the following illnesses?

	Yes	Relationship		Yes	Relationship
abnormal genitals			learning problems		
birth defects			mental retardation		
bleeding disorders			early menopause <age 40		
breast cancer			metabolic disorder		
chromosomal disorders			ovarian cancer		
delayed development			pituitary tumor		
early puberty			hormone disorders		
endometriosis			2 or more miscarriages		
excess body hair			other inherited disorders		
infertility					

Comments: _____

To assist us in reviewing and interpreting any prior tests, please complete this section to the best of your ability. Pertinent records should also be obtained so the results can be confirmed.

Previous female fertility tests:	(result)	(date)
basal body temperature	_____	_____
ovulation predictor kits	_____	_____
endometrial biopsy	_____	_____
post-coital test	_____	_____
HSG	_____	_____
hysterosonogram	_____	_____
hysteroscopy	_____	_____
laparoscopy	_____	_____
ultrasound, pelvic	_____	_____
other	_____	_____

Previous male fertility tests:	(result)	(date)
semen analysis	conc _____ motility _____ morphology _____	_____
	conc _____ motility _____ morphology _____	_____
	conc _____ motility _____ morphology _____	_____
post-coital test	_____	_____
antisperm antibodies (semen)	_____	_____
antisperm antibodies (serum)	_____	_____
other	_____	_____

Previous hormonal tests:	<u>Male</u>		<u>Female</u>	
	Result	Date	Result	Date
testosterone	_____	_____	_____	_____
prolactin	_____	_____	_____	_____
TSH	_____	_____	_____	_____
FSH (random)	_____	_____	_____	_____
FSH (day 3)	_____	_____	_____	_____
FSH (day 10)	_____	_____	_____	_____
progesterone	_____	_____	_____	_____
DHEAS	_____	_____	_____	_____

Infectious disease**Male****Female**

	Result	Date	Result	Date
HIV-1	_____	_____	_____	_____
hepatitis B surface Antigen	_____	_____	_____	_____
rubella IgG	_____	_____	_____	_____
varicella IgG (Chicken Pox)	_____	_____	_____	_____
toxoplasmosis IgG	_____	_____	_____	_____

Medical screening tests:

blood group and Rh	_____	_____	_____	_____
CBC	_____	_____	_____	_____
chemistry panel	_____	_____	_____	_____
chest x-ray (CXR)	_____	_____	_____	_____
cholesterol (lipid profile)	_____	_____	_____	_____
EKG	_____	_____	_____	_____
fasting glucose	_____	_____	_____	_____
PT/PTT	_____	_____	_____	_____
urinalysis	_____	_____	_____	_____

Previous fertility treatments:

	(yes)	(no)	# cycles	Comments
clomiphene	_____	_____	_____	_____
dopamine agonist*	_____	_____	_____	_____
glucocorticoids (Dex)	_____	_____	_____	_____
insemination (IUI)	_____	_____	_____	_____
clomiphene and IUI	_____	_____	_____	_____
FSH and IUI	_____	_____	_____	_____
IVF or ICSI	_____	_____	_____	_____
other:	_____	_____	_____	_____
Comments:	_____			

* dopamine agonist - bromocriptine (Parlodel), pergolide mesylate (Permax), cabergoline (Dostinex)

** FSH - Pergonal, Humegon, Repronex, Metrodin, Fertinex, Gonal-F, and/or Follistim

INFECTIOUS DISEASE RISK QUESTIONNAIRE

HUSBAND:

PLEASE ANSWER THE FOLLOWING QUESTIONS (circle yes or no):

Have you ever been refused as a blood donor? Yes No
If yes, why? _____

Have you ever been tested for AIDS? Yes No
If yes, why? _____

Have you ever received Pituitary-derived Human Growth Hormone? Yes No
If yes, what year? _____

