Australian Government

National Health and Medical Research Council

How do training and/or quality assurance activities fit within the Commonwealth legislation?

Information from the Embryo Research Licensing Committee

The *Prohibition of Human Cloning for Research Act 2002* (PHCR Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act) require researchers and ART clinic staff to obtain a licence issued by the NHMRC Embryo Research Licensing Committee ('Licensing Committee') before conducting certain activities that use **excess ART embryos**. While the application of the legislation in the research context is clear, it may be less obvious whether training and/or quality assurance (QA) activities in the clinical context require a licence.

NHMRC anticipates that most training and quality assurance activities would be conducted in the course of providing clinical treatment, using embryos which are intended for transfer to a woman. However, in some circumstances it may be necessary to undertake these activities using excess embryos, or those not suitable for transfer.

The purpose of this information[1] is to provide a decision-making framework that clarifies the circumstances in which training and/or QA activities:

- can be undertaken without a licence,
- require a licence issued by Licensing Committee, or
- are prohibited under the legislation.

1. When is an embryo an 'excess ART embryo' under the RIHE Act?

Under section 9 of the RIHE Act, the definition of 'excess ART embryo' requires that an embryo must exist before it can be declared to be excess. An embryo is an excess ART embryo when the people responsible for making decisions about it either:

1. Declare in writing that the embryo is excess to their needs, or
2. Consent, in writing, to use of embryo for a purpose other than the ART treatment of the woman concerned.

This means that if, for example, the responsible people give consent for an embryo to be discarded or donated to another woman to achieve her pregnancy or to be used in research, training or QA activities **after** the embryo has been created, it becomes an 'excess ART embryo' under the Act.

[1] This information does not constitute legal advice. If you have any concerns about compliance with the legislation, you should seek your own advice specific to your circumstances.

2. What are the permitted uses of ART embryos under the RIHE Act?

2.1 Once an embryo is an **excess ART embryo**, the options for its subsequent use are limited to activities that are either:

- authorised by a licence [RIHE Act, section 20], or
- exempt uses[2] [RIHE Act subsection 10(2)].

Any other use is an offence under subsection 10(1) of the RIHE Act.

2.2 It is an offence to use an embryo that is **not an excess ART embryo** unless the use is 'for a purpose relating to the assisted reproductive technology treatment of a woman' [RIHE Act section 11]. Licensing Committee is of the view that some training and/or QA activities relate to the ART treatment of a woman because they improve the quality of treatment that a woman will receive.

See item 3 for information about the circumstances where training or QA activities may be permitted, as different pathways apply depending on whether the embryos are to be used in clinical treatment, are unsuitable for transfer or excess ART embryos.

3. Under what circumstances are training and/or QA activities permitted?

Training and/or QA activities involving embryos can be undertaken **without a licence** providing that the use is for a purpose relating to the ART treatment of a woman. This may occur in one of two ways:

- using clinically usable embryos, where:
  - the training and/or QA activity occurs during the course of ART treatment of a woman, **and**
  - specific written consent has been obtained for the training or QA activity,

or

- using embryos that are unsuitable for transfer[3], where:
  - specific written consent for the training and/or QA activity has been provided, **and**
  - the consent for the use of these embryos in training and/or QA activities was obtained **before** the embryos were created[4]

Clinics can undertake the following activities **under licence issued by NHMRC's Licensing Committee**:

- the use of excess ART embryos with proper consent in accordance with section 9 and subsection 24(1) of the RIHE Act, or
- training that involves the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division[5], where the egg is being fertilised for the purposes of training (ie. not for

[2] Neither training nor QA are specifically listed as exempt uses under subsection 10(2).

[3] Based on the clinic's established policies and procedures

[4] The written consent must still be in force at the time the training or quality assurance activities are undertaken. Any changes to consent after the embryos have been created is likely to mean that they become excess ART embryos, and can no longer be used in training or QA activities without a licence.

[5] In this case, the fertilised egg must be destroyed before the first mitotic division occurs and the fertilised egg becomes a 'human embryo'. Section 12 of the PHCR Act prohibits the creation of a human embryo for a purpose other than achieving pregnancy in a woman.

reproduction). This only applies for the purposes of training and does not apply for QA purposes [paragraph 20(1)(e) of the RIHE Act].

The following training and/or QA activities are **prohibited by the Commonwealth legislation**:

- the creation of a human embryo by fertilisation solely for the purposes of training and/or QA [PHCR Act section 12], and
- the use of an excess ART embryo for training and/or QA, unless the use is an exempt use under subsection 10(2) of the RIHE Act or is authorised by a licence [section 10]. This includes the use of an embryo that is unsuitable for transfer[3], where the use is not authorised by a licence and consent for the use was obtained **after** the embryos were created.

4. Why does the timing of consent matter when using unsuitable for transfer[3] embryos in training and/or QA activities?

The time when consent is provided for training and/or QA activities using unsuitable embryos is critical in determining whether embryos become 'excess ART embryos' under the RIHE Act (see item 1 above).

If consent to use an unsuitable for transfer[3] embryo in training and/or QA activities is provided **before** the embryo is created, it does not become an 'excess ART embryo', as it did not exist at the time that consent for the 'other use' (training and/or QA) was provided. Such embryos may be used **without a licence**, provided that the use is for 'a purpose relating to the ART treatment of a woman carried out by an accredited ART centre' [RIHE Act section 11] (see item 2.2 above).

If consent for the training and/or QA activity is obtained **after** the unsuitable for transfer embryos have been created, they are '**excess ART embryos**' under section 9 of the RIHE Act (see item 1). Any use of 'excess ART embryos' must be either an exempt use[2] under subsection 10(2) of the RIHE Act or authorised by a licence issued by Licensing Committee [RIHE Act section 10]. The use of 'excess ART embryos' in training and/or QA activities requires a licence (see item 3 above).

Additional resources and information

The following resources have been developed to assist clinics in applying the framework in practice:

- Schematic diagram: When is a licence required under the Commonwealth Legislation?
- Decision tree: Is a licence required for the use of an ART embryo in training and / or QA activities?
- Flowchart: Steps required for clinics to undertake certain training and/or QA activities without a licence
- Case studies: How does the Commonwealth legislation apply to various real world scenarios?

For further information, please contact NHMRC via embryo.research@nhmrc.gov.au or 02 6217 9468.