Patient Details		
First Name:	Last Name	
Preferred Contact No:	DOB:	IVF ID:

Partner Details *(if applicable)*		
First Name:	Last Name	
Preferred Contact No:	DOB:	IVF ID:

Consent

1. I/we understand that Monash IVF and Repromed are part of the Monash IVF Group and are referred to in this form as the Company. The Laboratory refers to The Monash IVF and Repromed Genetics Laboratories.

2. I/we understand and acknowledge that my/our embryos may be aneuploid *(i.e. have extra or missing chromosomes).*

3. I/we confirm that I/we wish to have cell/s biopsied from my/our embryo/s with the intention of identifying embryos which are aneuploid.

4. I/we understand that there is a fee associated with PGT-A, which will be charged in addition to the fees for IVF.

5. I/we understand that The Company requires blood/DNA samples from both egg and sperm provider to perform PGT-A. I understand that the DNA samples may be stored until there is no DNA remaining or until the sample has degraded and that I/we can request for this sample to be discarded at any time by sending a written and signed request to my treating clinic.

6. I/we understand that in cases where DNA is unavailable from one or both sperm and egg providers (e.g. if donor gametes were used) PGT-A can still be performed. However, this may increase the chance of an inconclusive result.

7. I/we understand that rarely this test identifies genetic changes that are unexpected and unrelated to the original reason for performing this test (i.e. incidental findings). If incidental findings are identified they will only be disclosed if they have an impact on the PGT-A test design.

8. I/we understand that if I/we are undertaking a stimulated IVF cycle, it is strongly recommended that my/our embryos should be created using Intracytoplasmic Sperm Injection (ICSI) as the fertilisation method. ICSI involves the injection of one sperm into one egg. The use of standard fertilisation has the potential to result in the presence of additional sperm around the embryo. I/we are aware that if I/we elect to have my/our embryos created using standard fertilisation, there is a small risk that these additional sperm may impact on the ability to obtain a conclusive PGT-A result and/or that these additional sperm may reduce the accuracy of the PGT-A result.

9. I/we understand that suitable embryos will be biopsied at the blastocyst stage on Day 5, 6 or 7 after egg collection.

10. I/we are aware that I/we will not know upfront how many embryos may be suitable for biopsy over the course of Days 5, 6 and 7 *(as this is dependent upon the growth of the embryos)*. I/we understand that I/we will be updated on how many embryos were able to be biopsied at the completion of the biopsy process.

11. I/we understand that due to the time taken for PGT-A, my/our embryos will need to be frozen following embryo biopsy and, if suitable, transferred in a subsequent frozen embryo transfer cycle. Only embryos that meet specific freezing criteria will be considered suitable for freezing. The risks involved in freezing embryos are outlined under the 'Risks and Limitations' section below.

12. I/we understand that the cell/s biopsied from my/our embryo/s may be transported between IVF centres/Laboratories to facilitate PGT-A. Such transportation takes place in specialised transport containers under strict transportation conditions and all samples are handled by appropriately trained staff or professional courier services.

a. I/we consent to biopsied cell/s or amplified embryonic DNA from my/our embryos being transported between IVF centres/Laboratories as required for PGT-A testing.

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b. I/we understand that during transportation, accidents beyond the control of all parties involved can occur resulting in the loss of viability of the biopsy sample/s *(meaning the sample is no longer suitable for genetic testing and/or no PGT-A result will be possible)*. In these circumstances the Company and its affiliated genetic testing clinics do not accept any responsibility for, or liability for, the biopsied cells or their condition upon arrival.

13. I/we understand that once the biopsied cell/s have been screened and the PGT-A results reported, these processed sample/s may be archived for long term storage. The Company does not accept any responsibility for, or liability for, the loss or degradation of these stored samples.

14. I/we understand that:

a. I/we have watched the PGT-A information session video on the Monash IVF/ Repromed website.

b. A fact sheet on "Preimplantation Genetic Testing with aneuploidy screening" was provided to me/us and I/we have read it and understood the information contained in it.

c. I/we have been given the opportunity to ask questions about PGT-A, as well as the information contained in this consent form and the fact sheet. I/we acknowledge that if I/we have additional questions, I/we can arrange to speak with a member of the Genetics team.

d. Information relating to the results and embryos for transfer will be discussed with me/us by a member of the Genetics/Embryology team at the completion of PGT-A.

e. If a pregnancy is achieved following PGT-A, my/our IVF doctor strongly recommends routine prenatal screening for chromosome conditions and diagnostic testing where appropriate *(please refer to the "Confirmatory prenatal diagnosis following PGT" fact sheet for further information).*

f. If a pregnancy is achieved following PGT-A, my/our IVF doctor strongly recommends non-invasive prenatal screening to screen for chromosome conditions. Diagnostic testing in pregnancy should be performed if/when appropriate (please refer to the "Confirmatory prenatal diagnosis following PGT" fact sheet for further information).

