

Pacific Reproductive Services

444 DeHaro Street, Suite 222
 San Francisco, CA 94107
 Tel: (415) 487-2288

65 N. Madison Ave. Suite 610
 Pasadena, CA 91101
 Tel: (626) 432-1681

Email: info@PacRepro.com

Dear Recipient,

Thank you for allowing Pacific Reproductive Services (PRS) to assist you with screening of your Directed Donor as you embark on one of the most important events of your life.

The information that follows is to help you understand our **Policies and Procedures** regarding the use of Directed Donor sperm. These policies and procedures, which have been developed in compliance with **California Law and FDA Regulations**, are designed for your protection.

Please take the time to read the information about **Using Directed Donors** and about your **Registration**, so that the services we provide to you can be done more efficiently and be more cost-effective for you. It is also important to read about **ICI - and IUI- Prepared Specimens** on page five (5), so you can let us know how you want your donor's specimens prepared.

PRS requires that Recipients of Directed Donor sperm register and have their introductory appointment prior to, or at the same time as the Donor's first appointment.

Other information that will help you get started includes the Registration forms, tips for increasing your chances of getting pregnant, PRS fees and our policy about reporting pregnancies.

The section about "**How to Detect Ovulation and Time Your Insemination**" will help you chart your cycles, (use our down-loadable *Basal Body Temperature Chart*) and increase your chances for best results.

If you are registered as Domestic Partners in any state, we recommend that you complete and return the appropriate Declaration for Registered Domestic Partners.

If you are legally married in any state, please complete and return the Acknowledgement of California Family Code Section 7613 by Married Couple.

The registration forms to be completed and returned to PRS are:

- Patient Account Set-up and Registration Form
- Notice of Privacy Practices Summary
- Agreement for Administration of Directed Donor Sperm
- Medical Certification Form (for your clinician to complete)

Please call, email or fax PRS if you need more information or help. We will be happy to answer any questions you may have.

Sincerely,

Sherron Mills, NP
 Sperm Bank Director

USING DIRECTED DONOR SPERM

TABLE OF CONTENTS

SECTION I. USING DIRECTED DONOR SPERM	Page
Laws and Regulations	3
Screening a Directed Donor	3
Releasing or Administering Your Donor’s Sperm to You	4
SECTION II. RECIPIENT REGISTRATION AND RELEASE OF DONOR SPECIMENS	
How to Register	5
About ICI-Prepared and IUI-Prepared Specimens	5
How to Request Use of Your Donor’s Specimens	6
How to Schedule Shipments	7
About Dry Shippers	7
Materials That Accompany a Sperm Shipment	7
PRS Specimen Return Policy	7
SECTION III. HOW TO DETECT OVULATION AND TIME YOUR INSEMINATION	
How to Detect Ovulation	8
How to Insure a Well-Timed Insemination	9
Weekend Scheduling-How to Get Services During the Weekend	9
Using a Home Pregnancy Test	10
Once You’re Pregnant	10
Folic Acid Supplementation	10

USING DIRECTED DONOR SPERM

LAWS AND REGULATIONS

The following information describes **California Law and FDA Regulations** governing the use of donor sperm, including Directed Donor sperm. These laws and regulations were designed for your protection and are reflected in Pacific Reproductive Services' policies and procedures. Please feel free to contact us with any questions you may have about using Directed Donor sperm. Additionally, the *National Center for Lesbian Rights* (www.nclrights.com) is an excellent resource for single or coupled lesbians considering parenthood.

HEALTH REGULATIONS

- The U.S. Food and Drug Administration (FDA) issued regulations in May of 2005, which require that sperm donors are screened and tested for communicable diseases by FDA-registered facilities and that the screening and testing be done in accordance with FDA-established procedures. The purpose of these regulations is to reduce the risk that communicable diseases, including hereditary disorders are passed to either the recipient of donor sperm or any children conceived thereof. Pacific Reproductive Services is registered with the FDA and performs donor screening, as well as semen collection, processing, storage and distribution in accordance with FDA regulations. PRS cannot accept donors screened or tested by non-FDA registered and compliant facilities.
- The California Department of Health Services regulations stipulate that human tissue, including sperm, may not be released to or administered to a recipient until the Donor of that tissue has been tested for communicable diseases and the test results are reported as negative or non-reactive.

