Informed Consent for Preimplantation Genetic Testing (PGT-A, PGT-SR and PGT-M)

I. PREVIOUS INFORMATION FOR PATIENTS

Our personal or family history indicates that there is a risk of transmitting a hereditary condition or severe chromosomal alteration to our offspring.

Therefore, the medical team attending to us has advised us that, in our specific case, one of the medical alternatives to significantly reduce these risks is to include our pre-embryos/embryos[1] in the preimplantation genetic diagnosis program.

We have been informed that the risk of such a genetic condition/chromosomal alteration can be reduced by performing genetic analysis on our pre-embryos generated through in vitro fertilization. Additionally, we have been informed about the diagnostic procedures and methods that can be used to analyse the pre-embryos, the chances of success, and the limitations and risks associated with this type of testing.

II. WHAT DOES PREIMPLANTATION GENETIC TESTING (PGT) INVOLVE?

Preimplantation Genetic Testing (PGT) is a type of genetic analysis conducted on the pre-embryo before its implantation in the uterus. PGT is performed on patients at risk of transmitting chromosomal or genetic abnormalities to their offspring, aiming to improve the selection of only unaffected pre-embryos for transfer to the uterus.

The PGT technique involves the combination of:

A. Pre-PGT studies, where applicable.
B. In vitro fertilization.
C. Biopsy of pre-embryonic cells through micromanipulation.
D. Genetic diagnostic techniques using molecular genetics methods.
E. Pre-embryo transfer.

III. WHEN IS PGT INDICATED?

This technique is indicated for the detection of pre-embryos carrying serious hereditary diseases, structural or numerical chromosomal abnormalities that could have a significant impact on the quality of life and/or life expectancy of the future newborn, as well as the successful implantation of such pre-embryo.

IV. PROCEDURE

A. Pre-PGT Phase (Pre-PGT). In this phase, genetic characterization tests for the specific genetic alterations to be diagnosed are performed in patients carrying the genetic condition. The aim is to gather maximum information before applying PGT in relevant cases.

B. Obtaining Pre-Embryos. The objective of this step is to obtain the pre-embryos for analysis. Assisted reproductive techniques, such as in vitro fertilization (IVF), are employed for this purpose. This is necessary even if patients do not have any reproductive abnormalities, as no other method of obtaining pre-embryos is allowed at this early stage of development. In some cases, if there are cryopreserved (vitrified) untested pre-embryos from previous cycles, they may need to be used for analysis. In such cases, the pre-embryos must be thawed (de-vitrified) and their viability confirmed before biopsy.

C. Pre-Embryo Biopsy. The biopsy is usually performed on the fifth, sixth, or seventh day after fertilization when the pre-embryo is in the blastocyst stage. The embryonic biopsy involves extracting approximately five cells from the trophoectoderm of the pre-embryo. As mentioned earlier, the biopsy can be performed on pre-embryos generated in the current IVF cycle or on cryopreserved pre-embryos from previous cycles. Regardless, once the biopsy is done, the pre-embryos will be vitrified until the analysis results are obtained.

D. Genetic Diagnosis. The cells obtained from the biopsy will undergo genetic analysis. Depending on the clinical indication, different analysis strategies in PGT may be followed, or even a combination of them. These strategies are briefly explained below:

Preimplantation Genetic Diagnosis for Aneuploidies (PGT-A)

In patients with an indication to analyse numerical chromosomal abnormalities, the test used will be Preimplantation Genetic Testing for Aneuploidies (PGT-A). This technique allows determining the number of copies of each of the 23 pairs of chromosomes in the pre-embryo samples and identifying both the pre-embryos negative for chromosomal aneuploidy (no alteration in the number of chromosomes) and those positive for aneuploidy (with an alteration in the number of chromosomes) (aneuploids). PGT-A has been shown to detect all whole-chromosome aneuploidies and certain segmental aneuploidies. Additionally, some abnormalities involving a complete set of 23 extra or missing chromosomes (triploidy or haploidy) can be detected. PGT-A will be performed using a method called Next Generation Sequencing (NGS) through the PGTseq platform. The embryonic biopsy will be performed at the blastocyst stage.

