Training, Quality Assurance (QA) and the Commonwealth Legislation: Case studies

These case studies aim to demonstrate the application of the Commonwealth legislative framework[1] to various scenarios. Where the scenarios describe consent as having been obtained, this includes all the people legally and ethically required to give consent in each situation.

Case Study 1: Fertilising eggs to train embryologists in ICSI *A woman has 10 eggs retrieved but only wants 4 fertilised. She does not want the remaining eggs frozen.*	
Scenario	**Explanation**
A. When providing her consent for treatment, the woman also consents for a trainee embryologist, who is not yet proficient in the use of ICSI, to perform this technique on two of the four eggs to be fertilised for the woman's treatment.	Section 12 of the PHCR Act prohibits the creation of human embryos by fertilisation unless the intention is to attempt to achieve pregnancy in a particular woman. As these embryos are being created for the purpose of achieving pregnancy in the woman, this is a permitted use under the Act. Paragraph 4.5 of the NHMRC *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (ART guidelines) requires that clinicians must ensure that specific consent is obtained from all participants. In seeking the woman's explicit consent to the proposed training on embryos created for the purpose of achieving pregnancy, the clinic has met this requirement.
B. The remaining 6 eggs are used to train embryologists in ICSI. The eggs are fertilised and cultured to the four cell stage to assess the success of the ICSI procedure. The embryos are then discarded. The woman is not told that her extra eggs will be used this way and her consent is not obtained.	Section 12 of the PHCR Act prohibits the creation of human embryos by fertilisation outside the body of a woman unless the intention is to attempt to achieve pregnancy in a particular woman. These embryos were not created for pregnancy purposes. Section 12 is a criminal offence provision with a penalty of 15 years imprisonment. In addition, in failing to obtain consent for this procedure, the clinic is not acting in accordance with the ART guidelines, and this may have consequences for the clinic's RTAC accreditation.
C. The woman is asked for, and consents to, the use of the remaining eggs to train embryologists in ICSI under a licence issued by Licensing Committee.	An ART clinic can apply for a licence for training involving the fertilisation of a human egg by a human sperm outside the body of a woman <u>up to but not including the first mitotic division</u> (RIHE paragraph 20(1)(e)). This use would therefore be permitted, providing that Licensing Committee had issued a licence to the clinic for this specific activity, and as long as the fertilised eggs were destroyed before the first mitotic division. The licence holder would need to keep records that allow inspectors appointed under section 33 of the RIHE Act to verify that the eggs were destroyed before the first mitotic division, as required by law.

[1] These case studies reflect the application of the Commonwealth legislative framework to training and/or QA activities, and do 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.

