INFORMED CONSENT TO OBTAIN A BIOLOGICAL SAMPLE FOR PRE-PGT STUDY

Female patient full name:	
Female patient Date of Birth:	
Clinic ID (female patient):	

Partner full name (if applicable):	
Partner Date of Birth (if applicable):	
Clinic ID (partner):	

This consent is intended for patients who are planning to undergo in vitro fertilization (IVF) treatment and want Preimplantation Genetic Testing (PGT) to be performed on cells (biopsies) taken from their embryos. Juno Genetics UK Ltd. (Juno Genetics) is the clinical diagnostic laboratory that will receive the biopsies from the embryos and will perform PGT.

For certain PGT, the laboratory requires additional studies to be undertaken before any embryos can be examined.

1. These studies often require genetic information from the patients who undergo PGT, to maximise accuracy when analysing their embryos.

    a) For cases in which PGT is used to reduce the risk of a child with a particular monogenic disease, an analysis of polymorphic genetic markers (DNA sequences that vary between different people) is often performed. The purpose is to identify a set of variations that are close to the defective gene. Some of these variations in the DNA are inherited along with the mutation and indicate a risk of disease, while others are always inherited with the normal copy of the gene. In some cases, a piece of DNA where the mutation responsible for the disease is located is also tested. This allows confirmation that the mutation can be detected.

    b) For cases in which the PGT is used to reduce the risk of specific chromosomal abnormalities, it may be necessary to undertake additional studies. This is usually needed if an abnormality, present in one of the patients, involves very small pieces of chromosome, or if it involves a microduplication or a microdeletion. The studies allow evaluation of whether detection of such an abnormality is technically possible with the method used by Juno Genetics. In cases of microdeletions, microduplications, or other chromosome rearrangements that are challenging to detect, samples from other family members may also be necessary.

2. The information obtained during additional studies, carried out to support the development of a preimplantation genetic test, has no clinical or diagnostic value for the people who provided samples (blood, mouth swab, or DNA), but it is necessary to perform the PGT test.

3. Any genetic analysis undertaken will be strictly limited to those required to help with the detection of the specific mutation(s) and/or chromosome abnormality that are the reason why PGT has been requested.

4. The genetic testing will be performed by Juno Genetics.

5. The sample (blood, mouth swab, or DNA) to be used in this genetic analysis will be obtained using standard techniques, with no, or very low risk, to health.

6. The length of time needed to complete the additional studies, prior to beginning a PGT cycle, is typically 6-8 weeks. The time begins from the date on which Juno Genetics has received all the necessary samples and paperwork (consent form, test request form). The samples required from patients and any relatives would have been communicated by Juno Genetics to the IVF clinic and/or genetic counsellor prior to the acceptance of the case. A small percentage of cases may suffer a variable delay due to technical challenges developing a test, which are often impossible to predict. Should this occur, Juno Genetics will notify the clinic about the delay as soon as possible.

7. Even when PGT is carried out appropriately, and although the benefits of the test are usually considerable, there are limitations as described below:

a) In cases of PGT for monogenic disease (PGT-M), the tests will be strictly limited to an attempt to detect the disease/mutation specified in the genetic reports provided to Juno Genetics. No other mutations will be tested. However, chromosome abnormalities, unrelated to PGT for monogenic disease, may be detected in some cases.
b) There is a small chance that the additional studies undertaken prior to PGT will be inconclusive or that they will indicate a risk that PGT may be unreliable due to difficulties in accurately detecting the genetic abnormality. In such cases, subsequent PGT cannot be offered.

8. The staff that accesses the genetic data while performing their functions will be permanently subject to a duty of confidentiality. Genetic data of a personal nature cannot be disclosed to third parties except with the patient's express and written consent.

9. The test results are confidential in compliance with the current data protection legislation – Regulation *(EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data*, and implementing legislation, hereinafter, "data protection regulations" or "GDPR", tailored by the *Data Protection Act 2018*. In accordance with the provisions of GDPR, as well as national regulations on data protection, you have the right to exercise, if you wish, to access, rectify or delete your data, as well as request that the processing of your personal data is limited by emailing PGT@junogenetics.com

10. It is important for Juno Genetics to be able to use surplus or discarded samples from patients for the purpose of optimisation and validation of new tests and to develop new methodologies that might help future patients. In the event that you authorize Juno Genetics to use your surplus/discarded samples for that purpose, we would aim to do this in a blinded fashion, removing any information that could identify you. As the samples would be entirely anonymous, it would not be possible to report any additional findings to you. These actions will be only undertaken within the Juno Genetics laboratory.

    Kindly choose one option:

    ☐ Yes, I authorise
    ☐ No, I don't authorise

With this authorization,

I am also informed that this consent is revocable at any time before the tests are performed.

Likewise, I am informed that the medical team / geneticist / genetic counsellor is at my disposal for any questions or additional genetic advice that I may require.

_____ _____

Female patient's Signature **Date**

_____ _____

Partner's Signature (if applicable) **Date**

The above patient(s) have been counselled by me and others with respect to the risks and benefits of the test. The patient(s) appeared capable of understanding the information presented as demonstrated by the discussion and their participation.

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Clinician/ Genetic Counsellor Name (if applicable)

_____ _____

Clinician/ Genetic Counsellor Signature **Date**