



**CONSENT FOR DISPOSITION OF PGS/PGD TESTED IN VITRO PRE-IMPLANTATION
EMBRYOS**

Please read the following Consent for Disposition of PGS/PGD Tested In Vitro Pre-Implantation Embryos (“Consent”) carefully. If you do not understand the information provided, do not feel comfortable with the information provided to you by the Heartland Clinic physician, or have additional questions, please do not sign this Consent before speaking with your treating Provider.

This Consent must be signed by you, the patient and any spouse or partner of yours (hereinafter “Spouse/Partner”), with PICTURE IDs in the presence of a Heartland Clinic staff member. Unless the context otherwise requires, references to “you” “your” or “I” in this Consent refer to both you and your Spouse/Partner, if applicable, and words in the singular form shall be construed to include the plural form and vice versa. All sections of the Consent must be completed. These signature pages will be maintained at Heartland Clinic and will remain in effect indefinitely unless you execute a new Consent to replace it—this may be done any time at your request. If you and/or your Spouse/Partner are unable to sign the Consent in the presence of a Heartland Clinic staff member, that signature must be *notarized* and the notary page returned to and maintained at Heartland Clinic. You should keep a copy of this fully executed Consent for your records.

For purposes of this Consent, the term “Spouse/Partner” means a spouse, if legally married, or another individual involved in a relationship with the patient who has presented with the patient for assisted reproductive services and whom Heartland Clinic considers to be a partner of the patient.

To be completed by Heartland Clinic staff:

Printed Name: Patient Spouse/Partner (if applicable)

PHIN

Patient Spouse/Partner (if applicable)

Heartland Clinic employee completing above information:

Printed name

Signature

Date provided to the patient

1“*In Vitro Pre-Implantation Embryo*”: “A fertilized egg that has begun cell division in a laboratory dish (“*in vitro*”) prior to its intended purpose for a potential transfer into a woman’s uterus to achieve conception and pregnancy. An *In Vitro Pre-Im-plantation Embryo*, which may or may not be cryopreserved, may hereinafter be referred to as an “*Embryo*.”

I had previously authorized Heartland Clinic to biopsy my embryos, including cryopreserved (frozen embryos that I may have in storage at Heartland Clinic) and then send the biopsied specimen to the outside laboratory for Pre-Implantation Genetic Screening (PGS) or Pre-Implantation Diagnosis (PGD). PGS is screening that looks for chromosomal aneuploidy (an abnormal number of chromosomes) and the embryos will be either normal or abnormal. PGD is screening for single gene disorders and involves testing of the embryos for one or more genetic diseases or disorders. I have received the report from the outside laboratory where the PGS/PGD testing was performed and have had the opportunity to review the report with my treating Provider and with the outside laboratory and my genetic counselor. I understand that there are risks associated with the biopsy of the embryos and with the results of the testing, including, without limitation, the following:

- The embryo biopsy, performed on my embryos, may have unknown and unknowable consequences on the embryo and that a child born as the result of embryo biopsy may have birth defects or a mental or physical disability.
- PGD/PGS though very reliable, are not perfect technologies and PGD/PGS are not considered routine medical care.
- The goal of these technologies is to reduce the likelihood of having a child at risk for genetic disorder or abnormality such as cystic fibrosis or to minimize the likelihood of an abnormality in chromosome number such as Down syndrome. However, because PGS/PGD are not perfect diagnostic tools and technologies, the certainty is not 100%.

- Because PGD/PGS screens for either a specific disorder (PGD), or an abnormal number of chromosomes (PGS), there remain genetic disorders that will not be detected. PGS/PGD reduces but does not eliminate the chance of having a child with a genetic disorder.
- Errors have been described in both PGS/PGD technologies, therefore, 100% accuracy is not guaranteed, expected or possible.
- Prenatal testing will still be recommended to confirm the impressions based on PGS/PGD diagnostics.

I hereby agree and make the following disposition choices with respect to the tested embryos:
Disposition Choices related to Pre-Implantation Genetic Screening (PGS):

PGS is screening that looks for chromosomal aneuploidy (an abnormal number of chromosomes) and the embryos will be either normal or abnormal as described below: If your treatment plan includes both PGS and PGD, you will need to also initial and sign the section below on PGD. Please Initial (no check marks) (both patient and any Spouse/Partner, if applicable) to indicate your decisions regarding the embryos screened for chromosomal aneuploidy (PGS):

I understand the situations described below are possible:

- a) "Genetically Abnormal Embryos." Genetically Abnormal Embryos refers to those tested for the number of chromosomes and found to have an abnormal number of chromosomes (aneuploidy), the majority of which are incompatible with life. Abnormal embryos will not be transferred by Heartland Clinic to create a pregnancy and will be discarded in accordance with Heartland Clinic's standard laboratory policies and procedures. I hereby authorize Heartland

Clinic to discard all embryos reported as being abnormal in accordance with Heartland Clinic's standard laboratory policies and procedures.