Have you ever had Creutzfeldt-Jacob disease? Yes No

In the last 12 months, have you

Had a blood transfusion? Yes No

Had a tattoo? Yes No

Had your body pierced? Yes No

Received non-viral inactivated Factor VIII or Factor IX concentrate? Yes No

Been exposed to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, non-intact skin or mucous membrane? Yes No

Had Hepatitis B or C? Yes No
If yes, which one? _____ When? _____

Sexual History:

In the last 12 months, have you had sex with

A person other than your current spouse? Yes No
If yes, vaginal, anal, and/or oral? _____

A person having non-medical intravenous, intramuscular, or subcutaneous injections of drugs? Yes No

A person having engaged in sex in exchange for money or drugs? Yes No

A person that has been diagnosed as positive for the HIV virus? Yes No

A person who has had sex with another partner described in any of the above? Yes No

I certify that the information contained in this questionnaire, to the best of my knowledge, is true and complete.

Husband NAME: _____

DATE: _____

SIGNATURE: _____

FOR CLINICAL USE ONLY:

LR HR

S NS

12M 1M

INFECTIOUS DISEASE RISK QUESTIONNAIRE

WIFE:

PLEASE ANSWER THE FOLLOWING QUESTIONS (circle yes or no):

Have you ever been refused as a blood donor? Yes No
If yes, why? _____

Have you ever been tested for AIDS? Yes No
If yes, why? _____

Have you ever received Pituitary-derived Human Growth Hormone? Yes No
If yes, what year? _____

Have you ever had Creutzfeldt-Jacob disease? Yes No

In the last 12 months, have you

Had a blood transfusion? Yes No

Had a tattoo? Yes No

Had your body pierced? Yes No

Received non-viral inactivated Factor VIII or Factor IX concentrate? Yes No

Been exposed to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, non-intact skin or mucous membrane? Yes No

Had Hepatitis B or C? Yes No
If yes, which one? _____ When? _____

Sexual History:

In the last 12 months, have you had sex with

A person other than your current spouse? Yes No
If yes, vaginal, anal, and/or oral? _____

A person having non-medical intravenous, intramuscular, or subcutaneous injections of drugs? Yes No

A person having engaged in sex in exchange for money or drugs? Yes No

A person that has been diagnosed as positive for the HIV virus? Yes No

A person who has had sex with another partner described in any of the above? Yes No

I certify that the information contained in this questionnaire, to the best of my knowledge, is true and complete.

Wife NAME: _____

DATE: _____

SIGNATURE: _____

FOR CLINICAL USE ONLY:

LR HR

S NS

12M 1M

MicroSort

A Division of the Genetics & IVF Institute

3015 Williams Drive, Suite 101
Fairfax, Virginia 22031

800-277-6607 Fax: 703-698-7293
E-mail: microsort@givf.com

MicroSort® Separation of X- and Y-Sperm INFORMED CONSENT TO TEST FOR HIV

1. I, _____, have been requested by my clinician to have a blood test to detect the presence of antibodies to the Human Immunodeficiency Virus (HIV), the virus that causes Acquired Immunodeficiency Syndrome (AIDS). I understand that the blood tests for the virus, which is the probable cause of AIDS, are not 100 percent accurate, and that these blood tests sometimes produce false positive or false negative test results. I have been informed that a positive test will necessitate further testing to confirm the results and I agree to be responsible for any additional laboratory fees. I further understand that the presence of antibodies means that a person probably has been infected with the AIDS virus, but does not necessarily mean that a person will develop AIDS.
2. I have been informed of the procedure for taking blood and the possible risks and consequences of such a procedure.
3. I have been informed about the nature of the blood tests, their expected benefits and risks, and have been given the opportunity to ask questions about the blood tests.
4. I understand that my clinician will notify me of the results of the blood tests and that the results will be explained to me. I also understand that my test results will be recorded in my medical record.
5. The Genetics & IVF Institute, to the best of its ability, will not disclose the results of the tests to others except to the extent required by law or except to the extent such disclosure is required in order to safeguard the well-being of patients and employees at the facility or entity or other persons at risk. Virginia law requires that the physician notify the Virginia Department of Health if an individual has tested positive for exposure to HIV.

