

## Consent for Embryonic Biopsy During In Vitro Fertilization for Pre-Implantation Genetic Diagnosis

Name of Patient: \_\_\_\_\_

Name of Partner: \_\_\_\_\_

We, the Patient and Partner named above, are each over the age of twenty-one (21) years. By our signatures below, we request, authorize and consent to the performance of embryonic blastomere biopsy and preimplantation genetic diagnosis (PGD) at time of in vitro fertilization and embryo transfer (IVF/ET).

We understand and acknowledge that Regional One Health operates a laboratory responsible for our IVF/ET cycle management and laboratory testing and services including semen analysis, sperm preparation, oocyte (egg) identification and preparation, embryo culture, embryo micromanipulation and cryopreservation. Regional One Health will be utilizing a third party genetics laboratory to carry our PGD on our embryos.

We will be undergoing IVF/ET and that we suffer from a condition that may result in a genetic disorder in some of our embryos. The procedure of PGD has been developed to diagnose these disorders in embryos before embryo transfer is accomplished in an attempt to avoid a pregnancy and child afflicted with the disorder. The following is a general outline of the steps that may be required in this procedure. We understand and consent to the performance of these steps:

1. We will undergo IVF/ET and may use intracytoplasmic sperm injection (ICSI) that has been explained and consented to, separately. This results in the fertilization of the eggs by the sperm. When an egg successfully fertilizes it will become an embryo.
2. When our viable embryo(s) have reached an appropriate stage of development, an opening is created in the outer shell (zona) of the embryo by microscopic manipulation. One or more cells (blastomeres or trophoderm) are extracted while retaining the integrity of the embryo for further development and growth. This process is going to be repeated for each of our viable embryo(s).
3. The blastomeres will be appropriately prepared (fixation) and sent for genetic analysis. The type of genetic analysis necessary will be explained and consented to, separately. Results of the genetic analysis will be available within 48 hours of the biopsy.
4. The results of these studies will determine which embryo(s) are selected for subsequent transfer procedure to the uterus or cryopreservation (freezing) for future attempts at pregnancy.
5. In order to protect the biopsied embryo(s) in the uterus, a short course of corticosteroids (prednisone) is required for the female patient prior to embryo transfer.

We understand that an embryo biopsy can only be performed on viable embryos at appropriate stages of growth. We acknowledge that due to either an inadequate number of sperm or egg, and/or to poor fertilization or embryo development, embryonic blastomere biopsy may not be possible.

We understand that embryonic blastomere biopsy and PGD are relatively new procedures with unknown risks. While current research demonstrates minimal risk to a developing embryo, there is the potential for embryo injury. This may result in our losing the opportunity to become pregnant in this IVF/ET cycle.

We understand and acknowledge that according to current research, there is a misdiagnosis rate of up to 10% for PGD. We acknowledge that a misdiagnosis may result in a pregnancy and child afflicted by a genetic disorder.

We acknowledge that the blastomeres are extremely fragile and that events during biopsy, fixation, or transport may make PGD impossible. In that case, we understand that we may not have genetic results to guide our decision-making for embryo transfer.

We understand that we should experience no additional discomfort by adding embryonic blastomere biopsy and PGD to "standard" IVF.

We acknowledge that we have been strongly urged to have a thorough discussion of PGD with a qualified genetics counselor. Furthermore, we have been urged to have confirmation of the PGD results by amniocentesis or chorionic villus sampling (CVS) in the early stages of our pregnancy.



Consent form Embryo Biopsy

Form No. ROH.566 (Created 1/15) \*OB0481\*

1 Copy - Medical Record 1 Copy - Patient 1 Copy - Partner



Affix Patient Label

Patient's Initials \_\_\_\_\_

Partner's Initials \_\_\_\_\_

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We understand that our alternatives may include the use of donor sperm or eggs.

We understand that if pregnancy is successfully established, miscarriage, ectopic pregnancy, stillbirth and/or abnormalities (birth defects) may occur.

We hereby release Regional One Health, UT Regional One Physicians, Inc. and their respective employees, agents, directors, officers, and contractors (the "Releasees") from any claim of injury or damage, known or unknown, that might result should our embryo(s) cease to be viable while in the custody of the Releasees.

