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

Full name:	
Date of Birth:	
Clinic ID (if applicable):	

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 and their relatives on occasion, 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 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.

7. 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

8. 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.

OR

If the consent is being filled by a parent for their child: I provide consent to process my child's sample and data for the purpose of PGT test development. Results of my child's previous genetic tests (as applicable to PGT-M/ SR test) may be used for confirmation of the accuracy of this test.

_____ _____

Patient's Signature **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**