I authorize the Genetics & IVF Institute, its clinicians, and anyone authorized by them to perform the blood tests for HIV.

Patient Signature

Date

Clinician Signature

Date

Witness

Date

MicroSort®

A Division of the Genetics & IVF Institute

3015 Williams Drive, Suite 101
Fairfax, Virginia 22031

800-277-6607 Fax: 703-995-4928
E-mail: microsort@givf.com

MicroSort® Separation of X- and Y-Sperm PATIENT CONSENT TO PARTICIPATE

Introduction

We are volunteering to be subjects in a multi-center research study. Before agreeing to participate, it is important that we read and understand the information in this form. This form is designed to provide us information that we should know about this study. It describes the study's purpose, procedures, benefits and risks. It also describes alternative procedures and our right to withdraw from the study at any time.

This information is provided to us so that we can make an informed decision about whether to participate in this study. We should take as much time as we wish to make our decision about signing this informed consent. We are free to ask any questions we may have about this research study before agreeing to participate in it.

Purpose of Research Study

The purpose of this research study is to evaluate the safety and effectiveness of a new technique to sort sperm to increase the likelihood of conceiving a baby of the desired gender. This new technique is known as MicroSort.

Certain couples who have had a child with a sex-linked or sex-limited disease, or who have a family history of a sex-linked or sex-limited disease, may be at increased risk of bearing children affected with the disorder. For example, if a woman is a carrier of an X-linked disease (i.e., classic hemophilia), the chance that a male child will be affected is 50% in every pregnancy. The chance that a female child will be a carrier is 50% in every pregnancy. Most carriers of X-linked diseases are clinically normal. If carrier women could increase the likelihood of female offspring prior to conception by selecting X chromosome-bearing (female) sperm, they could reduce the risk of having affected sons. There are also some sex-linked or sex-limited genetic disorders in which a couple could reduce the risk of passing on the disorder to their offspring by selecting Y chromosome-bearing (male) sperm. In addition, certain couples with a majority of children of one sex may wish to increase the probability of having another child of the opposite sex (example: a couple with 1 or more boys who would like to have a girl).

MicroSort Separation of X- and Y-Sperm

PATIENT CONSENT TO PARTICIPATE

Increasing the probability of having a child of a particular gender can now be accomplished by sperm sorting followed by artificial insemination or *in vitro* fertilization (IVF) using MicroSort separated (sorted) sperm. This research program provides us the opportunity to have sperm sorted and to have an artificial insemination or IVF cycle using the sorted sperm.

Study Procedures

If agreement is made to participate in this program, both husband and wife will be tested for HIV, hepatitis B and hepatitis C. The husband will also provide a semen sample for evaluation and sorting. A semen donor may be chosen for the sorting, if medically indicated.

Sperm are sorted into a sample that is enriched (the percentage increased) for the desired sperm using a flow cytometer (cell sorting device). To obtain a sperm cell sample enriched in either X-(female) or Y-(male) bearing sperm cells, MicroSort exploits the fact that X-bearing sperm cells have 2.8% more total DNA content than Y-bearing sperm. Human sperm cells are treated with a non-cytotoxic, non-intercalating (not inserted within, outside) DNA stain (Hoechst 33342) and processed through a specialized flow cytometer instrument that uses an ultraviolet laser. The treated sperm cells are briefly exposed to ultraviolet light from the laser, which causes the stain to fluoresce. Since X-bearing (female) sperm cells contain more DNA and thus more stain than Y-bearing (male) sperm, the female sperm fluoresce brighter than the male sperm. The flow cytometer detects and separates the X- and Y-bearing sperm based upon their fluorescence. The gender-enriched sample may then be used in combination with various assisted reproductive technologies, such as intrauterine insemination (IUI), *in vitro* fertilization (IVF), or IVF with intracytoplasmic sperm injection (ICSI).