In some cases, there may be a need for the combined analysis of a monogenic disease and aneuploidies. In such cases, the blastocyst biopsy

[1] In countries such as Spain, the legislation refers to in vitro embryos with less than 14 days of development as "pre-embryos", while in other countries the legislation defines them as "embryos" from the moment of fertilization, without making this distinction. For the purposes of preimplantation genetic diagnosis tests, there is no difference, since the biopsy to obtain the sample takes place between days 5 and 7 after fertilization.

will be conducted, and both types of analysis can be performed on the same biopsy sample.

Preimplantation Genetic Diagnosis for Structural Chromosomal Abnormalities (PGT-SR)

In patients where the indication is a structural chromosomal abnormality, such as chromosomal translocations or inversions, Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR) is used to identify pre-embryos that are negative/balanced for the chromosomal segments involved in the rearrangement. The embryonic biopsy will be performed at the blastocyst stage. Similar to PGT-A, PGT-SR will be performed using Next Generation Sequencing (NGS) with the PGTseq platform.

The number of copies of the remaining chromosomes not affected by the structural rearrangement will also be analysed. In other words, in addition to the chromosomes affected by the structural alteration, the rest of the chromosomal set will be examined for the detection of aneuploidies.

Preimplantation Genetic Diagnosis for Monogenic Disorders (PGT-M)

In patients where the indication is a monogenic disease, Preimplantation Genetic Testing for Monogenic Disorders (PGT-M) is a molecular diagnostic technique that allows the identification of pre-embryos that are genetically normal with respect to the specific variant and gene being analysed. This enables the distinction of pre-embryos that have inherited the genetic alteration associated with the monogenic disease. PGT-M can be performed using the PGTseq-M method or alternatively, Karyomapping along with the study of familial mutations when possible. The embryonic biopsy will be performed at the blastocyst stage. The chromosomal analysis PGT-A is conducted in addition to PGT-M and is intended to reveal embryos that have an incorrect number of chromosomes in their cells.

E. **Pre-embryo Transfer.** The medical team at the centre will decide which pre-embryos will be transferred to the patient after considering the chromosomal or genetic makeup and viability of the pre-embryos.

V. RESULTS

The results of genetic assays and tests should be interpreted in the context of additional laboratory test results, family history, and other clinical findings. Genetic counselling is recommended to analyse the implications of these test results.

Despite the high reliability of PGT, the technique has inherent limitations. Therefore, in any pregnancy obtained after PGT, there is an indication to offer a confirmatory prenatal study as PGT testing should not be considered a substitute for prenatal testing. It is recommended to discuss this point with your maternal-fetal medicine team in the case of an on-going pregnancy.

The overall efficiency of PGT depends on factors such as the number of available pre-embryos, their developmental stage, and the effectiveness of the cytogenetic or molecular diagnostic method used. Furthermore, when PGT is employed to detect a monogenic disease, the final outcome will be influenced by the inheritance pattern of the gene (recessive or dominant) and the number of healthy pre-embryos available at the end of the process.

In general, the average pregnancy rate per embryo transfer in PGT treatments ranges between 50% and 60%. These rates largely depend on the patient's age, embryo quality, and underlying causes that led to the treatment indication. Different PGT techniques have been used for over 25 years, and no abnormalities associated with their use have been reported in the literature, suggesting that the procedure is safe.

The possible results in PGT-A cases may include:

- Negative: No complete chromosome aneuploidies or segmental abnormalities were detected. This result indicates that no extra or missing complete chromosomes or segmental abnormalities were detected.
- Positive: Complete chromosome aneuploidies and/or segmental abnormalities were detected. This result indicates that at least one complete chromosome is present in excess or is missing, and/or segmental abnormalities were detected.
- No Result: Refers to a failure in DNA amplification or inconclusive results. In these cases, a new biopsy is recommended to obtain another sample for analysis, provided that the pre-embryo quality allows this.

