BIOGENETICS CORPORATION

FDA Registered • Licensed by New York State Department of Health •Licensed by New Jersey Department of Health (CLIA)
187 Mill Lane <> Mountainside, New Jersey 07092 <> 908-654-8836 <> 800-637-7776 <> Fax 908-232-2114

RECIPIENT ACKNOWLEDGMENT AND CONSENT FOR THERAPEUTIC ASSISTED REPRODUCTION BY CRYOPRESERVED DONOR SPERM

ACKNOWLEDGMENT dated as of _____

Recipient's Name:_____
and if applicable
Recipient's spouse or partner: _____
(collectively referred to as "Recipient")
Address: _____

_____

WHEREAS:

A. BioGenetics is a New Jersey Corporation, which operates as a human sperm bank. The business of which is to recruit, process, preserve and store and distribute anonymous donor sperm for purchase by licensed physicians and health care facilities for use by their patients **or** purchased directly by individual recipients under the supervision of the medical entity named below for the purpose of therapeutic assisted reproduction.

B. Recipient is a Patient of: _____**(Insert Physician's Name)**

Physician's Address: _____

_____

For the purpose of having a child conceived through therapeutic assisted reproduction, in consideration of the procurement of cryopreserved (frozen) anonymous donor sperm ("Specimens") to be used by Physician/Medical Facility in the process of aiding the recipient through therapeutic assisted reproduction, and as a condition of this procurement ***RECIPIENT ACKNOWLEDGES:***

REPRESENTATIONS OF RECIPIENT:

A. Recipient has read this acknowledgment and consent and understands it. Recipient has the opportunity to review it and seek legal counsel advise to understand terms and content of this acknowledgement and consent. Regardless of whether Recipient has taken the opportunity to so review it. Recipient executes this acknowledgment and consent freely.
B. Recipient has executed and delivered to the Physician/Medical Facility the acknowledgement and consent form for therapeutic assisted reproduction by cryopreserved donor sperm**. Document must be forwarded to BioGenetics**.
C. Recipient shall not permit therapeutic assisted reproduction, which is not carried out under the supervision of a licensed physician.
D. Recipient acknowledges that the Specimens used to carry out the therapeutic assisted reproduction have been donated by a man other than Recipient's spouse or partner.
E. Recipient has been advised, acknowledges and understands legal relationship to any child born as a result of therapeutic assisted reproduction from Specimen procured by BioGenetics.
F. Recipient has been advised, acknowledges and understands that, BioGenetics is not able to nor guarantees or in any way represents or warrants that any therapeutic assisted reproduction will result in a pregnancy.
G. Recipient has been advised and understands that within the normal human population a certain percentage of children are born with physical or mental defects and the occurrence of such defects are beyond the control of BioGenetics.
H. Recipient, and not BioGenetics, has selected the donor Specimens to be used for therapeutic assisted reproduction.
I. Recipient has been counseled by, and is under the care of, a Physician/Medical Facility that has advised Recipient that the use of the cryopreserved Specimens may involve several risks and is not limited to the following:
    1. Infection borne from virus, bacteria or other unknown elements;
    2. Development of sperm antibodies;
    3. Psychological disturbances as a result of therapeutic assisted reproduction being performed on Recipient, her spouse or partner, if any, or upon any other person;
    4. Anaphylactic or allergic responses by Recipient to the sperm and seminal implantation;
    5. Any abortion, natural or induced, resulting from a pregnancy induced by the Specimens;
    6. The occurrence of any congenital abnormality to the off-spring, including, but not limited to, genetic, chromosomal, environmental, metabolic, whether internal or external;
    7. Abnormalities relating to appearance and/or features of the newborn including, without limitation, ethnic or racial variation, skin color, eye color, hair color and/or abnormalities related to these structures or to any other internal or external structure;
    8. Neuro-psychological or other aberrations of the offspring;
    9. Physical or mental abuse by Recipient, or sibling(s) of the newborn or any other person(s);
    10. Subsequent diseases, whether foreseeable or unforeseeable; potential psychological implications of off-spring as a result of the therapeutic assisted reproduction with regards to the relationship with spouse or partner, if any, the child or children, any other child or children, or any other relationship.

PURCHASE OF SPECIMENS:

A. Recipient must submit to BioGenetics, verbally an order for a given donor Specimens to be followed, in writing sent by mail or fax a "Phone Confirmation" developed and available from BioGenetics. A "Phone Confirmation Form" is to be completed and sent every time an order is placed for Specimens by the Recipient. The order shall set forth the desired donor number as made available through The "Donor Quarterly". The provisions of this acknowledgement and consent shall supercede the terms of any form or purchase order supplied by the Recipient.