Case Study 2: Training and/or quality assurance using embryos that are unsuitable for transfer *A couple undergoes an ART cycle where several embryos are determined to be unsuitable for transfer, based on the clinic's established policies and procedures for grading embryos. The clinic uses these embryos for training and/or quality assurance before they are discarded.*	
Scenario	**Explanation**
A. Prior to commencing ART treatment, the couple is told that not all embryos will necessarily be suitable for transfer. At this time, they sign a 'consent for treatment' form that stipulates that they agree to the use of embryos that are unsuitable for transfer in the clinic's training and/or quality assurance activities.	These 'unsuitable for transfer' embryos could be used for training and/or QA without a licence. This is because (1) the couple consented to the training and/or QA on the consent for treatment form, (2) this consent was provided before the embryos were created (and therefore they are not 'excess ART embryos'), and 3) the use of embryos to conduct clinical training or quality assurance activities is 'for a purpose related to the ART treatment of a woman' as required by section 11 of the RIHE Act. This is because these activities improve the quality of treatment that women in general will receive.
B. The couple is not told that this will happen and the consent for treatment form signed by the couple prior to treatment does not mention the possibility of training and/or QA being conducted on embryos that are unsuitable for transfer.	These embryos are not excess ART embryos under the RIHE Act, as the couple has not provided consent for another use. Under the RIHE Act, these embryos could be used for training or quality assurance without a licence, as this use is 'for a purpose related to the ART treatment of a woman' (section 11). However, paragraph 4.5.1 of the ART Guidelines requires that consent forms should document consent from the relevant participants for each proposed procedure. As consent was not obtained for the training or QA activities in this instance, the use of the embryos would be contrary to the RTAC Code of Practice which requires clinics to comply with the ART Guidelines (CC1) and ensure that treatment occurs with fully informed consent (CC14).
C. Prior to treatment commencing, the couple's consent is sought for training and/or QA using their unsuitable embryos. They feel overwhelmed and can't decide at that time so the clinic agrees to freeze any 'unsuitable for transfer' embryos and seek their consent for this use at a later time. After the embryos have been created, the couple provides consent for the clinic to use their stored unsuitable embryos in training activities.	These 'unsuitable for transfer' embryos must not be used for training and/or QA activities without a licence. This is because • the consent to use the unsuitable embryos in training and/or QA activities was obtained after the embryos were created, thereby making them 'excess ART embryos' under the RIHE Act (section 9) • any use of 'excess ART embryos' must be either an exempt use under subsection 10(2) of the RIHE Act or authorised by a licence issued by Licensing Committee (section 10). • The use of these 'excess ART embryos' in training and/or QA activities is not an exempt use under subsection 10(2) and would require a licence. Use of these embryos in this way without a licence is an offence under RIHE Act subsection 10(1) with a penalty of 5 years imprisonment.

Case Study 3: Use of excess ART embryos for training *A couple had embryos created and stored. They decide that their family is complete and that they no longer require the stored embryos.*	
Scenario	**Explanation**
A. The couple sign a form declaring their existing embryos excess and expressing an interest in donating them to training activities. The clinic has a licence issued by the Licensing Committee for the purposes of training embryologists in embryo biopsy. The couple receive information about the proposed training and provide proper consent to this use.	These embryos are 'excess ART embryos' as the decision to donate them for another purpose was made after the embryos were created (section 9 of the RIHE Act). This use of 'excess ART embryos' is permitted under subsection 10(1) of the RIHE Act because it is authorised by a licence issued by the Licensing Committee. In providing information about the proposed training, and obtaining specific consent for this use, the clinic has complied with its conditions of licence and the relevant requirements of the ART Guidelines.
B. The couple sign a form declaring their existing embryos excess and expressing an interest in donating them to research or training activities. The clinic wants to train embryologists in embryo biopsy using live healthy embryos. The clinic is not authorised by a licence issued by the Licensing Committee. The couple receive information about the proposed training and consent to this use.	As these are 'excess ART embryos', any subsequent use must be authorised by licence or must be an exempt use allowed by RIHE subsection 10(2). The use of excess ART embryos in training and/or QA activities is not an exempt use under subsection 10(2), and a licence is required before the proposed training can be conducted. The use of these embryos without a licence is an offence under subsection 10(1) with a penalty of 5 years imprisonment.
C. The couple sign a form asking for their existing embryos to be discarded. The clinic wants to train embryologists in embryo biopsy using embryos that have succumbed (as a precursor to training staff in the use of live embryos). However, in order to increase the number of cells available the clinic thaws the embryos and cultures them for 24 hours before allowing them to succumb.	As these are 'excess ART embryos', any subsequent use must be authorised by licence or must be an exempt use allowed by RIHE subsection 10(2). Removing the embryos from storage and allowing them to succumb are exempt uses under paragraphs 10(2)(a)(ii) and 10(2)(c) of the RIHE Act. However, culturing the embryos after removal from storage, and before allowing them to succumb, is not an exempt use. If a clinic were to do this without a licence, it is a criminal offence with a penalty of 5 years imprisonment (subsection 10(1) of the RIHE Act). Additional issues may arise depending on what information the couple was given about the proposed training activity, and whether specific consent was obtained.

For further information, please contact the Embryo Research Licensing Committee of NHMRC via embryo.research@nhmrc.gov.au or 02 6217 9468