



## NHMRC statement on iBlastoids

### *Nature* paper: *Modelling human blastocysts by reprogramming fibroblasts into iBlastoids*

Monash University's Polo Laboratory published research in the scientific journal *Nature* on 18 March 2021 (online) that demonstrates the creation of human embryo-like structures by reprogramming adult human skin cells. These structures are called iBlastoids by the research group because they are artificially induced and closely resemble human blastocysts (an early stage of human embryo development). iBlastoids can be created in large numbers in the laboratory, which is expected to allow researchers to more easily study early human development, and could be used for a number of other applications, such as development and/or mass screening of various drugs and therapies.

The [NHMRC Embryo Research Licensing Committee](#) (ERLC), as the regulator, made a decision based on the principles of statutory interpretation that iBlastoids come within the definition of a human embryo under the *Research Involving Human Embryos Act 2002*, and therefore require regulation and oversight. This decision was made, and communicated to the Polo Laboratory, in October 2020.

### Regulation of research involving human embryos in Australia

Under Australian law, research involving human embryos must meet strict ethical and legislative requirements, overseen by ERLC.

The *Prohibition of Human Cloning for Reproduction Act 2002* and the *Research Involving Human Embryos Act 2002* were developed to address community concerns about scientific developments in relation to human reproduction and the use of human embryos in research activities. The legislation prohibits human cloning for reproductive purposes and regulates research activities that involve the use of human embryos created by assisted reproductive technology or other means. There are strong penalties for non-compliance.

The *Research Involving Human Embryos Act 2002* defines a **human embryo** as a *discrete entity that has arisen from either:*

- a) *the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or*
- b) *any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;*

*and has not yet reached 8 weeks of development since the first mitotic division.*



The *Research Involving Human Embryos Act 2002* requires that research involving human embryos, including excess embryos from assisted reproductive technology treatments and the creation and/or use of embryos arising by processes other than fertilisation, can **only** be conducted under a licence issued by ERLC.

Strict licence conditions apply, and the criteria that ERLC must consider before it issues a licence are outlined in the legislation. For example, before issuing a licence, ERLC must be satisfied that the consent protocols are appropriate and that the donors will receive appropriate information to enable them to make an informed decision about whether to donate the embryo, egg, genetic material or cell/s to research. In addition, under the *Prohibition of Human Cloning for Reproduction Act 2002* the development of a human embryo (including a human embryo clone) outside the body of a woman for more than 14 days is prohibited.

### **Engagement with Monash University on iBlastoids**

Monash University's Polo Laboratory contacted ERLC on 29 June 2020, when it became evident that the research had produced embryo-like structures.

The published research was undertaken with the oversight and approval of the Monash University Human Research Ethics Committee (HREC). The HREC would have considered compliance with the *Australian Code for the Responsible Conduct of Research, 2018*, and the *National Statement on Ethical Conduct in Human Research*. NHMRC understands that, during its research, the Polo Laboratory adhered to the 14-day rule by not allowing the iBlastoids to develop beyond 11 days.

In July 2020, the Polo Laboratory agreed not to create any further iBlastoids until ERLC made a decision on whether a licence is required. In November 2020, following receipt of ERLC's determination that a licence was required, the Polo Laboratory confirmed its intention to work under an appropriate licence and its conditions for all future research involving iBlastoids. NHMRC has continued to work with the Polo Laboratory, including developing a new licence application form specific to the creation and use of embryos created by processes other than fertilisation and advising on requirements for an application. ERLC is yet to receive a formal, complete application for a licence for this work.

### **ISSCR Guidelines for Stem Cell Research and Clinical Translation**

There has been renewed discussion internationally about research using human embryos following the recent release of revised guidelines by the International Society for Stem Cell Research (ISSCR).

While ERLC pays close attention to international developments, any decision taken by ERLC, once it receives a valid licence application for this research, must be based on the requirements outlined under Australian law. The ISSCR Guidelines make the point that, where there is legislation, research should comply with local law and policy.



## Further information

As the agency within the Commonwealth's Health portfolio that has responsibility for the legislation and supports the work of the Embryo Research Licensing Committee, NHMRC will not be providing interviews. Questions can be submitted in writing to [media@nhmrc.gov.au](mailto:media@nhmrc.gov.au).

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