

REPRODUCTIVE MEDICINE & INFERTILITY ASSOCIATES
Woodbury Medical Arts Building
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**INFORMED CONSENT AND AUTHORIZATION FOR THE MICROSURGICAL BIOPSY OF
PRE-EMBRYOS FOR PREIMPLANTATION GENETIC DIAGNOSIS (PGD)**

We, the undersigned as patient and partner, have requested Reproductive Medicine & Infertility Associates (RMIA) in conjunction with a laboratory specializing in genetic testing to biopsy our pre-embryos produced from our In Vitro Fertilization (IVF) procedures. We understand that RMIA will assist in the biopsy procedure and that all genetic testing will be performed by the laboratory specializing in these techniques.

I. DEFINITIONS

- A. A PRE-EMBRYO is a fertilized egg, which prior to implantation in the uterus has divided to form a small number of simple, non-specialized cells. At the pre-embryo stage of development each of these primitive cells is identical.
- B. BIOPSY is a process where by cells are removed from the pre-embryo and sent for genetic testing.

II. PREIMPLANTATION GENETIC DIAGNOSIS

We understand that RMIA will assist in the biopsy only. Genetic testing of the biopsied cells will be performed by the laboratory specializing in genetic testing. We understand that there are risks associated with all phases of these procedures including those relating to routine In Vitro Fertilization (separate consent form with RMIA). In addition, risks related to the biopsy cell(s) during processing and shipping, and inconclusive results from the genetic analysis. Furthermore, we understand that additional risks exist with the genetic analysis of the cells (consent with genetic testing laboratory).

III. PRE-EMBRYO DISPOSITION

We agree, as additional consideration for the services to be performed by RMIA, as follows:

- A. **Genetically affected Pre-embryos**
“Affected Pre-embryos” refers to those pre-embryos that are considered positive for the disease, chromosome abnormality, or non-preferred gender being tested. We understand that all Pre-embryos reported as being genetically affected will be:

_____ (initials) Disposed of using RMIA standard procedures

_____ (initials) Donated to RMIA for research

_____ (initials) Cryopreserved if pre-embryo meets RMIA qualifications (separate cryopreservation consent)

_____ (initials) Transferred if no other “genetically unaffected” pre-embryos exist

_____ (initials) transferred if “Genetically unaffected” pre-embryos exist but are of lesser quality but are of lesser quality

Family Balancing only:

_____ (initials) Transfer if no other preferred gender pre-embryos exist

_____ (initials) Transfer if preferred gender pre-embryos exist but are of lesser quality

B. Genetically partially affected Pre-embryos

“Partially affected” Pre-embryos refer to those pre-embryos which are generally termed “carriers”. In these cases, the pre-embryos will usually not express the disease being tested for (depending on the particular disease). However, should individuals resulting from these pre-embryos reproduce, there may be an increased risk of their children developing the disease (e.g. if they produced children with another individual that was a carrier). We understand if pre-embryos that are partially affected exist we wish to:

_____ (initials) Dispose of partially affected pre-embryo/s using RMIA standard procedures

_____ (initials) Donate to RMIA for research

_____ (initials) Cryopreserve if pre-embryo/s meets RMIA qualifications (separate cryopreservation consent)

_____ (initials) Transfer if no other “genetically unaffected” pre-embryos exist

_____ (initials) Transfer if “Genetically unaffected” pre-embryos exist but are of lesser quality

C. Genetically Unaffected Pre-embryos

“Unaffected Pre-embryos” refers to those pre-embryos that are considered negative for the selected disease, of preferred gender, or to have a normal chromosome analysis. These pre-embryos are candidates for transfer, cryopreservation (separate consent) or discard as any pre-embryo produced from routine In Vitro Fertilization.

D. Genetically Inconclusive Pre-embryos

“Inconclusive” Pre-embryos refers to those pre-embryos that genetic testing could not identify as affected, partially affected or unaffected. If these pre-embryos exist we wish to:

_____ (initials) Dispose of according to RMIA standard procedures

_____ (initials) Donate to RMIA for research

_____ (initials) Re-biopsy and cryopreserve (separate cryopreservation consent) qualifying pre-embryos and incur additional costs at RMIA and possibly the genetic analysis provider

_____ (initials) Transfer if no other “Genetically Unaffected/Partially Affected” pre-embryos exist

_____ (initials) Transfer if “Genetically Unaffected/Partially Affected” pre-embryos exist but are of lesser quality

E. Cancellation

Due to the variability of medication responses of patients only a few pre-embryos may be created in a given cycle.

If $<$ or $=$ _____ pre-embryos fertilize we wish to:

_____ (initials) Cancel the cycle and pre-embryo transfer

_____ (initials) Cancel PGD analysis and perform a pre-embryo transfer without any analysis

_____ (initials) Cancel PGD biopsy and analysis for this cycle, but freeze all fertilized pre-embryos to combine with another future cycle and biopsy.

We understand and agree that if indicated on this consent to dispose of all Pre-embryos that are found to be either unaffected or partially affected no pre-embryo transfer will take place and all Pre-embryos will be discarded according to RMIA standard procedures.

Patient's signature

Partner's signature

IV. RELIANCE ON AGREEMENT

The patient/partner understand and agree that RMIA shall rely upon this Informed Consent and Authorization and decisions made by the patient and partner in this Informed Consent. RMIA shall not be obligated to contact the patient or the partner prior to acting pursuant to the direction and authorization in this Informed Consent. RMIA shall have no duties except those which are expressly set forth in this Informed Consent and its duties shall not be changed, unless RMIA has given its prior written consent thereto.

Patient's signature

Partner's signature

V. SEVERABILITY

In the event that any part of this Informed Consent and Authorization is declared by any court or other judicial administrative body to be null, void, or unenforceable, the said provision shall survive to the extent it is not so declared, and all of the provisions of this agreement shall remain in full force and effect.



VI. COPY OF CONSENT FORM MADE AVAILABLE

We may request a copy of this consent form for our records.

VII. OPPORTUNITY OF LEGAL REPRESENTATION.

We acknowledge by our signatures below that we have read the foregoing, all questions have been answered to our satisfaction and that we have each been advised to, and have had the opportunity to consult with legal counsel of our own choosing. We have been advised and understand that we, as partner and patient, may have conflicting interests and should, if either of us desires, each seek our own independent legal counsel.

Having been fully informed, we freely and voluntarily sign below:

Patient's Printed Legal Name

Patient's ID #

Patient's Signature

_____/_____/_____
Date

Partner's Printed Legal Name

____-____-_____
Partner's SSN

Partner's signature

Date

Witness

Date

Patient and Partner's Address

RMIA

By: _____

Its: _____

