

CENTER FOR REPRODUCTIVE BIOLOGY OF INDIANA
at Methodist Medical Plaza North
201 Pennsylvania Parkway-Suite 205, Indianapolis IN 46280

RELEASE OF CRYOPRESERVED SEMEN FOR DIRECTED DONATION

I, the undersigned, authorize the withdrawal of _____ (indicate number of vials or straws) units of cryopreserved (frozen) semen from storage at the Center for Reproductive Biology at Methodist Medical Plaza North. I request that these samples be shipped in _____ (number of) shipments. The Center for Reproductive Biology recommends that two separate shipments be made to guard against any potential loss during shipment. A shipping fee is charged for each shipping container.

I request that these specimens be shipped in a liquid nitrogen dry shipper via Airborne Express for overnight delivery _____ (date) to the following facility:

Address:

I also release results of infectious disease testing that was performed prior and following cryopreservation. These results are necessary for release and storage of the semen. If these specimens were cryopreserved after May 25, 2005, an "FDA Required Donor Eligibility Record" will be included as a package insert with my specimen. **CRBI will not release specimens for Directed Donation unless they are accompanied by a summary of infectious disease screening and testing results as required by FDA on the form "FDA Required Donor Eligibility Record".**

I acknowledge that the Center for Reproductive Biology will not make any representation or warranty with respect to:

- (i) the viability of frozen specimens
- (ii) the possibility of the successful use of the frozen semen
- (iii) the infallibility of the shipping service
- (iv) the infallibility of the equipment of the Center for Reproductive Biology
- (v) the lack of risk of birth defects, miscarriage or complications in any pregnancy resulting from the use of these specimens

I acknowledge that these specimens were cryopreserved for use in a directed donation. All initial testing has been performed and the results noted on the FDA Required Donor Eligibility Record. Testing must be repeated 180 days after date of sperm freezing and all results must be negative and available to the Laboratory, in accordance with Indiana State Law, before the specimens can be released for use in Indiana. The FDA permits an exception for the recipient of a Designated Donor to accept specimens from an Ineligible Donor if appropriate informed consent and special labeling Requirements are met. **Because my specimens will NOT be used on-site at the Center for Reproductive Biology, I understand that my receiving laboratory is responsible for meeting all FDA requirements for obtaining the recipient's informed consent for use of this designated donor specimen. CRBI will provide all FDA required screening and testing information on these specimens that were performed at the time of specimen collection.**

I understand that the Center for Reproductive Biology will inform the receiving facility of the manner in which the specimens should be thawed. I understand that once the frozen specimens have been withdrawn from storage at the Center for Reproductive Biology and received by the shipper, that the Center for Reproductive Biology cannot be responsible for the handling of said specimens. I further understand that I am financially responsible for the costs of shipment.

(Printed Name of Donor/Designee/Guardian)

(Signature of Donor/Designee/Guardian)

(Date)

(Printed Name of Program Witness
or Physician/Representative)

(Signature of Witness)

(Date)

If this form is not signed in the presence of a member of the Center for Reproductive Biology or the patient's physician/representative, the form must be signed in the presence of a Notary Public (see the back of the form).

A copy of this form will have the same legal effect as the original.

Witness by Notary Public

(Name of Donor/Designee/Guardian)

State or Province of _____

County of _____

I certify that I know or have satisfactory evidence that _____
is the person who appeared before me, and said person acknowledged that he signed this instrument
and acknowledged it to be his free and voluntary act for the uses and purposes mentioned in the
instrument.

Date: _____

(Signature of Notary Public)

(Title)

My appointment expires: _____

Residing in: _____

**CENTER FOR REPRODUCTIVE BIOLOGY OF INDIANA
AT METHODIST MEDICAL PLAZA NORTH**

**NOTIFICATION OF RELEASE OF CRYOPRESERVED SEMEN SPECIMENS
FOR DIRECTED DONATION**

_____ (Name of Semen Donor) has requested the Center for Reproductive Biology at Methodist Medical Plaza North to release cryopreserved semen samples to you and your facility.

I, the undersigned, acknowledge that I am prepared to receive the cryopreserved specimens for (Name of Recipient): _____. I acknowledge that I have been informed that these specimens were cryopreserved within the context of directed donation. I am aware of the infectious disease testing required of the recipient and donor as stated in ISDH IAC.25-2-2 and Federal Statute 21 CFR Part 1271.

I acknowledge that these specimens were cryopreserved for use in directed donation. All initial testing has been performed and the results negative. Testing must be repeated 180 days after sperm freezing is complete and all results must be negative and available to the laboratory, in accordance with Indiana State law, before the samples can be released for use in Indiana. I understand that the Center for Reproductive Biology will not release any cryopreserved semen samples until written results of all testing are available to the laboratory can be summarized in the FDA Required Donor Eligibility Record (provided as a package insert with the specimen).

I understand that the Center for Reproductive Biology will provide information regarding the proper thawing of these specimens. I will advise the Center for Reproductive Biology of available storage (liquid nitrogen dewar) at my facility and when the specimens will be needed.

I understand that I must provide at least **1 week notice** to the Center for Reproductive Biology to arrange for shipping and that such notice must be provided Monday through Friday. A shipping fee will be charged for services, if a pre-paid, charged shipping dewar is not provided. Delivery will not be provided for Saturday or Sunday.

If it is known when the samples will be needed, please indicate here: _____ (date)

Complete address at which specimens can be received:

Name and Phone Number of contact person the Laboratory can call to verify information and to confirm shipping:

_____ (Name) _____ (Telephone/Facsimile)

(Name of Physician)

(Signature of Physician)

(Date)

The cryopreserved semen samples will not be shipped until all required documentation is received by the Center for Reproductive Biology. Please return this completed form to:

Center for Reproductive Biology at Methodist Medical Plaza North
201 Pennsylvania Parkway-Suite 205
Indianapolis, IN 46280
FAX 317-817-1316 **Phone:** 317-817-1147

Please call the laboratory if you have not received confirmation of shipping 3 business days in advance of the date needed. Samples will be shipped only Monday, Tuesday or Wednesday to insure delivery by Friday.

A copy of this form will have the same legal effect as the original