Consent Form (M)
Preimplantation Genetic Testing with Aneuploidy Screening (PGT-A)

MONASH IVF GROUP

I/we

Patient Label
First Name:
Surname:
Date of Birth:
Address:

Partner Label
First Name:
Surname:
Date of Birth:
Address:

CONFIRM

- That I/we have received a copy of the Preimplantation Genetic Testing (PGT-A) Fact Sheet and counselling regarding all of the following matters (all of which I/we understand):
  - The nature of the testing conducted, what it tests for, and what it does not test for. I/we understand that the results obtained from PGT cover chromosome copy number errors only and does not detect the presence of single gene disorders or balanced chromosomal rearrangements. There is a possibility that the embryo or a child developing from the embryo may have an abnormality or genetic defect that was not tested for.
  - A spontaneous pregnancy may occur at the time of frozen embryo transfer of a screened embryo and in this case no genetic defects can be excluded.
  - We understand that some or all of our embryos may not be suitable for embryo transfer after this procedure.
  - The possibility of a misdiagnosis occurring and its attendant consequences (which may include an embryo affected by an abnormality or genetic defect being transferred, resulting in a pregnancy and birth), and that the interpretation of results from PGT cannot be guaranteed due to technical limitations which may include (without limitation): failure of the sequencing technology and the inability to analyse all the cells from the embryo.
  - That in cases of embryos that are not tested or embryos that are tested but do not return a result, the decision of what to do with each of our embryos will be discussed with my treating IVF fertility specialist.
  - I/we understand that PGT is a screening test only and prenatal diagnosis is strongly recommended during pregnancy following embryo transfer of a PGT embryo.
  - That information relating to the results and embryos for transfer may be discussed with me/us by the PGT team, your treating doctor, or genetic counsellor.

If undergoing PGT with embryo biopsy:

- That the process involved in PGT includes the need for embryo biopsy.
- That some embryos may not be suitable for embryo biopsy.
- That after embryo biopsy some embryos may be damaged or not develop to a stage suitable for transfer.
- The cell(s) taken at biopsy are assumed to represent the whole embryo and results for other cells within the embryo, but not included in the biopsy sample, may differ.
- That there are certain limitations on obtaining results from some cells.
- The laboratory will grow embryos in the laboratory until day 6 (biopsy will occur on day 5 and/or 6). Any embryo that has not formed a viable blastocyst by day 6 will not be tested.
- That the results are 98% accurate, and that published estimated error rates for PGT analysis are approximately 2%.
- This screening test is recommended for the detection of unbalanced chromosome translocations.

If undergoing non-invasive PGT:

- The laboratory will grow all embryos until day 6. Any embryo that has not formed a viable blastocyst by day 6 may not be suitable for testing.
- Non-invasive PGT is performed by testing the media that the embryo has been cultured in.
- In-house verification studies for non-invasive PGT results are identical to the embryo biopsy PGT results in approximately 95% of the cases.
- This screening test cannot be used for the detection of unbalanced chromosome translocations.

- I/we understand that I/we are entitled to a copy of this completed consent form.
- I/we understand that I/we may vary this consent at any time by notice in writing to your clinic.
- I/we understand that I/we, individually and/or together, may revoke this consent at any time by notice in writing to your clinic.
- That this consent may be given subject to conditions and that provision is made for me/us to specify such conditions below:

……

……

(set out in full any conditions, in addition to the conditions otherwise stated in this form, to which the consent is subject. If additional space is required, attach an extra page signed by the consenting person(s) and the Medical Practitioner.)

CONSENT

I/we, the above named, having read the contents of this consent form, hereby consent to pre-implantation genetic testing and storage of my/our embryos on our behalf.

- That embryos found not suitable for transfer (due to chromosomal abnormalities detected) are to be either:

(please tick) ☐ Donated to research

☐ Disposed of without further use

Patient Signature

Partner Signature

Date

Date

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STATEMENT BY MEDICAL PRACTITIONER

I ..... *(print full name of Medical Practitioner)* confirm that I have fully informed and counselled the patient(s) regarding pre-implantation genetic testing, and have provided a copy of the PGT-A patient fact sheet to: ..... *(print full name of consenting person)* and ..... *(print full name of consenting partner, if any)*.

SIGNED BY THE MEDICAL PRACTITIONER: .....

DATED THIS……..... **DAY OF** .....**20**…….....

Duration of Consent: *This consent is an 'enduring consent' that can be reviewed and altered by request in writing to your clinic*