The average purity of 2570 sorts (August 1994 to December 2002) for X- bearing sperm was 87.6%. The average purity of 555 sorts for Y-bearing sperm was 69.3%. The actual percentage of female fetuses after sorting for a girl (XSORT®) is 91%. The actual percentage of male fetuses after sorting for a boy (YSORT®) is 76%. The mean number of total motile sperm cells available prior to processing was 192.6 million. After processing, the average number of total motile cells was 169.7 thousand sperm. Due to the relatively low number of motile sperm cells available after processing, an assisted reproductive technology treatment such as IVF, ICSI or IUI is considered necessary in order to conceive.

Pregnancy rates vary significantly from patient to patient based on factors such as age, sperm quality, egg quality, tubal disease, and prior infertility as well as by the type of procedure that is being performed. As of December 2002, the clinical pregnancy rate after IUI was 15% / cycle with 271 women achieving a pregnancy after 1824 inseminations. The clinical pregnancy rate for IVF (includes ICSI) was 34%/cycle with 169 women achieving a pregnancy after 502 embryo transfers. Pregnancy rates have been 34 %/cycle using frozen embryos with 17 women conceiving after 50 attempts.

If we agree to participate in this program, the wife will undergo an insemination or an IVF cycle using the enriched sorted sperm. A separate informed consent for either artificial insemination or for IVF must also be signed.

Follow-up Evaluations

If we become pregnant following a reproductive procedure with sorted sperm, we agree to participate in a long-term follow-up program to collect information about the health of our child (or children). A summary letter of the care we received and an outline of the clinical trial follow-up requirements will be sent to my obstetrician. We agree to sign forms to release to MicroSort the medical records for prenatal care and our child's (our children's) birth and pediatric records. MicroSort will review these records to learn more about the pregnancy and health of children conceived from a sorted sperm sample. If an early miscarriage occurs, we agree to request a chromosomal analysis on the fetal tissue, if available. If there is a late pregnancy loss, we agree to request an autopsy with chromosomal analysis. If we have prenatal testing such as an amniocentesis or chorionic villi sampling, we will send MicroSort a copy of the results for review. We agree to maintain our contact with MicroSort every 3 months during the pregnancy, and for at least one year after our child's (or children's) birth. Notification can be accomplished through email at MicroSort@GIVF.com or by calling (703) 289-4220. We agree to provide change of address information if applicable.

Risks and Discomforts

This technique has been effective in sorting the sperm in multiple animal species. The method does involve the exposure of sperm to a DNA-binding dye and very briefly to ultraviolet light; one or both of these could cause DNA damage in the sperm. However, numerous normal animals have now been born after sperm sorting with this technique. Based on these animal experiments, there is no evidence that this type of sperm sorting increases the risk of birth defects. Additional laboratory studies are ongoing to help further understand any potential risk to sperm from MicroSort® treatment.

Since sperm sorting is new, there may be risks from the study that are currently unknown or unforeseen, including risks to an embryo or fetus. It is not known if sperm that are sorted with MicroSort are associated with an increased risk of congenital malformations, developmental delays, genetic damage induced diseases including cancers, ectopic pregnancy, reduced implantation and pregnancy rates, increased rates of spontaneous abortion, or other unknown risks. Clinical experience, to date, with MicroSort pregnancies have resulted in some major and minor congenital abnormalities. The expected major malformation rate is 4% in the general population. To date, a 2.3% major malformation rate (aneuploidies, such as Downs Syndrome are included) and 2.6% minor malformation rate has been noted in children born using sorted sperm. In addition to the malformations noted at birth, of 457 pregnancies there were 5 cases of spontaneous abortion associated with chromosomal abnormalities and 5 pregnancies

MicroSort Separation of X- and Y-Sperm

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were found to exhibit abnormalities based on prenatal testing. At this time, there is insufficient information to draw conclusions about whether these abnormalities are caused by the MicroSort technology.