The possible results in PGT-SR cases may include:

- Negative/Balanced: Pre-embryos in which a normal number of chromosomes (46,XX or 46,XY) is predicted, or a balanced chromosomal rearrangement is detected in the biopsy sample (since the technology used does not differentiate between these two states).
- Positive: Pre-embryos in which an abnormal number of chromosomes is predicted in the biopsy sample. These are pre-embryos for which a high risk of chromosomal abnormality has been determined.
- Positive/Unbalanced: Pre-embryo that has inherited the structural chromosomal alteration in an unbalanced state. These pre-embryos show gains and/or losses of chromosomal fragments related to the structural alteration carried by the patient.
- No Result: Refers to a failure in DNA amplification or inconclusive results. In these cases, a new biopsy is recommended to obtain another sample for analysis, provided that the pre-embryo quality allows this.

The possible results in PGT-M cases may include

- Negative: Pre-embryos that are not expected to have inherited the genetic alteration associated with the monogenic condition. Additionally, no chromosomal abnormalities have been identified.
- Positive: Pre-embryos that are expected to have inherited the genetic alteration associated with the monogenic condition. This category also includes embryos with chromosomal abnormalities.
- Carrier: Pre-embryos that are expected to be healthy carriers of the monogenic disease under study. This applies to autosomal recessive and X-linked recessive diseases. Additionally, no chromosomal abnormalities have been identified.
- No Result: Refers to a failure in DNA amplification or inconclusive results. In these cases, a new biopsy is recommended to obtain another sample for analysis, provided that the pre-embryo quality allows it.
- Non-Informative: The accuracy of the test depends on the results obtained in Karyomapping or PGTseq-M, with or without analysis of the mutation site. If there is a recombination between the mutant gene and the linked polymorphisms, this can also lead to inconclusive results in PGT-M, compromising the accuracy of the test and resulting in the pre-embryo being classified as "non-informative." The genetic status of a pre-embryo with a "non-informative" status is unknown. In such cases, a second biopsy is not recommended.

VI. LIMITATIONS OF PGT. SO-CALLED "NON-INFORMATIVE" PRE-EMBRYOS. INCIDENTAL FINDINGS.

Common Limitations of all PGT Tests (PGT-A, PGT-SR, PGT-M)

It is crucial to avoid unprotected sexual intercourse from 15 days prior to egg retrieval until after the pregnancy test, which is performed approximately two weeks after the embryo transfer to the uterus. Sexual intercourse during this time could lead to a natural pregnancy from an untested embryo, invalidating any PGT results.

PGT minimizes the possibility of transferring embryos carrying the chromosomal and/or genetic alteration under study. Like any diagnostic medical technique, there is a margin of error in the test, estimated to be between 1-2% theoretical possibility of diagnostic error in the genetic status of the embryo. Therefore, in any pregnancy obtained after PGT, there is an indication to offer a confirmatory prenatal study as PGT testing should not be considered a substitute for prenatal testing. It is recommended to discuss this point with your maternal-fetal medicine team in the case of an on-going pregnancy. While highly unlikely, there is a possibility that a biopsy sample may be lost or damaged at some point in the clinic, during transport, or in the laboratory. In such cases, a new embryo biopsy will be necessary, provided that the pre-embryo quality allows for this.

Like any other laboratory technique, PGT can be affected by errors that can compromise the obtained result. Common sources of these errors are associated with human errors during sample collection and processing, errors in laboratory equipment and materials, contamination of samples by other cells or external genetic material, or non-compliance with established pre-analytical conditions to ensure the validity of the results obtained.

PGT does not offer any guarantee of achieving a pregnancy or having a healthy child (free from all genetic or non-genetic defects).

Since PGT does not analyse all types of chromosomal or genetic abnormalities, it cannot exclude the possibility that an embryo may have other types of genetic abnormalities and/or birth defects. In the general population, there is a 3-5% risk of a child being born with a birth defect or intellectual disability due to genetic and/or non-genetic causes. The use of PGT does not reduce that risk.