CIVIL LAW

- Under the provisions of California Civil Code, Section 7613(b), when a donor provides his semen to a licensed medical facility supervised by a physician for use in the reproductive procedure in a woman who is not his wife or partner, he is seen in law as not the natural father of any child conceived thereof.

In California, women wanting to guarantee exclusive parental rights for themselves and their partner through directed semen donations must do so through a physician supervised facility. This affords protection against a potential court challenge by a donor for custody of offspring.

SCREENING A DIRECTED DONOR

Donor screening is done in order to prevent when possible, and to reduce the risk of the introduction, transmission or spread of communicable diseases, including hereditary conditions, and to assess the performance of the donor sperm intended for use by a recipient. Donor screening includes the following assessments:

1. An assessment for Infectious Disease Risk
2. A Personal and Family Health History Review
3. An assessment of sperm count, motility and response to being frozen
4. A complete physical examination
5. Screening and testing blood and urine for infectious and hereditary diseases

We recommend that the screening be performed in two steps, in order to minimize any unnecessary expenses. The donor screening may be done all in one visit, if you prefer.

- **Step One:** A PRS clinician will perform an infectious disease risk assessment and medical history review with your donor. Afterwards, he will be asked to deposit his semen, which will be analyzed and frozen. A post-thaw analysis of his frozen semen will be done the following business day.

If your donor's semen analysis shows low sperm count and/or motility, or if the sperm shows poor survival from the freezing process, you will be asked to instruct PRS whether or not to proceed with the physical exam and laboratory tests. We will make recommendations, based on the estimate of his sperm's fertilizing potential.

Additionally, after the infectious disease risk assessment and review of your donor's health history, PRS must make a determination of whether your donor is eligible - under FDA regulations - before we may proceed to the second step.

- **Step Two:** We will perform a physical exam and some laboratory tests, and ask your donor to make another deposit of semen, which will be frozen for your future use.

Once all screening results are reviewed and your donor's eligibility has been verified by one of our clinicians, we will notify you and the donor. It takes about two (2) weeks to receive all of the lab results.

Your donor may make additional sperm deposits to be frozen before or after his lab results are reported; however, if any tests show evidence of communicable diseases in your donor, PRS may be required to dispose of those specimens.

RELEASING OR ADMINISTERING YOUR DONOR'S SPERM TO YOU

FDA regulations require that after the eligibility determination is made, and before your donor's sperm may be released or administered to you:

1. It must first remain frozen in quarantine for at least 180 days, after which PRS must re-test your donor for certain infectious diseases. The specimens may be released to you or your clinician once those test results show no evidence of infectious diseases. This is called a sperm *quarantine*. In such cases, please be sure your donor's appointment is *at least seven (7) months before* your planned reproductive procedure to allow for the six-month quarantine period.
OR
 2. Prior to releasing or administering *un-quarantined* sperm to you, your donor must be tested for infectious diseases within seven (7) days *before or after each* donation. We recommend that your donor make several donations over a two (2) week period and be tested in the middle of that two weeks as the most cost-effective way to comply with this regulation. If you wish for PRS to transfer your donor's specimens to another facility, it will be necessary for you to find out from that facility whether they require a six-month sperm quarantine *before* proceeding with having your donor screened.
- PRS does not distribute or release fresh (unfrozen) donor sperm for use in a reproductive procedure, nor do we perform inseminations with fresh donor sperm.
 - Please see the section for information about how to arrange for your donor's specimens to be administered to you by a PRS clinician or released to you or your clinician.

RECIPIENT REGISTRATION

HOW TO REGISTER

Choosing parenthood often involves many complex decisions, so PRS would like to help you simplify the process of getting pregnant. We hope you will find the following information helpful.