MicroSort will not assume any responsibility or liability for participant’s travel, medication or treatment costs in the event the MicroSort laboratory is unable to sort a semen sample due to any unexpected condition, such as; equipment failure, power outage or any situation that would deem the laboratory unsafe or un-operational. For those couples using a frozen specimen, there are certain inherent risks in the process of freezing, sorting, refreezing, and shipping sperm specimens (the ultimate consequence of which could be failure of fertilization). These risks include, but are not limited to, damage to the sperm during the freezing, sorting, refreezing, and thawing process; handling during shipment; loss during shipment; and liquid nitrogen tank failure during shipment and storage. MicroSort will not assume any responsibility or liability for participant’s travel, medication or treatment costs in the event that sorted, frozen sperm is deemed unusable due to no motility post thaw.

We understand and accept that MicroSort and the Genetics & IVF Institute, its physicians, clinicians, laboratory directors, and laboratory personnel do not assume responsibility or liability for the condition or survival of the sorted sperm specimen or the physical, mental, or other characteristics of any child or children born as a result of the use of the sorted sperm. We agree to indemnify, hold harmless, and provide defense from any claim, demand, cause, or action for damages or otherwise asserted against MicroSort, the Genetics & IVF Institute, or its officers, directors, laboratory personnel, agents and contractors arising out of the freezing, sorting, refreezing, storage, shipping, handling, thawing and any other action involving the receipt and handling of the sperm samples.

Potential Benefits to Us and Others

MicroSort sperm separation is a new technology that does not result in complete exclusion of undesired sperm from the sperm sample used for the insemination; therefore, we may not conceive a child of the desired gender. In the case of sorting for X-bearing sperm, a male child could still be conceived in this procedure; and in the case of sorting for Y-bearing sperm, a female child could still be conceived.

The current separation technology (June 1994 - December 2002) has resulted in an average increase in the percent of X-bearing sperm from 50% in the unsorted sample to 87.6% in the sorted sample (the other 12.4% having the Y chromosome or undetermined). This increase would be expected to make it approximately 7 times more likely to have a female than a male child ($87.6 / 12.4 = 7.06$). The increase in the percent of Y-bearing sperm is from 50% in the unsorted sample to an average of 69.3% in the sorted sample (the other 30.7% having the X chromosome or undetermined). This increase would be expected to make it over 2 times more likely to have a male than a female child ($69.3 / 30.7 = 2.25$)

We may benefit by participating in this study although a benefit cannot be guaranteed. We may be able to increase the likelihood of conceiving a child (or children) of the desired gender. If we have a family history of a sex-linked or sex-limited genetic disease, we may be able to prevent our child (or children) from having the disorder. Our participation in this program may provide new and useful information in medical science and may aid in the development of new techniques to help other couples select the gender of their children.

Alternative Treatments

There are no other methods approved by the U.S. Food and Drug Administration (FDA) to increase the likelihood of conceiving a child of the desired gender.

We do understand that there are methods to detect X-linked or sex-linked disorders that involve post-conceptual DNA analysis performed on tissue obtained by amniocentesis or chorionic villus sampling. It has been explained to us that if a specific DNA alteration has been identified in our family, then this will allow direct and highly accurate fetal diagnosis. Alternatively, the gender of the fetus can be determined by chromosomal analysis or mid-trimester obstetrical ultrasound study. We also understand that the only way to prevent the birth of an affected child with post-conceptual diagnosis is by termination of such a pregnancy.

Confidentiality

If we agree to participate in this study, our identities will remain as confidential as possible within the limits of a study. Information from this study may be submitted to the FDA, or it may be submitted to the governmental agencies of other countries where the device may be considered for approval. The FDA may inspect our medical records, including those of our child (or children). The results of this research study may be presented at meetings or in publications, but our identities will not be disclosed in these presentations. MicroSort and the FDA must treat all patient names as confidential.