B. BioGenetics shall have the right, during the period between the date on which the actual order was placed and the date on which the phone confirmation form is received, to exhaust its inventory of any of the Specimens, without liability to Recipient.

C. If BioGenetics does not have Specimens suitable to fill Recipient's order, BioGenetics shall so notify Recipient, verbally within a reasonable time, and Recipient shall have the option of changing its requested donor Specimens or canceling the order. If the order is cancelled, neither party shall have any obligation of any kind to the other with respect to the order.

D. The fees to be paid to BioGenetics with respect to each purchase of Specimens shall be those set forth on BioGenetics current fee schedule in effect at the time of the order. BioGenetics shall furnish copies of its fee schedule to Recipient on request. Fees paid to BioGenetics shall include all shipping costs and other charges associated with the delivery of the Specimens to Physician/Medical Facility.

DONOR'S NAME:

Neither Physician/Medical Facility nor the ultimate user of the Specimens shall have the right to learn the donor's identity or donor's personal information other than the information provided by the donor with regards to the donor's personal and family medical history. Recipient acknowledges that BioGenetics is relying totally upon the representation of its donors that; **(1)** the Specimens collected by that donor is the donor's own; and **(2)** the donor's genetic and hereditary characteristics as well as the donor's medical history provided in the donor profile is accurate and correct to the best of the donor's knowledge. *Neither BioGenetics nor any laboratory employed by BioGenetics makes an independent supervision of the donation. Neither BioGenetics nor any laboratory employed by BioGenetics makes an independent verification of any information contained in the donor profile. Neither BioGenetics nor any laboratory employed by BioGenetics shall not be liable to Physician/Medical Facility or to any other party by reason of the breach of any representation made to it by the donor. Neither BioGenetics nor any laboratory employed by BioGenetics shall not be liable to Physician/Medical Facility or to any other party for any claim based in whole or in part on information which BioGenetics or the laboratory could have learned had it made any independent investigation or any information contained in the donor profile or any supervision of the donation*.

WARRANTIES:

A. Except as otherwise specifically set forth in this Acknowledgement and Consent, BioGenetics hereby disclaims all express and implied warranties INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY AND ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR USE. In no event shall BioGenetics be liable for incident or consequential damages of any kind to Recipient, Physician/Medical Facility, or to any child born as a result of therapeutic assisted reproduction with Specimens supplied by BioGenetics.

B. Recipient acknowledges that Specimens are subject to spoilage and other risks inherent to organic and inorganic matter.

C. The sole warranty of BioGenetics with respect to the Specimens is that, within thirty (30) minutes after thawing according to BioGenetics' specifications the Specimens will have the following indices:

   1. Motility of not fewer than 10 million motile sperm cells per vial(s).

   2. Index of motility 2.0 (0=non motile, 3=excellent forward progressive motility)

   Specimens that are found by a Physician/Medical Facility not to meet the above indices set forth by BioGenetics may qualify for credit. The Physician/Medical Facility must notify BIOGENETICS, on behalf of the recipient, using a Product Complaint Report Form (Available from BioGenetics), within twenty-four (24) hours or the first day of business following the post- thaw evaluation of the Specimens. This only applies when the Specimens are kept in BioGenetics dry shippers or appropriately transferred to a liquid nitrogen storage container allowing for the Specimens to remain in a vapor phase environment for long term storage, a period greater than four (4) days.

D. The effective holding time of the dry shipper, used by BioGenetics for transport, is based on BioGenetics quality assurance protocol for accessing dry shipper performance. BioGenetics therefore limits the holding capacity of cryopreserved Specimens in its dry shipper to a period not to exceed four (4) days**. BioGenetics recommends that Physician/Medical Facility maintain Specimens in BioGenetics dry shipper for a period not greater than four (4) days from date of shipping of the Specimens.**
   Approval for EXTENDED STORAGE OF CRYOPRESERVED SPECIMENS, other than the recommended method proposed by BioGenetics, must be obtained by directing all inquiries to the sperm bank Director at BioGenetics.

E. **Specimens not used due to over-stock, cancelled or missed treatment cycle may not be returned to BioGenetics for credit.**

F. The sole liability of BioGenetics for breach of the warranty set forth in paragraph C, (specifically line 1 thru 4) or any other breach of this acknowledgement and consent shall be the return of monies paid for the Specimens to which the warrant relates. BioGenetics shall not assume liability for breach of warranty unless a claim is made using the Product Complaint Report Form supplied by BioGenetics. The Product Complaint Report Form is to be completed in its entirety. The Product Complaint Report Form is to be completed by the Physician/Medical Facility, on behalf of the Recipient.
   Failure to assert a claim for breach of warranty strictly within the time limit and in the manner described in paragraph C, D and E of this section shall constitute a waiver of claim with respect to the Specimens to which the claim would have related.

