Training and quality assurance: When is a licence required under the Commonwealth Legislation?[1]

Activities that don't require a licence

Training or QA activities can be undertaken without a licence:

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

or

- using embryos that are unsuitable for transfer, where:
  - specific written consent for the training or QA activity has been provided, and
  - consent for the training or QA activity was obtained before the embryos were created.[2]

Activities that require a licence

Training or quality assurance activities may be undertaken under a licence issued by the Licensing Committee, where:

- excess ART embryos will be used with proper consent in accordance with section 9 and subsection 24(1) of the RIHE Act
- training will involve the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division,[3] where the egg is being fertilised solely for the purposes of training (ie. not for reproduction). This only applies for the purposes of training and does not apply for QA purposes [RIHE Act paragraph 20(1)(e)].

Activities that are prohibited

The following training and quality assurance activities are prohibited under the legislation:

- The creation of a human embryo solely for the purposes of training or quality assurance[3] (see PHCR Act section 12).
- The use of an excess ART embryo unless the use is an exempt use under subsection 10(2) or is authorised by licence. This includes the use of an embryo that is unsuitable for transfer to a woman for the purposes of achieving pregnancy, where consent for the use was obtained after the embryos were created.[2]

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[1] This schematic reflects the application of the Commonwealth legislative framework (*Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) and *Research Involving Human Embryos Act 2002* (RIHE Act), administered by the Embryo Research Licensing Committee of NHMRC) to training and quality assurance activities and does not constitute legal advice. The clinical practice of ART may be subject to additional State or Territory legislation. You should seek your own advice regarding the legality of any proposed training or quality assurance activities.

[2] The timing of consent is critical as to whether embryos become 'excess ART embryos' under the RIHE Act, and therefore whether a licence is required or not. See *Information from ERLC* for further explanation.

[3] While training involving the fertilisation of a human egg by a human sperm may be conducted under licence (see orange box), the resulting entity must be destroyed before the first mitotic division, when it becomes a 'human embryo' (as defined by section 7 of the RIHE Act). Section 12 of the PHCR Act prohibits the creation of a human embryo for a purpose other than achieving pregnancy in a woman.