Compensation

We will not be paid or financially compensated to participate in this research study. We will be responsible for all associated fees and payment. By signing this agreement, we acknowledge that we have been made aware of the costs of our care in the program and agree to be fully responsible for them, including any additional costs of collection in the event of nonpayment. We also understand that we are financially responsible for any other medical costs incurred at the Genetics & IVF Institute or any collaborating facility.

Study-Related Injury

In the event that we believe participation in this study led to injury, we should contact Dr. Donald Marazzo at (703) 698-7355 and he will review the matter with us, identify any medical resources which may be available to us and assist us in obtaining appropriate medical care. We understand that MicroSort and the Federal Government does not have any programs to provide compensation for persons participating in research projects who experience injury. If we require information about our rights as research subjects, we may contact Tricia Nugent at the Genetics & IVF Institute IRB at (703) 698-7355.

If an injury occurs as a result of participating in the study, we will be required to file a claim through our insurance company, and there will be no compensation for us from Genetics & IVF Institute. Emergency medical treatment is provided by Institute personnel whenever possible or by our personal physician or local emergency room.

New Information

Any significant new findings discovered during the course of this research study that may relate to our willingness to participate in this study will be provided to us.

Our Rights as Subjects

If we have any questions about this study or if we experience an adverse effect that we believe may be related to our study participation, we should contact Dr. Donald Marazzo at (703) 698-7355.

If we require information about our rights as research subjects, we may contact the Genetics & IVF Institutional Review Board Coordinator, Tricia Nugent, at (703) 698-7355.

Voluntary Participation/Withdrawal

Our participation in this research study is entirely voluntary. We may refuse to participate or withdraw from participation at any time without penalty or loss of benefits to which we are otherwise entitled. Neither our withdrawal from this study, nor our refusal to participate, will affect our ability to receive future medical care from MicroSort.

Our decision whether or not to participate is voluntary and will not prejudice our future medical care. If we decide to participate, we are free to discontinue participation at any time, for any reason, without prejudice. However, if we choose to withdraw, I understand that MicroSort and the Genetics & IVF Institute may elect not to release my sorted semen or embryos created with sorted semen after withdrawing from the clinical trial. Due to the constraints of the clinical trial, if I choose to transfer my sorted semen or

embryos (resulting from the use of sorted semen) it may only be transferred to a collaborating facility that is in good standing with MicroSort.

MicroSort may end our participation in the research study without our consent. This may occur if it appears to be medically harmful to us, if we fail to follow directions for participating in the study, if we do not meet the study requirements, or if the study is canceled. This specific research study is expected to have a 4-year duration and will include enrollment of 3500 patients.

Consent to Participate

This Informed Consent/Authorization will be governed by the laws of the Commonwealth of Virginia.

We have read the above information, the Patient Information Packet, and have had an opportunity to ask any questions and all of our questions have been answered.

We have received a copy of this consent form. We voluntarily consent to participation in this research study and specifically request that the sperm be sorted for enrichment of the gender indicated below for the reason indicated below. We understand that this consent is valid for a maximum of 12 treatment cycles.

Check and initial one selection regarding the type of sperm sorting desired:

<input type="checkbox"/> XSort [®] (female)	<input type="checkbox"/> YSort [®] (male)
_____ (husband's initials)	_____ (husband's initials)
_____ (wife's initials)	_____ (wife's initials)

Check one selection, fill in the blanks, and initial regarding the reason for participation:

Genetic Disease Prevention (name of disease: _____)
 _____ (husband's initials) _____ (wife's initials)

Family Balancing (previous children: # of sons _____, # of daughters _____)
 _____ (husband's initials) _____ (wife's initials)

Husband's Name: _____

Wife's Name: _____

Address: _____

City: _____ State: _____

Postal Code: _____ Country: _____

Home Phone: _____ Work: _____

Clinician's name: _____

Facility Name: _____

Signature of Husband Date

Signature of Wife Date

Signature of Clinician Date

Signature of Witness Date