DIAGNOSTIC TESTS:

BioGenetics represents that the following diagnostics tests **AND NO OTHERS** will have been performed on Specimens or on the donor. CLIA licensed medical laboratories are sub-contracted to perform laboratory tests on the donor's semen, blood and urine samples. These tests will have been conducted in accordance with parameters recommended by various scientific and government agencies, while using FDA approved procedures and/or testing kits, to qualify the use of donor Specimens for therapeutic assisted reproduction procedures.

THE INITIAL EVALUATION TO CONSIST OF THE FOLLOWING TESTS:

Blood Group and Rh	Chemistry Profile	Complete Blood Count
Hepatitis C Virus Antibody	Hepatitis B Surface Antigen	Hepatitis B Core Antibody
HIV-1/2 screening	HTLV-I&II	Syphilis serology screen
Cytomegalovirus screen (CMV)	Chlamydia/ PCR	Urinalysis
G.C./PCR	Herpes Virus culture	B-Strep. Bacterial culture
Myco\Ureaplasma culture	B-Thalassemia screen	Tay Sachs screen
Sickle Cell screen	Cystic Fibrosis screen	HIV/HCV/HBV (NAT)
Karyotyping/Chromosome Analysis	Urine Drug screen (unscheduled randomized testing)	

IN ADDITION ALL DONORS ARE TESTED FOR THE FOLLOWING:

Gaucher Disease	Canavan Disease	Niemann-Pick Disease

AND ON A MONTHLY BASIS THE FOLLOWING TESTING MAY VARY WITH FREQUENCY OF SPECIMEN COLLECTION:

Hepatitis C Virus Antibody	Hepatitis B Surface Antigen	HTLV-I&II
Syphilis serology screen	HIV-1/2 screening	Cytomegalovirus screen (CMV)
Herpes Virus culture	Myco\Ureaplasma culture	Chlamydia/ PCR
G.C./PCR	Beta-Strep. Bacterial culture	Chemistry Profile (Bi-annually)
Hepatitis B Core Antibody (Bi-annually)		
Urine Drug screen (unscheduled randomized testing)		

NO TESTS ARE PERFORMED FOR cancer markers or multiple sclerosis.
All laboratory test results were within acceptable limits prior to the release of donor's Specimens

Warning: Even if the tests described in the preceding paragraph were found to be within normal limits, and even when properly administered, the tests have their own limitations and may not produce reliable results. Consequentially, Physician/Medical Facility and its Patient(s) take the risk that certain Specimens will not be disease free even though the test results may indicate otherwise.

BioGenetics represents that **ALL SPECIMENS ARE QUARANTINED for 180 days** minimum and are released starting on the 210th day.

DISCLAIMERS:

BioGenetics shall not be responsible for, and recipient hereby releases BioGenetics donors, agents, officers, directors, employees, advisors and consultants from all liability of any kind or nature with respect to:

