

# ADDITIONAL INFORMATION ON OBTAINING CONSENT

The information in this document clarifies and expands on the information in Chapter 2 of the Information Kit and the consent checklists attached to the application forms. Please refer to the Information Kit for the Explanation of Key Terms.

## Obtaining Informed Consent from Donors for Stem Cell Research Projects

All donors of material – excess ART embryos, reproductive material, genetic material or cells – that will be used to develop human embryonic stem cell lines are ‘responsible persons’ as defined in section 8 of the RIHE Act. They must be fully informed about the possibility that the research can produce ongoing, live biological material that can be used indefinitely as a source of new cells for other research projects. They must be fully informed about the commercial potential of their donation. They must also be informed that cell lines will contain their genetic information and that they may be re-identifiable from their genetic material. At this stage, the potential for products of the research to be used for clinical treatment by the donors or their families appears to be limited. Thus the participant information should not overstate the expected benefits of the research.

## Obtaining Informed Consent for the Use of Excess ART Embryos

### Embryos That Have Been Cryostored

A two-stage consent process is required if excess ART embryos that have been cryostored are to be used in a licensed activity. First, the woman for whom the embryo was created, and her spouse (if any) at the time the embryo was created, must declare in writing that the embryos are excess to their reproductive requirements (see RIHE Act section 9). At that time they are asked to advise the clinic about their wishes for the embryos. The information provided by the clinic will outline the available options, and in this context, will include donating the embryos to research (ART Guidelines paragraph 4.1.3). If they select the research option, cryostorage of the embryos is continued until a research project is identified.

Once a research project has been identified, the second stage of consent, ‘proper consent’, as defined in section 8 of the RIHE Act, must be obtained from each responsible person. If the embryo was created using donor gametes all applicable responsible people must give consent at this stage. In addition, the ART Guidelines require that this consent is subject to a ‘cooling-off’ period of 14 days (see ART Guidelines paragraph 13.19).

### Embryos That Are Unsuitable For Implantation

Patients may donate excess ART embryos that have been determined to be ‘unsuitable for implantation’ to research (RIHE Act subsection 24(8)). There are two circumstances where embryos can be considered unsuitable for implantation (RIHE Act s subsection 7(1)):

- *Preimplantation genetic diagnosis (PGD)*. In a situation involving the use of PGD, some embryos may be designated as unsuitable for implantation because they are diagnosed as having a particular genetic condition. Following the declaration that the affected embryos are excess, consent to use the embryos must be obtained from all the responsible persons.

- *Embryos that fail to develop normally.* In any ART treatment cycle, some embryos will not develop to the stage where they are suitable for implantation. Such embryos are usually discarded by the embryologist. The RIHE Act allows the use of such embryos as long as they are designated as unsuitable for implantation according to the Objective Criteria<sup>1</sup> (see <https://www.nhmrc.gov.au/research/embryo-research-licensing/information-applicants/objective-criteria-embryos-unsuitable>).

These amendments allow the use of fresh, rather than frozen, excess ART embryos under licence. Consent for the use of such embryos still requires two stages: the embryos must be declared to be excess and consent must be obtained to use them in a particular project and these decisions must be recorded in writing. However, the NHMRC Licensing Committee may allow a modification to the consent process or the length of the cooling-off period if it is considered appropriate or necessary (see ART Guidelines 13.19). Embryos cannot be declared to be excess until after they exist – advance directives obtained as part of consent for ART treatment are not sufficient.

## Obtaining Informed Consent for the Use of Other Embryos

'Other embryos' is the term used in the RIHE Act to refer to human embryos created by processes other than fertilisation of a human egg by a human sperm. As provided by section 20 of the RIHE Act, licensed uses of other embryos may include:

- research into the development of disease treatments, such as by creating human embryo clones to produce embryonic stem cells for cellular therapies, or to produce embryonic stem cells of known genotype for disease modelling (a technology referred to as 'therapeutic cloning').
- training in ART practices and methods, to improve efficiency and accuracy, and to minimise the risks to ART embryos intended for achieving pregnancy in a woman.

All responsible persons involved in the creation or use of other embryos must give consent, in writing, to the use of their material. As defined in section 8 of the RIHE Act, responsible persons relating to the creation other embryos includes each person whose reproductive material, genetic material or cell is proposed to be used.

### Obtaining Informed Consent for the Use of Human Eggs

As the use of human eggs in the creation of other embryos is permitted under licence by the RIHE Act (RIHE Act subsection 20(1)), women may choose to donate eggs to research.

Consent must be obtained in writing from the woman who was the biological donor of the egg before the egg can be used in a licensed activity. Refer to the instructions for completing the application for the information that must be included in the application with respect to approaching women during their first treatment cycle for consent to use clinically useful eggs.

## Management of Unused Donated Embryos and Other Materials Following Licence Expiry, Surrender or Revocation

When a licensed activity ceases for any reason, the licence holder must make appropriate arrangements for unused materials remaining in storage. Since consent is obtained for specific projects, it is not permissible to transfer materials to another licensed activity. Consequently, applicants are advised to consider Standard Condition 4201 during the development of the licence application, because it will affect the development of the consent process and documents (see <https://www.nhmrc.gov.au/research/embryo-research-licensing/database-licenc>).

Condition 4201 requires the licence holder to review the consent forms relating to any unused excess ART embryos or other material and to deal with them according to the instructions (if any) on the consent forms. This may require the licence holder to contact the responsible persons for instructions

<sup>1</sup> The Objective Criteria differ from the criteria that clinics use to determine that embryos are unsuitable for transfer. Not all embryos considered unsuitable for transfer will satisfy the Objective Criteria.

and then to deal with the embryos or other material in accordance with those instructions). The outcome could be permission to approach the responsible persons for consent to use the embryos in another project or instructions to allow them to succumb.

When the responsible persons have given proper consent for their excess ART embryos to be used in research they believe that the embryos will be used in the research project. It can be upsetting for these donors to find out, sometimes years later, that their embryos have not been used. To avoid the need to re-contact donors in these circumstances, clinics may decide to include words to the following effect in their consent documents:

'In the unforeseen circumstance that your embryo(s) are not used in the project would you like us to re-contact you to discuss the fate of your embryo(s) or allow your embryo(s) to succumb'.

It is also advisable for clinics to make provisions for responsible persons to record their preferences on the consent form.

Similar considerations apply to donated eggs and other cells. Consequently the same process should be followed for dealing with any unused materials.

An alternative approach would be to inform donors in the Participant Information that any unused material will be discarded at the end of the project without further contact.

## Restrictions on Consent

Paragraph 21(3)(a)(ii) of the RIHE Act requires that the NHMRC Licensing Committee must be satisfied that protocols are in place to enable compliance with any restrictions that responsible persons may place on their consent. Similarly, paragraph 24(1)(b) requires that any such restrictions are reported to the NHMRC Licensing Committee before an embryo or egg is used.

Therefore, when developing consent processes and documents, applicants are required to consider what restrictions donors may wish to place on their consent and how these will be recorded and managed. For example, some restrictions may mean that the eggs or embryos cannot be used under the licence and thus it would be inappropriate to accept the signed consent form; other restrictions may allow the material to be used but may limit later uses of products derived from the material; and some donors may wish to be informed when their material is used or to prevent further contact with the researchers. Applicants should consider these and other scenarios and develop suitable responses and management strategies.