Please Initial here: Patient: _____

Spouse/Partner: _____

- b) “Genetically Normal Embryos.” Genetically Normal Embryos refers to those embryos that have the correct number of chromosomes (23 pairs). These embryos are candidates for transfer in an attempt to create a pregnancy, cryopreservation (separate consent required, unless previously frozen) or other disposition as any embryo produced from routine IVF.
- c) “High Probability of Abnormal Embryos.” High Probability of Abnormal Embryos refers to those embryos that genetic testing indicates are abnormal but not with the same degree of certainty of Genetically Abnormal Embryos. In most cases these embryos will not be considered for transfer. You may choose to authorize Heartland Clinic to discard these embryos in accordance with Heartland Clinic’s standard laboratory policies and procedures, or choose to continue to store such embryos for either a subsequent attempted biopsy or transfer if further review and discussion support.

Please initial your choice below (you must choose one option):

Patient: _____

Spouse/Partner: _____

Discard according to Heartland Clinic’s standard laboratory policies

Continue to store to be later transferred or thawed with a subsequent attempted biopsy (a separate consent for storage and the payment of storage fees and/or a treatment consent (e.g., FET) will be required)

Disposition Choices related to Pre-Implantation Genetic Diagnosis (PGD)

PGD is screening for single gene disorders and involves testing of the embryos for one or more genetic diseases or disorders. If your treatment plan includes both PGS and PGD, you will need to also initial and sign the section above on PGS. Please Initial (no check marks) (both patient and any Spouse/Partner, if applicable) to indicate your decisions regarding the embryos undergoing PGD:

- a) “Affected embryos” refers to those embryos that are considered positive for the evaluated disease or condition. I hereby authorize Heartland Clinic to discard all

embryos reported as being genetically affected in accordance with Heartland Clinic's standard laboratory policies and procedures.

Please Initial here: Patient: _____ Spouse/Partner: _____

- b) "Partially affected embryo" refers to embryos which are generally termed "carrier." In many cases, these embryos will not express the evaluated disease (depending on the particular disease). However, should the individuals resulting from these embryos reproduce, there may be an increased risk of their children developing the disease. Depending upon the disease, in many cases these embryos may be considered candidates for embryo transfer. I have had the opportunity to discuss the risks of transferring partially affected (carrier) embryos with my treating Provider and genetic counselor, and I request that these embryos be:

Please initial your choice below (you must choose one option):

Patient: _____

Spouse/ Partner: _____

_____ Transfer to uterus to attempt to create a pregnancy (a separate treatment consent (e.g., IVF or FET) and a waiver for positive genetic carrier results will be required).

_____ Discard according to Heartland Clinic's standard laboratory policies and procedures.

- c) "Genetically Unaffected embryos" refers to those embryos that are considered negative for the evaluated disease or condition. These embryos are candidates for transfer, cryopreservation (separate consent required, unless previously frozen) or other disposition as any embryo produced from routine IVF.

- d) "Genetically Inconclusive Embryos" refers to those embryos that genetic testing could not identify as affected, partially affected or unaffected. In most cases these embryos

will not be considered for transfer. You may choose to authorize Heartland Clinic to discard these embryos in accordance with Heartland Clinic's standard laboratory policies and procedures, or choose to continue to store such embryos for either a subsequent attempted biopsy or transfer if further review and discussion support.

Please initial your choice below (you must choose one option):

Patient: _____

Spouse/ Partner: _____

_____ Discard according to Heartland Clinic's standard laboratory policies

_____ Continue to store to be later transferred or thawed with a subsequent attempted biopsy (a separate consent for storage and the payment of storage fees and/or a treatment consent (e.g., FET) will be required)

ACKNOWLEDGEMENT

I have met with my treating Provider and healthcare team to discuss the disposition options relating to my embryos tested for abnormal chromosomes (PGS) and single gene disorders or diseases (PGD). I have been fully informed of the purpose of PGS/PGD, the reliability of the test results, the risks and benefits of the biopsy procedure and the potential damage to the embryo, and available alternatives to PGS and PGD and agree to hold Heartland Clinic, its physicians, agents and staff harmless from any and all liability or unfavorable outcome, including, the birth of a child with a genetic disease or disorder, or chromosomal abnormality. I have had the opportunity to ask questions and have all my questions answered to my satisfaction. I understand that I have the option of meeting with a genetic counselor to discuss any aspect of the dispositional choices I have selected with regard to my PGS/PGD tested embryos.



SIGNATURES MUST BE WITNESSED BY A HEARTLAND CLINIC STAFF MEMBER OR A NOTARY

Signature- Patient

Signature – Spouse/Partner (if applicable)

Print Name:

Print Name:

Date:

Date:

Picture Identification:

Patient:

Type:

Exp. Date:

Souse/Partner (if appliciable):

Type:

Exp. Date:

Picture Identificaiton Confirmed on (date):

Witness – Print Name and Title

Signature

(if not signed in the presence of Heartland Clinic Staff Member, your signature must be notarized)

Notary Public

Sworn and subscribed to me on this _____ day of _____, 2_____

X_____.

Notary Public

Date