A. A failure of the Specimens to induce pregnancy.
B. The handling or supervision of the Specimens after they have left BioGenetics' premises.
C. Any birth defects or abnormalities of any kind, including genetic, chromosomal, environmental, metabolic, whether internal or external resulting from a pregnancy induced by the Specimens.
D. Any failure of the Specimens to produce the characteristics set forth in The "Donor Quarterly" in any child born as a result of therapeutic assisted reproduction with the Specimens.
E. Any missed cycle scheduled for therapeutic assisted reproductive procedure whereby Specimens were obtained from BioGenetics.
F. Survival of embryo(s) created from cryopreserved donor Specimens obtained from BioGenetics
G. Successful implantation of embryo(s), which may have been created from cryopreserved donor Specimens, obtained from BioGenetics.
H. Any abortion, natural or induced, resulting from a pregnancy induced by the Specimens.
I. Any claim against Physician/Medical Facility which arises from, is connected with or is in anyway related to the Specimens and any therapeutic assisted reproduction in which they are used; (including, without limitation, the parent or parents of any child born as a result of therapeutic assisted reproduction with the Specimens, any such child, or the sibling or other relatives of any such child) which arises from, is connected with, or is any way related to any therapeutic assisted reproduction.
J. Performance or non-performance of any act to be performed (or not to be performed) by Physician/Medical Facility.
K. The failure of Physician/Medical Facility, or any Patient(s) of Physician/Medical Facility, to conform to applicable laws with respect to the Specimens or any therapeutic assisted reproduction in which the Specimens are used.
L. In addition, Recipient has been counseled and understands that the use of cryopreserved Specimens may involve several risks and is not limited to the following:
    1. Infection borne from virus, bacteria or other unknown elements;
    2. Development of sperm antibodies;
    3. Psychological disturbance as a result of therapeutic assisted reproduction being performed on recipient, or upon any other person;
    4. Any abortion, natural or induced, resulting from a pregnancy induced by the Specimens;
    5. The occurrence of any congenital abnormality to the off-spring, including, but not limited to, genetic, chromosomal, environmental, metabolic, whether internal or external;
    6. Abnormalities relating to the appearance and/or features of the newborn including, without limitation, ethnic or racial variation, skin color, eye color, hair color, and/or abnormalities related to these structures or to any other internal or external structure;
    7. Neuro-psychological or other aberrations of the offspring;
    8. Physical or mental abuse of the recipient, or sibling(s) of the newborn or any other person(s);
    9. Subsequent diseases, whether foreseeable or unforeseeable;
    10. Potential psychological implications of off-spring as a result of therapeutic assisted reproduction with regards to the relationship with her spouse or partner, if any, the child or children, any other child or children, or any other relationship.

LIMIT OF LIABILITY:

In the event of any breach of any warranty, representation of covenant on the part of BioGenetics shall be limited to the return of any monies paid by Physician/Medical Facility or the Recipient on account of the Specimens with respect to which the breach occurred.

RELEASE AND INDEMNITY:

Recipient hereby releases, holds harmless, and indemnifies BioGenetics, with respect to the Specimens, the donors, the agents, officers, directors, employees, advisors and consultants from and against all losses, liability, damage and expenses (including reasonable attorneys fees) of any kind or nature which any of them may suffer or incur by reason of any claim by any party including, without limitation, the claim of any child born as a result of therapeutic assisted reproduction with the Specimens or the siblings or other relatives or any such child which arises from, is connected with, or is in any way related to any of:

1. The Specimens and any therapeutic assisted reproduction in which they are used;
2. Performance or non-performance of any act to be performed (or not performed) by Physician/Medical Facility;
3. Any condition, warranty, representation or state of facts as to which BioGenetics has disclaimed responsibility anywhere in this document;
4. The failure of Physician/Medical Facility or Recipient to conform to applicable law with respect to the Specimens or any therapeutic assisted reproduction in which the Specimens are used.

MISCELLANEOUS:

A. The initial term of this Acknowledgement and Consent shall be for a period of one (1) year from the date first set forth below.

B. For all the purposes of this Acknowledgement and Consent, except where a distinction is specifically made between Recipient and Recipient's spouse or partner, if any, or other relatives, the term "Recipient" shall include (a) Recipient, (b) Recipient's spouse, (c) partner if any, (d) all relatives of Recipient, whether by blood, marriage or adoption.

C. This Acknowledgement and Consent shall govern all purchases of Specimens from BioGenetics by Physician/Medical Facility or directly by their Patient(s) during the term of this Acknowledgement and Consent without the requirement of any subsequent notice or incorporation by reference, even after BioGenetics receipt of a notice of termination from Physician/Medical Facility. The terms of any purchase order or the forms supplied by BioGenetics shall govern the terms and conditions of any sale of Specimens to Physician/Medical Facility and/or Recipient, even if those terms do not conflict with the terms of this Acknowledgement and Consent or any forms supplied by BioGenetics.

D. All notices permitted or required by this Acknowledgement and Consent shall be in writing and sent to the party entitled to receive the notice, at the address set forth in this Acknowledgement and Consent or at such other address as the parties may advise each other from time to time by similar notice. Notice shall be delivered three (3) days after the date of mailing.

E. This Acknowledgement and Consent contains the entire understanding between BioGenetics and Recipient with respect to its subject matter and may not be altered, amended or changed other than by a writing signed and interpreted in accordance with the laws of the State of New Jersey applicable to agreements wholly to be performed therein. This acknowledgment and consent is subject to changes without prior notice. The parties hereto consent to the exclusive jurisdiction and venue of the state and federal courts located in Union County, New Jersey.

IN WITNESS WHEREOF, the parties have signed, delivered and caused the acknowledgement and consent to be executed as of the date first set forth below.

_____ _____ Date: _____

Print Name Recipient Signature

_____ _____ Date: _____

Print Name Recipient's Spouse or Partner