Decision Tree: Is a licence required for the use of an ART embryo in training and / or quality assurance (QA) activities?

IMPORTANT NOTE:
Read this before using the decision tree

This decision tree is provided to assist clinics to determine whether the use of **a particular ART embryo** for **training and / or quality assurance** requires a licence. It should be noted that the decision tree:

- is intended to be used with a **particular embryo** in mind, as specific details are important.
- provides an outcome **at a point in time**. Subsequent decisions, such as **changes to consent** (eg. consent withdrawal, consenting to additional activities) and **the timing of these decisions may change the outcome** and require the decision tree to be consulted again **from the beginning**.
- provides guidance in the **Commonwealth** context. Note that there **may be additional State law** regulating the use of embryos in training / QA activities in your jurisdiction.

Start here after reading important note

Is the embryo in question being **used in clinical treatment**? (ie. is the training or QA activity occurring alongside clinical treatment)

Yes

No

Based on the clinic's policies and procedures, is the embryo **suitable for transfer?**

No

Yes

Have the responsible parties **declared the embryo to be excess** to their needs **in writing?** [RIHE Act s9(2)]

Yes

No

Had the embryo **already been created when** the written declaration was **provided?** [RIHE Act p9(1)(a)]

Note 1: The 'no' option for this question is largely hypothetical, as there should be no circumstances where an embryo that is suitable for transfer can be declared excess prior to its creation. This is because under the PHCR Act, embryos can only be created for the purpose of achieving pregnancy in a woman.

No (see Note 1)

Have the responsible parties **consented** for the embryo to be used for a **use other than their own ART treatment?** (for example, training / QA, research) [RIHE Act p9(2)(a)]

Yes

No

Had the embryo **already been created** when **consent for another use** was **provided?** [RIHE Act p9(1)(a)]

Yes

No

A licence is required, unless the proposed activity is exempt
(Excess ART embryo [s9 RIHE Act])

The use of an excess ART embryo is permitted for an activity:

- that is authorised by a licence issued by Licensing Committee, or is an exempt use under subsection 10(2) of the RIHE Act, **and**
- for which **specific consent** has been obtained [Paragraph 4.5, ART guidelines].

One such exempt use is the use of an excess ART embryo for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created.

It is **unlikely** that training or QA activities can be **directly** linked with the achievement of pregnancy and therefore **training or QA activities involving excess ART embryos generally require a licence issued by Licensing Committee**.

Contact NHMRC for more information (see contact details below).

A licence is not required for training or QA activities under the following circumstances
(Not an excess ART embryo)

The use of this embryo is only permitted for an activity:

- that is for a purpose relating to the ART treatment of a woman [s11 RIHE Act], **and**
- for which **specific consent** has been obtained prior to the creation of the embryo [Paragraph 4.5, ART guidelines].

If the embryo is suitable for transfer: The embryo may only be used for the ART treatment of the woman for whom it was created (or the recipient in the case of embryo donation). Training and QA activities using the embryo can only be conducted **as a part of clinical ART treatment**, and must not be conducted unless the responsible parties have provided their **specific consent** for the proposed training or QA activity.

If the embryo is unsuitable for transfer: Some training or QA activities relate to the ART treatment of a woman, by improving the quality of clinical treatment. These activities are therefore permitted without a licence, as long as the embryo is unsuitable for transfer and **specific consent** has been obtained for the proposed training or QA activity **prior to the embryo being created** (see Note 2 below).

Note 2: consent must have been obtained **before the embryo was created**. If consent for training or QA activities is provided **after** the embryo was created, it becomes an **excess ART embryo** under the RIHE Act, and a licence is required unless the proposed activity is an exempt use (see red box).

Any questions? Contact embryo.research@nhmrc.gov.au or 02 6217 9000

Abbreviations: RIHE Act – *Research Involving Human Embryos Act 2002;* **PHCR Act** – *Prohibition of Human Cloning for Reproduction Act 2002.*