15. I/we acknowledge that I/we have been advised of the need to abstain from unprotected sexual intercourse during my/our treatment due to the possibility of a natural conception. I/we understand that this means I/we will need to abstain from unprotected sexual intercourse during the following times:

a. From day 1 of menstrual period in my/our stimulated IVF/PGT-A cycle up until 16 days post egg collection.

b. From day 1 of menstrual period in my/our frozen embryo transfer cycle, up until the time of pregnancy testing following a frozen embryo transfer.

Risk and Limitations

I/we understand that PGT-A has associated risks and limitations including, but not limited to, those listed below.

1. Risks of Embryo Biopsy

I/we understand that:

a. Not all embryos may be suitable for biopsy.

b. Embryos may be damaged during the biopsy procedure or may fail to survive.

c. A "no result" or "inconclusive" result may occur for some or all embryos. This means that the test is unable to determine whether the embryo is euploid *(i.e. has the typical number of chromosomes)* or aneuploid *(i.e. has extra or missing chromosomes).*

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d. Testing of all embryos may not be possible due to technical limitations.

e. Embryos may fail to develop to a stage suitable for transfer.

Thus far babies born after PGT-A *(or other types of PGT that include embryo biopsy)* have had a similar rate of birth defects to babies in the general population. However, the potential for unknown consequences to a liveborn baby cannot be excluded. There may also be a risk of decreased viability of the embryo due to the biopsy procedure itself.

2. Risks of freezing embryos

I/we understand that there are some risks associated with freezing embryos. These may include:

a. Not all embryos will develop to the stage suitable for freezing.

b. Not all embryos will survive the freeze/thaw process.

c. Embryos that do survive the freeze/thaw process may not continue to develop and may not be suitable for transfer from an Embryology perspective.

3. Possibility of a misdiagnosis

I/we understand that:

a. There are technical, biological and human errors which can contribute to diagnostic error and PGT-A will never achieve 100% accuracy.

b. If the reported result is incorrect the following may occur:

- A euploid embryo may be incorrectly classified as aneuploid and not considered suitable for transfer.
- An aneuploid embryo may be incorrectly classified as euploid and considered suitable for transfer. This may result in implantation failure, miscarriage, stillbirth or pregnancy/birth of a child with a chromosome condition.

c. There is a chance of misdiagnosis due to mosaicism *(i.e. the presence of both euploid and aneuploid cell lines in the embryo).* Mosaicism occurs by chance during embryonic development and can cause a PGT-A misdiagnosis if the biopsied cell/s are not representative of the remainder of the embryo.

d. Due to the risk of misdiagnosis occurring, prenatal testing should be considered in any pregnancy resulting from PGT-A treatment for confirmation of the PGT-A result.

4. Limitations of PGT-A

I/we understand that:

a. PGT-A is designed to test for aneuploidy involving the whole chromosome. It can also detect some cases of segmental aneuploidy *(a portion of a chromosome that is extra or missing)*, depending on the size of the chromosome segment involved. Small extra or missing chromosome segments will usually not be detected. The potential significance of any small extra or missing chromosome segments will vary depending on the chromosome region involved.

b. PGT-A can detect some, but not all, cases of mosaicism. The likelihood of detecting mosaicism will depend on the proportion of each of the cell lines in the biopsy sample, as well as the quality of the resulting data. Decisions relating to the fate of mosaic embryos will be made in accordance with the policy of my/our treating IVF clinic.

c. PGT-A does not analyse specific genes and will not detect conditions caused by monogenic variants (e.g. Cystic Fibrosis or Huntington disease).

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d. PGT-A does not guarantee that a baby resulting from a biopsied embryo will be free of other genetic conditions or other abnormalities. There is a 3-5% background population risk for birth defects or genetic conditions in any pregnancy. PGT-A only aims to detect the portion of birth defects caused by aneuploidy, and not these other risks.

e. There remain multiple rare chromosomal problems, including but not limited to uniparental disomy (i.e. when the embryo receives two copies of a chromosome from one reproductive partner and no copies from the other reproductive partner) and certain types of aneuploidy, which could arise and that may not or cannot be tested for using PGT-A.

5. No results or inconclusive results

I/we understand and acknowledge that the procedure of embryo biopsy may not be able to provide a diagnosis of some/all embryos. This may be due to, but not limited to, one of the following:

a. Poor quality of biopsied material *(e.g. very fragile or lysed cells).*

b. Limitations of testing only a few cells.

c. Unpredictable and uncontrollable problems with transportation of biopsied cell/s, such as weather and air travel issues, or other circumstances beyond the control of our IVF Clinic or Laboratory.

d. The embryo biopsy sample received by the Laboratory is unacceptable for analysis and results cannot be obtained.

