



## SPAR · SPECIAL PROGRAM OF ASSISTED REPRODUCTION

A Program of the Bedford Research Foundation Clinical Laboratory

Massachusetts 501(c)(3) not for profit organization

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### Overview & Program Guide

A brief history and overview of SPAR, along with a step by step guide to the program.

*The goal of SPAR is to take advantage of research findings that approximately two-thirds of semen specimens produced by healthy, HIV infected men have an undetectable amount of HIV. Sperm from such specimens are safer for use in assisted reproduction than “washed sperm” from untested specimens, or from specimens that test positive for virus.*



### A Brief History

The *Special Program of Assisted Reproduction* (SPAR) started in 1994 as a support group for couples living with incurable, sexually transmitted diseases, such as HIV/AIDS. The patient couples began raising money to fund the research needed to improve the safety of attempting pregnancy without transmitting the father's infection to the mother and baby.

By 1996 sufficient funds had been raised to establish the Bedford Research Foundation (formerly the Assisted Reproduction Foundation) as an independent Massachusetts public charity.

Within two years, the Foundation had supported the development of methods for reducing, and perhaps eliminating, the risks of infection to the mother and the child. These methods included sensitive assays for Human Immunodeficiency Virus (HIV) infection in semen. The goal was to develop laboratory tests and procedures to make it possible for couples living with HIV disease to

be cared for in the infertility center of their choice.

The first SPAR baby, Baby Ryan, was born in May 1999. Baby Ryan's birth was attended by Minnesota Public Radio reporter, Stephen Smith, whose prize winning story is posted at [www.americanradioworks.org](http://www.americanradioworks.org), along with his earlier story describing SPAR.

The success of SPAR demonstrates the speed and efficiency with which dedicated public charities can bring about biomedical advances.

*The Bedford Research Foundation's clinical laboratory is a not for profit, 501(c)(3) organization. The laboratory operates on the principle that revenues and information from existing laboratory tests should be used to support research and the development of new tests.*

## Quick Start Guide

### The goal

of SPAR is to help couples achieve a pregnancy without transmitting the father's infection to the mother or the child.

### The premise

is that using sperm from semen specimens with no detectable virus decreases, perhaps eliminates, the risk of transmitting infection.

Although each step can have several parts and complications may arise depending on the needs of the couple, SPAR has essentially four stages:

SPAR is the only program in the world that uses highly sensitive PCR tests for HIV in semen to minimize the risk of cryobanking sperm that could transmit the father's infection to the mother and child during assisted reproduction.

For more information about the PCR test for HIV RNA and DNA, refer to the *Understanding The Science* guide, enclosed in this packet, or on the web at: <http://www.sementesting.org>.

## 1 Evaluation of male and female partners

The process begins with an evaluation of the HIV infected male with respect to duration of disease, current health status, confounding infections, such as Hepatitis virus or prostatitis, and current antiviral therapy.

During a personal conference with Dr. Kiessling, she will explain the entire process, the potential pitfalls, and help locate collaborating infertility clinics.

## 3 Semen Specimens are tested for HIV, the sperm "washed" and cryopreserved

Cryopreserved sperm from specimens with an undetectable viral burden can be shipped to the collaborating clinic for use in IVF or Oligospermia cup procedures. Intra-uterine Insemination (IUI) is NOT an approved SPAR procedure. The clinic can either retain the liquid nitrogen dry shipper for the duration of the procedure and return unused sperm, or transfer the tested specimens to the clinic's nitrogen freezers.

## 2 Collection of two HIV Undetectable Specimens

The semen viral burden is determined by a highly sensitive PCR assay for HIV that detects both free virus particles (HIV RNA) in seminal plasma and virus infected cells (HIV proviral DNA).

Semen specimens may be collected in the privacy of the patient's home and shipped overnight to the laboratory for testing.

## 4 Treatment at a Collaborating Infertility Clinic

More than two dozen infertility centers worldwide collaborate with the Bedford Foundation with infertility procedures that meet the needs of the couple. The Bedford clinical lab will only send cryopreserved sperm from semen specimens with an undetectable viral burden. Most collaborating clinics offer IVF as the infertility treatment of choice, but an increasing number also offer insemination via oligospermia cup.