There is a possibility of not obtaining a result from a biopsy sample, which will be classified as "no result." This can happen if the cells extracted from the embryo contain degraded DNA, as well as due to other technical limitations. This typically affects less than 5% of the samples. If the final result is "no result," the medical team will advise against transferring the embryos to the uterus. In such cases, a rebiopsy of the embryo may be recommended if its quality allows for it.

PGT results may indicate an intermediate number of chromosomes, also known as "mosaic embryos." Mosaicism refers to a combination of chromosomally normal and abnormal cells in a single pre-embryo biopsy sample. Embryo biopsies in this category have at least one complete chromosome or a segment of a chromosome falling within the mosaic range. Juno Genetics does not routinely report the presence of mosaicism in a biopsy. According to current scientific evidence, these embryos have the same implantation potential and ability to generate a live newborn as embryos without mosaicism. Therefore, mosaic findings are considered secondary and of uncertain significance. Ultimately, the decision to report mosaic findings will be made by the medical team, who may request Juno Genetics to report mosaic pre-embryos.

In any case, the final clinical recommendation regarding the selection of embryos for transfer to the uterus will be the responsibility of the medical team.

Common Limitations of PGT-A and PGT-SR Tests

This test does not search for any hereditary/genetic or non-genetic conditions within a person's family history.

In PGTseq-A and PGTseq-SR, all 23 pairs of chromosomes are analysed, and most abnormalities in the number of copies or complete loss of a set of chromosomes (complete haploidy) can be detected. However, certain types of abnormalities cannot be detected, such as some forms

of polyploidies (e.g., tetraploidies like 92,XXXX).

Another class of abnormalities that may not be detected are related to losses or duplications of small fragments of chromosomes, known as segmental abnormalities. In general, segmental aneuploidies below 3Mb are not detected. However, the detection limits for segmental aneuploidies vary depending on the chromosome and the quality of the embryonic sample. The probability of a segmental aneuploidy being present in the fetus cannot be predicted.

The detection of uniparental disomies, where both sets of chromosomes come from the same parent instead of one from the father and one from the mother, cannot be guaranteed.

The PGT platform (PGTseq) was validated using embryos generated through Intracytoplasmic Sperm Injection (ICSI). The use of conventional insemination may increase the risk of contamination from maternal or paternal sources. If undetected contamination occurs, it can result in a false negative or false positive.

The PGTseq platform cannot detect all segmental aneuploidies or copy number variants (CNVs). A "Negative" result does not eliminate the risk of a segmental aneuploidy. It is recommended that patients meet with a genetic counsellor and consider the possibility of confirmatory prenatal diagnosis,. Most copy number variants (CNVs) identified prenatally and postnatally will not be detected by PGT-A as they are below the detection limit.

Breakpoints of segmental aneuploidies are not precisely determined using PGTseq. The deleted/duplicated chromosome segment may be smaller or larger than indicated in the PGT-A and PGT-SR report. Given this limitation, Juno Genetics does not provide a classification of the clinical significance of segmental aneuploidies.

Occasionally, the results of PGT-A and SR may indicate a chromosomal abnormality of parental origin in one of the couple members, such as a parental chromosomal rearrangement or extra/missing chromosomal material. This type of result is considered an incidental finding. If the results suggest a chromosomal abnormality in the parents, this result will be communicated to the patients. Additional genetic testing may be required in response to such results.

Specific limitations of the PGT-SR Test

While losses and duplications of chromosome fragments can generally be detected within pre-embryos, it is not possible to distinguish pre-embryos that have a balanced form of rearrangement (the same situation as the parent carrying the rearrangement) from those with a completely normal set of chromosomes. This is because in these two situations, the amount of chromosomal material is the same.

The accuracy of PGT-SR depends on the genetic information provided to Juno Genetics in medical records and reports from previously conducted genetic tests. The information provided to Juno Genetics will be evaluated to determine if the PGTseq-SR method could detect unbalanced products derived from the rearrangement. Incorrect definition of chromosomal breakpoints and/or errors in the family history information provided to Juno Genetics may affect the ability of the PGT-SR test to detect unbalanced rearrangement products.