If a conclusive result is not possible, I/we understand that I/we will need to choose between the following options:

a. Thawing the embryo/s and performing a repeat biopsy *(if possible)* to try to obtain a conclusive genetic result. If this option is chosen/available, re-biopsied embryos will need to be re-frozen while the repeat genetic testing is performed. An additional fee will apply in these cases.

b. Thawing the embryo/s and allowing them to succumb.

c. Thawing one or two embryos and transferring them to the uterus *(womb)* without a genetic result.

6. Possibility of no embryo for transfer

I/we understand that at the completion of PGT-A testing I/we may not have an embryo available for transfer. This may occur due to one of the following scenarios:

a. All embryo/s tested during an IVF cycle may be found to be aneuploid, meaning that no embryos are genetically suitable for transfer.

b. Embryo/s diagnosed as euploid may not survive the freeze/thaw process and therefore may not be suitable for transfer from an Embryology perspective.

c. Embryo/s diagnosed as euploid may survive the freeze/thaw process but may not continue to develop normally and therefore may not be suitable for transfer from an Embryology perspective.

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7. Decision making for ongoing storage or disposal aneuploid embryos

I/we understand that at the completion of PGT I/we may need to choose between the following options for the ongoing storage or disposal of embryos. This may occur if the embryos are found to be aneuploid for any of the chromosomes screened and not genetically suitable for transfer or are excess to my/our treatment.

If embryos are screened as euploid / no abnormalities detected (NAD) for chromosome errors (i.e. suitable for transfer), I/we understand that these will be stored and made available for our future use.

Embryos screened as aneuploid
If an embryo is screened as aneuploid (i.e.: extra or missing chromosomes and not genetically suitable for transfer), I/we instruct The Company to - *please tick one option below:*

Option 1 ☐ **Remove embryos from storage and allow them to succumb with no further consent**
I/we do not wish to utilise an embryo classified as aneuploid. I/we acknowledge that this is a screening test only and not 100% accurate and that embryos will be removed from storage and allowed to succumb with no further consent required.

Option 2 ☐ **Keep for potential future use subject to further consent and consultation**
I/we consent to the storage of the above embryos, knowing that they have been screened as aneuploid.

I/we agree to subsequently either:

a) Consent to these embryos being removed from storage and allowed to succumb OR

b) Consent to attend a consultation with a genetics healthcare professional to discuss the potential use of any aneuploid embryo/s before making a decision. I/we understand that in most circumstances aneuploid embryo/s will not be suitable to transfer and The Company may, at its discretion, refuse to transfer the aneuploid embryo. In these cases, if I/we wish to transfer an aneuploid embryo, I/we would need to identify an alternate clinic who would be willing to perform the transfer.

I/we are aware that if I/we select this option:
- Further consents and consultation will be required
- Preference must be given to transferring euploid embryo/s
- Aneuploid embryo/s will be stored for a maximum of 5 years. If I/we have not made a decision regarding these embryos after this time, these embryo/s may be removed from storage and allowed to succumb, without further consent.

Option 3 ☐ **Donate to research (i.e. transfer these embryos to another clinic for the purpose of donating to research, storage and transport fees may apply)**
I/we consent to aneuploid embryo/s being donated to research. I/we understand and acknowledge that research on certain human embryos may only be conducted under a license issued by the NHMRC Embryo Licensing Committee, and that currently there are no active research projects accepting embryos at The Company. Where this is the case, I/we would need to identify an alternate clinic who would be willing to accept the aneuploid embryos. I/we understand that, I/we would need to identify an alternate clinic who would be willing to accept these embryos. I/we understand that storage fees will continue to apply.

Consent to Preimplantation Genetic Testing with aneuploidy screening (PGT-A)

Patient Details		
First Name:	Last Name	
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Partner Details *(if applicable)*		
First Name:	Last Name	
Preferred Contact No:	DOB:	IVF ID:

Statement of Intent

By signing this form, I/we acknowledge that:

- I/we have read and understood the information provided on this consent form.
- I/we have read and understood the patient information sheet on "Preimplantation Genetic Testing with aneuploidy screening (PGT-A)" provided to me/us.
- I/we have been offered the opportunity to ask questions and seek further information if required.

Please note that PGT-A treatment cannot commence without signed consent forms.

Consent to Preimplantation Genetic Testing with aneuploidy screening (PGT-A)		
Based upon the information included in these documents, I/we would like to proceed with PGT-A and accept all risks and limitations outlined in this consent form.		
Patient Signature	*Partner Signature (if applicable)*	*Date*

Was a healthcare interpreter used to complete this form?		☐ Yes ☐ No	
Name of Company		Ref No/ Name of interpreter	

Trained bilingual staff, on staff interpreters, contract interpreters, telephone interpreters and trained volunteers can serve as healthcare interpreters. Patient's family and friends, people under 18, other patients and visitor and untrained volunteers should not serve as health care interpreters.