# Steps Check List

## 1 Patient Information Packet

Thoroughly review this packet. These pages are also available at: [www.sementesting.org](http://www.sementesting.org).

## 2 Consultation

At this initial meeting, Dr. Ann Kiessling, the Director of SPAR, will review your specific circumstances, risks, treatment options available for you, and answer your questions. If needed, a special plan for patient confidentiality will be developed.

She will be your advocate with fertility clinics and other physicians as needed.

Complete and mail the *Patient History Questionnaire* and the *Consult Request*

Schedule Initial Consultation

## 3 Evaluation of Male Partner

Evaluation of the male partner begins with the specialized semen analyses provided when the specimen is submitted for viral testing.

However, it is possible that SPAR staff may recommend not going forward with a pregnancy cycle, or postponing the cycle if a problem has been found, such as multiple semen specimens testing positive for virus. This may be caused by common problems in semen producing organs, such as inflammation of the prostate, that can be treated by a urologist.

In addition to safety considerations for pregnancy attempts, it is in the long term health interests of the HIV-infected male to decrease or eliminate HIV in all semen producing organs.

- Submit Two Specimens for Testing (two separate kits)
- Enclose signed consent form for viral testing for each specimen
- If HIV is detected, submit a third specimen
- If two specimens in a row test positive for HIV, schedule a follow-up conference with Dr. Kiessling (no additional fee).

## 4 Cryopreservation of Sperm

Cryopreserve (freeze to keep alive) purified ("washed"), PCR tested, sperm from at least two specimens prior to beginning infertility treatment. This requires at least two *Live Semen Transport Kits*. Sperm from two specimens are required to guarantee the availability of viable sperm.

Each specimen will be tested for HIV by the specialized molecular biology PCR test for virus particles and for infected cells. **Sperm only from specimens with an undetectable viral burden will be used to attempt a pregnancy.**

Additionally, if necessary, sperm may be recovered from the testis (testicular sperm aspiration, known as TESA) or the epididymis (microepididymal sperm aspiration, MESA). This is accomplished by delicate surgical procedures developed for male-factor infertility. It is possible to test the aspirates for HIV.

- Receive test results from two HIV-undetectable specimens
- Receive confirmation that you have two specimens cryopreserved and ready for shipment to an infertility center. (we request 30 days notice of shipment)
- Remember a \$25 monthly storage fee per specimen will apply after the first month of storage

## 5 Evaluation of Female Partner

The female partner will undergo a thorough evaluation by a gynecologist or an infertility specialist. Although most women entering SPAR will not have an infertility problem, infertility treatment requires medications and examinations that are costly and time consuming, so full evaluation of the female's reproductive tract is important in order to anticipate or correct problems that might arise.

(step 5 continued)

Hormone levels and antibodies against infectious diseases will also be measured. This information will help anticipate the possible response to IVF medications, determine prior exposure to infectious agents, and measure protective immunity important to all women seeking to establish a pregnancy.

- Visit a gynecologist or infertility specialist for evaluation
- Understand the type of procedure recommended
- Notify SPAR Coordinator of choice of infertility clinic.
- Notify SPAR coordinator of tentative schedule for infertility procedure.

## 6 Specimen Shipping

The Foundation can ship cryopreserved specimens to any location in the world.

The fee for shipment, and the signed consent form, are required in advance and all outstanding charges on the patient's account must be reconciled. In order to protect your specimen from loss, damage or delay during shipping, the Foundation will generally only ship specimens Monday thru Wednesday. Specimens are shipped in a dryshipper containing liquid nitrogen vapor. At least 30 days notice is required prior to shipping.

- Complete and mail the signed shipping consent form with payment.
- Confirm that all outstanding charges and fees on the account have been settled.
- Confirm date of procedure and date specimen is required with your infertility center or doctor.
- Confirm with SPAR coordinator that all paperwork, fees and dates for shipping have been set.