To get started quickly, Local Recipients can call PRS for an appointment for your Registration, Introductory Consultation and Medical Certification in one visit. We can have you ready to go in a few days. Or follow the easy steps below:

1. Please review, complete and sign the following three (3) forms: (You may also download these forms from our website at www.pacrepro.com).
 - **Recipient Account Set-Up & Registration Form**
 - **Notice of Privacy Practices Summary (HIPPA)**
 - **Agreement for Administration of Directed Donor Sperm**

2. You will need a completed **Medical Certification Form**. If you live in the San Francisco Bay Area or the Los Angeles area, you can get this completed at PRS along with your Registration and Introductory Consultation. Alternately, you can have your clinician (physician, nurse practitioner, nurse midwife or physician's assistant) complete this form for you.

3. Send these forms to PRS by Fax: to **415-863-4358**

Or by U.S. mail to:

Pacific Reproductive Services (PRS)
 444 De Haro St., Suite 222
 San Francisco, CA 94107

**Please include your "Initial Consultation and Account Set-Up" fee of \$150.
 You may enclose a check or provide your credit card information on the Registration form.**

When we have received all your completed forms, we will call or email you to schedule your Introductory appointment, a consultation in which we will give you general information about the timing and types of reproductive procedures available to you and help you decide which would be best suited for you. **(For clients living outside the San Francisco or Los Angeles area, these appointments may be conducted on the telephone.)**

- ❖ If you have been charting your Basal Body Temperatures (BBT) (see **HOW TO DETECT OVULATION AND TIME YOUR INSEMINATION**) it is helpful to have your charts when you have your introductory appointment. We will teach you how to use them in conjunction with the ovulation predictor kits to detect the time of your ovulation.

ABOUT ICI-PREPARED AND IUI-PREPARED SPECIMENS

NOTE: Please read this important information so you can instruct PRS as to how you want your donor's specimens prepared. Consult with one of our clinicians if you have questions. PRS prepares your Directed Donor sperm for ICI unless you instruct us to perform IUI preparation.

- ❖ **ICI (intracervical) prepared specimens** contain whole semen that has been frozen after the addition of a protective medium. These specimens may be safely placed in a woman's *vagina*, but can cause severe cramping and even shock if placed in a woman's *uterus* without first being "washed" (a laboratory process that separates the motile sperm cells from the seminal plasma). **PRS performs sperm washes on-site immediately prior to the intrauterine inseminations (IUI).** Most fertility specialists also perform sperm washing prior to performing IUI and always for IVF.

When to use ICI-prepared specimens:

- If you are doing a vaginal insemination at home or at your clinician's office
 - If you are having an insemination at PRS
 - If you are having In-Vitro Fertilization
 - If you are having an IUI by a Fertility Specialist. (Check with them first.)
- ❖ **IUI-prepared specimens** have been "washed", before being frozen. It is safe to place IUI-prepared specimens in a woman's uterus or vagina. **You will only need IUI specimens if you are planning an Intrauterine insemination and your clinician does not do sperm washing.**

HOW TO REQUEST RELEASE OF YOUR DONOR'S SPECIMENS

Note: Specimens cannot be *released to you* until your registration is complete, including your Medical Certification.

You can request your specimens by phone or you can fax or mail the enclosed PRS Specimen Order Form, which can also be downloaded from our website. The form provides information for your order.

If you are requesting release of specimens to be used in your current cycle, it is important to place your order as soon as you start your period, but **no later than the third day**, to allow time to process your order and also to avoid rush order fees.

Please provide the following information when you place your Order:

1. The first and last name of the Recipient who will be undergoing the insemination or other reproductive procedure.
2. The first day the most recent menstrual period started (actual bleeding, not spotting).
3. The usual length of the menstrual cycle; for example, 28 days.
4. Your Directed Donor's name and date of birth.
5. The date you plan to start testing for ovulation.
6. Where the procedure will be performed (home, PRS, or your clinician's office).
7. The type of procedure (Vaginal insemination, Intrauterine insemination or In-Vitro Fertilization).
8. If you are having an intrauterine insemination, does your clinician perform sperm washes?