We do jointly and severally release and forever discharge the Releasees from any and all claims, demands, costs, expenses, and loss of services incurred as a result of the physical or mental nature of any child or children produced using these procedures.

We fully understand that insurance coverage for any or all of the above procedures may not be available and that we will be personally responsible for the expenses of this treatment. The expenses may consist of hospital charges, laboratory charges and/or physician professional fees.

We consent to the photographing or televising of any laboratory procedure(s) to be performed for medical, scientific, or educational purposes, provided our identities are not revealed by the pictures or by descriptive text accompanying them.

Data from your Assisted Reproductive Technology (ART) procedure will be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect all data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Data collected by the Society of Assisted Reproductive Technologies (SART) is used to generate statistics published annually in medical and scientific publications and for selected research projects. Because sensitive information will be collected, CDC and SART applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). We understand that any information the CDC possesses that identifies us will not be disclosed to anyone else without your consent.

We each acknowledge that we have fully reviewed and comprehend the contents of this consent form as well as the separate Consent for In Vitro Fertilization and Embryo Transfer. In addition, we each acknowledge that we have fully reviewed and comprehend the contents of the separate PGD consent form from the genetics laboratory. The nature of embryonic blastomere biopsy and PGD at time of IVF/ET has been explained to us, together with the known risks. We understand the explanation that has been given us and understand that there may be unknown risks.

We each acknowledge that we have fully reviewed and comprehend the contents of this Consent Form as well as the separate Consent for In Vitro Fertilization and Embryo Transfer. In addition, we each acknowledge that we have fully reviewed and comprehend the contents of the separate PGD consent form from the genetics laboratory. The nature of embryonic blastomere biopsy and PGD at time of IVF/ET has been explained to us, together with the known risks. We understand the explanation that has been given us and understand that there may be unknown risks. We have had the opportunity to ask any questions we might have and those questions have been answered to our satisfaction. We acknowledge that embryonic blastomere biopsy and PGD at time of IVF/ET is being performed at our request and with our consent.

We understand that we may elect not to continue with the procedure at any time and that this decision will not affect any other present or future care and treatment from Regional One Health or UT Regional One Physicians, Inc.

With full knowledge and understanding of the attendant risks and consequences of our participation, we each consent to the medical procedure described in this Consent Form and agree to participate in embryonic blastomere biopsy and PGD at time of IVF/ET. We each acknowledge and affirm that we have given our consent and entered into this agreement without coercion or compulsion and of our own free will.



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Patient's Initials \_\_\_\_\_

Partner's Initials \_\_\_\_\_

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\_\_\_\_\_  
 Patient Signature                                      Date

\_\_\_\_\_  
 Partner Signature                                      Date

\_\_\_\_\_  
 Patient Printed Name

\_\_\_\_\_  
 Partner Printed Name

\_\_\_\_\_  
 Witness Signature                                      Date

\_\_\_\_\_  
 Witness Printed Name

**Physician Attestation**

The above mentioned Patient and Partner (if applicable) have been informed and counseled by me and others regarding the risks and benefits of the relevant treatment options, including non-treatment. The Patient and Partner (if applicable) expressed understanding of the information presented during the discussion.

\_\_\_\_\_  
 Physician Signature                                      Date

\_\_\_\_\_  
 Physician Printed Name

[Notary Page to Follow]



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Patient's Initials \_\_\_\_\_  
 Partner's Initials \_\_\_\_\_

**Consent for Embryonic Biopsy During In Vitro Fertilization for Pre-Implantation Genetic Diagnosis**

[Notary Page for: Consent for Embryonic Biopsy During In Vitro Fertilization for Pre-Implantation Genetic Diagnosis]

STATE of \_\_\_\_\_ )  
 ) :SS  
COUNTY of \_\_\_\_\_ )

The foregoing instrument was acknowledged before me this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by \_\_\_\_\_, referred to in this consent form as "Patient".

My commission expires: \_\_\_\_\_ .

\_\_\_\_\_  
Notary Public

STATE of \_\_\_\_\_ )  
 ) :SS  
COUNTY of \_\_\_\_\_ )

The foregoing instrument was acknowledged before me this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by \_\_\_\_\_, referred to in this consent form as "Partner".

My commission expires: \_\_\_\_\_ .

\_\_\_\_\_  
Notary Public



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