PGTseq-SR will only be able to detect unbalanced products of the specific chromosomal rearrangement within the records provided to Juno Genetics. The accuracy for detecting unbalanced products of the rearrangement is >98%, assuming that the karyotype information provided to Juno Genetics is accurate.

This test reduces, but does not eliminate, the risk of an unbalanced rearrangement in embryos identified as "negative/balanced".

Specific limitations of the PGT-M Test

The procedures performed for PGT-M focus on the identification of specific inherited genetic disorders, according to the indication for the test. However, the technique used for PGT-M allows for the detection of chromosomal status information of the pre-embryo. This information will be provided to patients whenever available. Chromosomal abnormalities frequently occur in the human pre-embryo and have the potential to cause implantation failure or miscarriage. In any case, the final clinical recommendation regarding the selection of embryos to transfer to the uterus will be the responsibility of the medical team.

This test does not rule out the possibility of other variants in the studied gene, including de novo variants.

The PGT-M test used is specifically designed to analyse the indicated region/gene of interest stated in the test request. Other additional genes/regions will not be studied.

The accuracy of PGT-M for the detection of a disorder caused by a mutation in a single gene is estimated to be at least 95%, depending on the methodology used. However, it is important to note that the risk of an affected child/pregnancy after transferring a pre-embryo predicted to be "normal" or "carrier" is not zero. The intention of the test is not to guarantee an unaffected pregnancy or delivery, but to reduce the risk of transferring an affected pre-embryo to the uterus. Despite the high reliability of PGT-M test, there are inherent limitations to the technique. Therefore, there is an indication to offer a confirmatory prenatal study as PGT testing should not be considered a substitute for prenatal testing. It is recommended to discuss this point with your maternal-fetal medicine team in the case of an on-going pregnancy.

The use of intracytoplasmic sperm injection (ICSI) as a fertilization method is highly recommended for PGT-M cases, as it helps reduce the risk of DNA contamination caused by sperm. If contamination is present but goes undetected, a misdiagnosis can occur.

VII. ALTERNATIVES TO THE PGT TECHNIQUE

- Natural conception followed by prenatal diagnosis, provided that the couple is willing to consider voluntary termination of pregnancy if fetal abnormalities are detected.
- Use of donor gametes (eggs or sperm) from a non-affected individual, depending on who is the carrier of the disease.
- Legal adoption.

VIII. ECONOMIC INFORMATION

The prices and conditions governing the performance of these tests, if applicable, will be detailed to you at the centre where you are being attended.

JUNO laboratory does not directly provide PGT services to patients, therefore, it cannot provide any quotes or approximate costs for this service under any circumstances.

IX. GENERAL LEGAL ASPECTS RELATED TO ASSISTED REPRODUCTION AND SPECIFIC DETAILS REGARDING PREIMPLANTATION DIAGNOSIS AND TREATMENT

The biological sample submitted, along with the necessary personal data for the provision of the service, will be sent for analysis to the facilities of Juno Genetics Spain, S.L., at Parque Tecnológico de Paterna (46980), Valencia, Spain, Ronda de Guglielmo Marconi, 11, Building A, second floor, premises A-1-2 and A-2-2. The genetic analysis of the sample will be carried out in accordance with the applicable Spanish regulations, primarily Law 14/2006 on Assisted Human Reproduction Techniques and Law 14/2007 on Biomedical Research.

However, please be informed that in the event of any temporary impediment or incident occurring in this Laboratory that could delay the result of your test (e.g., equipment breakdown in genetic analysis, technical maintenance shutdowns, interruptions in the supply of resources, etc.), in order to provide the committed service and obtain the analysis result in the shortest possible time, your sample and necessary personal data for the provision of the service will be sent to Juno Genetics Ltd., Hayakawa Building, Edmund Halley Road, Oxford Science Park, Oxford OX4 4GB, United Kingdom, at no additional cost. If this is the case, it will be noted in the report that will be provided to you regarding the analysis result of your sample issued by this Laboratory, which will have conducted the test in accordance with the provisions of the *Human Tissue Act* of 2004.