If you're placing your order by phone and a PRS staff member is not available to take your call, please leave all the above information on our voicemail system. We will call or email you as quickly as possible to confirm your order and to provide any help you may need.

If you are ordering a shipment, see "How to Schedule Shipments."

If you are planning a PRS insemination or a specimen pick-up from PRS:

Once you have placed your Order, we will place you on a "Standby" list for an insemination or to pick up your specimens at the time of ovulation (see "Testing with an Ovulation Prediction Kit"). You may pick up specimens Monday-Friday, 9:30 am to 4:30 pm by appointment.

If you are planning a reproductive procedure at another facility, you may arrange with PRS for transport of your specimens at a specific time. Please give PRS at least seven (7) days notice to ensure on-time delivery.

If you would like our assistance with the timing of your insemination please call our toll-free number at 1-

888-469-5800.

HOW TO SCHEDULE SHIPMENTS

When scheduling a shipment, please give us the information listed under “How to Request Release of Specimens”, above, and also the following information about your shipment:

1. Location PRS will be shipping to: your home or to a clinic or clinician’s office.
2. The name of the person who will be receiving the specimens.
3. The full address and phone number where the specimens will be received.
4. Your credit card information:
 - The name on the credit card
 - The card number and type (PRS accepts Visa and MasterCard)
 - The expiration date

It is important to place your request as soon as you start your period (*no later than the third day*) to allow time for the processing of your order, including scheduling for the timely arrival of your specimens and to avoid having to pay Rush Order Fees. See price sheet for orders needed within 48 hours.

- ❖ **Semen is shipped in nitrogen vapor tanks** (dry shippers) and is sent via FedEx by Standard 2nd Day delivery. You may request a Priority Overnight shipment for an additional fee.
- ❖ **PRS ships specimens Monday through Friday**, for shipments to arrive Tuesday through Saturday. There is an additional \$30 fee for Saturday deliveries. Deliveries are not possible on Sunday.
- ❖ **PRS must receive your payment by the time the specimens are to be shipped.** Credit card information can be given by phone or provided on the PRS Specimen Order Form.

ABOUT DRY SHIPPERS

Your specimens will be transported in nitrogen vapor tanks (dry shippers) that maintain your specimens at very cold temperatures. Dry shippers hold their nitrogen vapor charge for approximately five (5) to seven (7) days, after which your specimens may thaw unless the dry shipper is re-filled. You may obtain more liquid nitrogen, from a biological gases company or a welding company.

Our shipping fee includes the dry shipper rental for five (5) days. **An additional tank rental fee of \$30 per day is charged if the tank is kept longer than five (5) days.**

PRS requires your credit card information as security deposit for the dry shipper. The replacement cost for lost or damaged dry shippers is \$800 to \$1000.

MATERIALS THAT ACCOMPANY A SPERM SHIPMENT

For your home inseminations, PRS includes syringes and instructions for thawing and performing the insemination with each shipment. If no syringes are included with your shipment, an eyedropper or medicine dropper (a larger size is preferable) from your local drugstore is an excellent alternative.

PRS SPECIMEN RETURN POLICY

Specimens that have been distributed from the PRS cryobank may be returned to PRS cryostorage only for the Recipient’s future personal use. In such cases, PRS storage fees will apply.

- We recommend the ovulation predictor kits listed below, since not all ovulation predictor kits are equally accurate. Some are more sensitive than others, but some tests may give false positive results, resulting in an ill-timed insemination.

Kits We Recommend:

Product: OVUSponse

OVUSponse is available for purchase at our office. It is a 1- step LH ovulation predictor test that yields results in about 3 minutes. The kit comes with 9 tests and each kit is \$30.00. For more information on OVUSponse go to: <http://www.ovusponse.com> or call: (877) 546-4223.

