



Enrolling a Patient for Preimplantation Genetic Diagnosis

IVF-Reproductive Center Patient Referral

- Register the Couple:** Simply complete our basic demographic intake information form for the couple. This acts as a physician's order for us to enroll them into the program
- DNA Diagnostic Report:** You probably have a DNA diagnostic report(s) in the patient's chart. For example, a cystic fibrosis mutation report defining the gene mutation(s). [If you do not have one, we can assist you in obtaining it from the university/commercial laboratory that determined the molecular basis of the inherited disorder for which the couple is at risk]. We use these data to custom design the molecular probes necessary for their single-cell PGD testing.
- Confidentiality:** Ask the patient to sign the HIPAA form so that we have permission to discuss their case with you. Fax these three items to us at 313-544-4006.

That's it! This is all you have to do. In our continuing goal to make this process as easy as possible for you and the couple, we will handle the Genetics aspects of the Case for you.

What does the Genesis Genetics Institute do next, once you have referred a case for PGD?

Genesis Genetics Institute Steps

- Collect and Review Genetic Information.**
 - We contact the patient, introduce Genesis Genetics to them, and explain that we are working with your IVF team to assist them in building a healthy family.
 - Our Certified Genetic Counselors then take a Genetic History, review the existing DNA information, and answer her initial questions.
 - We FedEx the couple a packet of information about Preimplantation Genetics including a DVD for them to watch together, as part of the Informed Consent process.
- Obtain DNA Samples.**
 - Based on the family pedigree our Counselors obtain, we send (via FedEx) a buccal swab kit to the family members necessary to construct the DNA probes for the PGD testing. There is no need for you (the IVF clinic) to draw blood anymore. We handle collecting DNA for you.
- Design, Construct and Optimize Probes.**
 - EACH and EVERY PGD case is customized for each couple. We start immediately after receiving the necessary cheek swab samples and payment for this several week process.
- Notification that the Test is Ready.**
 - We contact the couple and you, the IVF Center, once the probes are constructed, optimized and certified for the couple's PGD case.
- Our Laboratory then waits until you tell us you need us to test the biopsied samples.**



Patient Intake Information for Preimplantation Genetic Diagnosis

Patient :

By Convention, the Woman

Last _____ First _____

Date of Birth 19__ __ __ Genetically Affected; a "Carrier"; a "Noncarrier"
Year Month Day (Has Gene Mutation) (Heterozygote) (No Gene Mutation)

Partner:

The Male Partner

Last _____ First _____

Date of Birth 19__ __ __ Genetically Affected; a "Carrier"; a "Noncarrier"
Year Month Day (Has Gene Mutation) (Heterozygote) (No Gene Mutation)

Affected Relative:

If Any

Last _____ First _____

Date of Birth _____ Relationship to Patient _____
Year Month Day (Son, Sister, Mother, Aunt, Nephew..... with this Genetic Disorder)

Genetic Disorder of Concern:

(e.g. Cystic Fibrosis, Fragile X)

Patient Address:

Street Address

City

State

Zip

Phone:

Home

Work

Mobile (This is important on testing day)

Best Email:

VERY important for us to interact with you and coordinate your care with your IVF doctors

Today's Date:

IVF Clinic Name:

IVF-Endocrinologist-Physician Name (primary):

IVF Coordinator with whom we can communicate:

Clinic Contact Phone:

____ - ____ - ____ Ext ____

Please fax this form and the DNA diagnostic report(s) that define the gene mutation (if you have it) to us at 313-544-4006. Call us at 313-579-9650 if you have any questions.

Genesis Genetics Institute considers this information to be private and confidential under HIPAA guidelines.



HIPAA Participant Authorization

Our Commitment to the Privacy & Security of Your Health Information

We are dedicated to assisting you in your medical care, and we are also deeply committed to maintaining your privacy. During the course of your treatment(s) in this Preimplantation Genetic Diagnosis (PGD) protocol, it will be important for us to discuss and exchange certain personal information about you with other members of your health care team. This information is called your Protected Health Information (PHI). Because these individuals (for example, your geneticist, genetic counselor, IVF center, PGD doctors/scientists, transplantation team) are often at different institutions/states/countries, we need your permission beforehand in order to participate in these medical and scientific discussions about you. Nonetheless, each individual on your health care team does not need to know or have access to everything. We believe in a minimal “need-to-know” approach to the exchange of your health information.