In the event that part or all of the tests cannot be performed in any of the aforementioned laboratories, Juno Genetics reserves the right to carry out the analyses through a reference laboratory. This circumstance will be indicated in the final report that is issued.

In any case, the provisions of the Convention on Human Rights and Biomedicine (Oviedo Convention) of 1997 shall apply, as it restricts the genetic diagnosis and research of genetic conditions only when the subject receives appropriate genetic counselling.

If the performance of this test has been indicated from a country other than Spain, the professional or clinic requesting the test will be responsible for ensuring that both the test itself and its application in the specific case is in accordance with the stipulations of its national or regional regulations, as well as for informing the subject of the test of any particularly relevant issue that such legislation contemplates.

X. DATA PRIVACY, STORAGE, AND USE FOR SAMPLE STUDY

Patient and donor privacy is a top priority at Juno Genetics. All personal information and genetic results are strictly confidential. The only individuals who can access this information are the personnel at the reproductive clinic, the Juno Genetics Laboratory analyzing the sample, and the relevant authorities if required by the laws of the applicable jurisdiction.

In accordance with the current data protection regulations, such as the EU General Data Protection Regulation (EU2016/679) and national data protection laws including the Spanish Organic Law 3/2018 on the Protection of Personal Data and Guarantee of Digital Rights, and, where applicable, the UK *Data Protection Act* 2018, you have the right to exercise your rights, if desired, including the right to access, rectify, erase, and revoke your consent, as well as the right to restrict processing, data portability, and to not be subject to automated decision-making based solely on your data. These rights can be exercised by contacting the following postal address:

- Juno Genetics España, S. L., Parque tecnológico de Paterna (46980), Valencia, Spain, Ronda de Guglielmo Marconi, 11, edificio A, segunda planta, locales A-1-2 y A-2-2 (if your analysis is carried out at this laboratory).
- Juno Genetics Ltd., Hayakawa Building, Edmund Halley Road, Oxford Science Park, Oxford OX4 4GB, United Kingdom (in exceptional circumstances as stated in this document, if your analysis is carried out at this laboratory).
- In both cases, you can also contact the Juno Genetics DPO (Data Protection Officer) at: Juno.DPO@junogenetics.com

Personal data will only be processed for the following purposes: (1) fulfilling obligations arising from the requested services (legitimate basis under Art. 6(1)(b) and 9(2)(h) of the GDPR); (2) reviewing and ensuring the quality of the provided services (internal audits, quality controls, laboratory validation studies based on Art. 6(1)(f) of the GDPR); (3) educational/training purposes, always subject to anonymization prior to use to prevent identification of the patient in question; (4) research purposes, scientific publications, and presentations, always subject to prior

anonymization to ensure non-identifiability of individuals. Research will be conducted in compliance with the General Data Protection Regulation and national data protection laws. (5) providing personalized responses to inquiries or suggestions from patients requesting the test and ensuring that the test has been carried out correctly and addressing any concerns (legitimate basis under Art. 6(1)(b) of the GDPR); and (6) monitoring patients in the future to obtain feedback on the service received (legitimate basis under Art. 6(1)(f) of the GDPR). Data will be stored for a minimum of five years unless local laws in the applicable jurisdiction state otherwise. Finally, if you believe that your data protection rights have been violated, you have the right to lodge a complaint with the competent Data Protection Authority.

In addition to the above, Juno Genetics will only distribute test results to your physician unless otherwise specified in writing by you (or a person legally authorized to act on your behalf) or required by a court of law.

Recipients of the data

In order to improve research and development in assisted reproduction techniques, other centres or entities within the group may have access to personal and genetic data in cases where information derived from the tests performed may be used in clinical studies by any of these entities, in accordance with the General Data Protection Regulation and national data protection laws. It is important to note that any data that may reveal your personal identity and/or that of your family will be anonymized, treated with absolute confidentiality, and used only for research and development purposes related to the services provided by the group. Necessary security measures will be implemented to ensure the security and confidentiality of your data.