HOW TO INSURE A WELL-TIMED INSEMINATION

We recommend doing an insemination the day your OPK is first positive and again the following day. PRS recommends two (2) inseminations per cycle when using frozen sperm, because frozen sperm only survives for about 12 to 24 hours in a woman's body.

If you are a local PRS client and plan to inseminate at PRS, at home or at another medical office, please be sure to test and call us by 1:00 p.m. (on weekdays) to let us know if your result is positive. We can then set up an appointment for an insemination or pickup for that afternoon, or as indicated by your clinician. *(Please see Weekend Scheduling below for how to get services during the weekend.)*

If you have received a sperm shipment and plan to inseminate at home, proceed with your insemination the same day your test is positive, and again the next day.

WEEKEND SCHEDULING-HOW TO GET SERVICES DURING THE WEEKEND

PRS does not conduct regular business on the weekends, nor are our regular telephone lines answered. Local clients whose ovulation might occur over the weekend are put on a weekend "Standby" list by PRS staff. **Be sure you call to request your donor sperm by the third day of your cycle. See section "How to Request Use of Your Donor's Specimens."**

- **If you are planning to pick up your specimens** for a weekend insemination at home or your clinician's, please make an appointment to retrieve your semen by **4:30pm on Friday**. Your specimens will be given to you in a nitrogen vapor tank (see "About Dry Shippers".) PRS requires your credit card information as security deposit for the dry shipper and the rental fee is \$30 for a weekend and \$30 per night week nights. The replacement cost for lost or damaged dry shippers is \$800 to \$1000.
 - **If you're planning a weekend insemination at PRS:**
Although PRS does not conduct regular business on the weekends, our Clinicians do come in to do inseminations for Recipients that have been put on the weekend Standby list. **It is necessary to be on the Standby list in order to be inseminated on a weekend.**
1. If you have already informed us your period has started and are intending to inseminate in the current cycle then PRS will confirm your weekend Standby status by Friday at 4 pm. and will remind you to test

- for ovulation both Saturday and Sunday mornings by 8:00 am.
2. Be sure you test your urine with an Ovulation Predictor Kit (OPK) by 8:00 am Saturday and Sunday. Do not test first morning urine because it is very concentrated and could result in a false positive result.
 3. If your OPK is positive, call PRS by 8:30 am at 415-705-0969. PRS staff will check the messages by 8:30 am and will prepare the specimens for your insemination by 11 am.
 4. After you have made the call, please come to the PRS office at 11 am. The main doors to the building are locked on the weekend. Please use the smaller doors on DeHaro Street closer to 17th street, where a guard is on duty.

In order to be certain that you don't miss your insemination:

- ❖ Please call to request your specimens and go on Standby within the first three (3) days of starting your period.
- ❖ Please be sure to talk with us by Friday afternoon before the weekend that you might inseminate at PRS.
- ❖ Please be sure to make that second call to confirm your positive OPK results by 8:30 am on Saturday or Sunday.

USING A HOME PREGNANCY TEST

If you have inseminated and want to test for pregnancy, we recommend that you test fifteen days after insemination if you have not had a period or if your period is abnormal. Use a first-morning urine specimen. You can also call our office or your regular medical practitioner if you want to do a blood pregnancy test.

ONCE YOU'RE PREGNANT

Reporting Pregnancies and Their Outcomes

PRS is required by FDA regulations to keep records of all pregnancies and their outcomes. Please report any positive pregnancy test to us as soon as possible and let us know about the outcome, whether it was a normal birth, a miscarriage or whether the pregnancy had to be terminated for any reason.

PRS guarantees that all information in your file is confidential, and will not be released to anyone without your express, written authorization.

FOLIC ACID SUPPLEMENTATION

For women considering or attempting pregnancy, we recommend that you begin to take a vitamin with .04 mg Folic acid (folate) even before you get pregnant, as this has been known to prevent spine defects in newborns. We recommend a vitamin such as Theragram or Centrum. Prenatal vitamins may also be taken, but they contain more iron than is usually needed before pregnancy.