Doctors have exchanged this sort of information for years in the practice of medicine. However, in this day of electronic databases, there is (rightfully) concern about how private health information about you is collected and shared. For that reason, we applaud the fact that the US Federal Government has now issued a regulation to provide safeguards for the privacy and security of health information that may identify you. This rule was issued under a law called the Health Insurance Portability and Accountability Act (HIPAA). This document that you are now reading is called a “Participant Authorization,” and it describes your rights and explains how your health information will be used and disclosed during your care.

Section A: Protocol Information

Protocol Title: Genetic Testing of Human Pre-embryos for Inherited Disease

Principal Investigator: Mark R. Hughes, MD, PhD
Address: The Genesis Genetics Institute
Genomic Technology Center of Michigan

Phone: 313-579-9650

You have agreed to participate in this research study and you have signed a separate “Informed Consent” that explains the procedures, the risks and the benefits of this protocol. This Authorization Form gives more detailed information about how your health information will be protected. By signing this document you are permitting The Genesis Genetics Institute to use your Protected Health Information (PHI) for research purposes and in your health care. You are also allowing us to exchange PHI with other members of your medical team at outside organizations.

Page: 1 of 3



Section B: Protected Health Information

1. What PHI is collected and might be shared amongst your medical team?

The following PHI items that have been checked below will be collected, used for research and may be disclosed or released during your involvement in this research project:

- Your names and potentially the name(s) of your child(ren).
- Your Address, Telephone Numbers, E-mail Address.
- Dates (e.g. birth, menstrual cycle, IVF-related dates, pregnancy, baby delivery)
- Clinical Outcome Information (embryo quality, which embryos are transferred/frozen, pregnancy outcome, CVS/amniocentesis test results, baby delivery information)
- Biometric Identifiers (e.g. photograph, finger print, voice print)
- Identifying Number (e.g. insurance, medical record)
- Genetic mutation, marker, polymorphism data, and your family genetic history.

2. Why is this information needed?

We are not your physicians in this process. Your doctors are at your IVF Center and we are acting as scientific consultants to them, in order to provide you with this complicated technology. This information is important to all of us on your clinical and research team in order to contact you during this protocol, keep you informed of the entire process, and effectively manage your treatment.

3. Which project personnel may use or disclose your PHI?

The following individuals and organizations may use or disclose your PHI for THIS protocol ONLY.

- The Principal Investigator, Dr. Hughes, and key personnel at Genesis Genetics who are involved in this protocol and in your care. This is limited to individuals who require access in the performance of their duties (for example: to provide treatment, to ensure integrity of the data, accounting, etc).
- Collaborating health care professionals involved in your care (e.g. your reproductive endocrinologist, embryologist, nurse coordinator, genetic counselor, molecular biologist/laboratory that found the gene mutation in your family, transplantation physician, geneticist, obstetrician, etc).
- The Human Investigation Committee and the Institutional Review Boards of the Genesis Genetics Institute, the University, and your clinic at a collaborating institution(s). (These Boards oversee research protocols and protect patient interests. They generally do not request any of your information unless there is a concern about the protocol or about your well being. Since your health care providers are at different universities/organizations, each one may have separate committees and boards and (sorry) more forms like this one.)
- Your health insurance company, but only if the Genesis Genetics Institute receives separate, written, and prior authorization from you to release any PHI to them.

Page: 2 of 3



4. Can you change your mind?

You may withdraw your permission for the use and disclosure of your PHI at any time, but you must do so in writing to the Principal Investigator at the address on the first page of this form. After receiving the request to withdraw from the protocol, you will be contacted concerning a plan for your withdrawal from the protocol. Even if you withdraw your permission and therefore withdraw from this protocol, the Principal Investigator may still use your PHI that was collected prior to your written request, if that information is necessary to the integrity of the study.

By signing below, you are authorizing the potential exchange between your health care providers of this information described above.

Printed Woman's Name

Woman's Signature

Date

Printed Man's Name

Man's Signature

Date