Regarding the communication of data for research and development purposes:

☐ YES, I wish for Juno Genetics to share my information for research and development purposes

☐ NO, I do not wish for Juno Genetics to share my information for research and development purposes

XI. AUTHORIZATION TO USE SURPLUS OR DISCARDED SAMPLES FOR THE OPTIMIZATION AND VALIDATION OF NEW TESTS

It is important for Juno Genetics to be able to use surplus or discarded samples for the optimization and validation of new tests and the development of new analysis methodologies, including new technologies based on the development of Artificial Intelligence applications, so that these advancements and improvements can benefit future couples, including your case. The surplus samples used for this purpose would be anonymized and processed blindly, ensuring that no findings can be reported to you. This would only take place in Juno Genetics' laboratory.

Clinical results, information, and raw data may be reviewed and/or reanalysed for future publications and scientific presentations. At all times, these data will be subject to prior anonymization, ensuring that personal identification is not possible under any circumstances. All treatments and processes will be carried out in accordance with the General Data Protection Regulation and national data protection laws.

I also understand that Juno Genetics may use the resulting information for scientific publications of results and their presentation after anonymizing any personal information.

I understand and accept that, since all information will have been previously anonymized, I will not be able to access new results or findings in the present or future, nor will I receive any financial benefits from publications and presentations, nor will I be compensated for products developed as a result of these activities.

XII. ONCE READ AND UNDERSTOOD THE ABOVE, WE ARE INFORMED OF:

- I have been informed that I am not obligated to undergo this genetic analysis, and I freely and voluntarily consent to its performance.
- The indication, procedure, success probabilities, limitations, risks, and complications of the proposed preimplantation diagnosis program.
- My test results may have implications for other members of my family. I acknowledge that my results may sometimes be used to provide appropriate medical care for others. This could be done by discussing it with me or in such a way that I am not personally identified in this process.
- Procedures may be cancelled at any time during their implementation, either for medical reasons or at the request of the interested party, provided that it does not cause harm to patients or viable pre-embryos produced.
- It is common practice in genetic analysis laboratories to store the DNA extracted from received samples, even after the current test is completed. My sample could be used as a "quality control" for other tests, such as those for family members. The DNA extraction methodology or the "raw data" generated may render it unfeasible for use by third-party laboratories.
- Both my test results and the test report will be part of my patient record.
- I am informed of the availability of the healthcare staff at this facility to further clarify any aspect of the information that has not been sufficiently clarified.

We have understood the explanations provided to us in clear and simple language. In the event that the test has been conducted in the context of assisted reproductive treatment, the healthcare professional who has attended to us at the clinic where we are patients has allowed us to make all observations, clarified all doubts we have raised, and explained the implications of potential test results.

We also understand that at any time and without the need to provide any explanation, we can revoke the consent we are now giving. However, please note that, depending on when the test is revoked, you may have to pay for any costs associated with the test that have already been incurred prior to the revocation. Mainly the materials and reagents associated with the test, as well as the costs of transporting the samples.

Therefore, we declare that we are satisfied with the information received and that we understand the scope and risks of the treatment.

XIII. PATIENT AND AUTHORISED HEALTHCARE PROFESSIONAL INFORMATION

PATIENT 1	PATIENT 2 (except for single woman)
Name PATIENT 1	Name PATIENT 2
Date of birth PATIENT 1	Date of birth PATIENT 2
Address PATIENT 1	Address PATIENT 2 (☐ Same address as PATIENT 1)
National Insurance Number (NIN) PATIENT 1	National Insurance Number (NIN) PATIENT 2

Authorisation:

After reading the COMPLETE document consisting of a total of 7 pages and 13 (XIII) sections, we authorize the personnel of the Reproductive Unit to carry out the proposed preimplantation diagnostic program with our pre-embryos.

Signature PATIENT 1	Signature PATIENT 2

Name of the AUTHORIZED HEALTHCARE PERSONNEL	Professional Registration Number	Date and signature
I declare that:		
I have explained the content of these tests and their risks, and clarified any doubts and questions raised by the individual. Furthermore, I commit to providing the necessary genetic counselling based on the test results.		