

## Authority Paper

<b>Committee:</b>	Authority
<b>Meeting date:</b>	9 September 2009
<b>Agenda item:</b>	7
<b>Paper number:</b>	515
<b>Paper title:</b>	Approval of the activities for which embryos may be used in training persons
<b>Author:</b>	Chris O'Toole, Head of Research Regulation
<b>For information or decision?</b>	Decision
<b>Resource implications:</b>	None
<b>Implementation</b>	The new licences will commence on 1 October 2009
<b>Communication</b>	A letter will be sent to centres explaining the process for licensing embryo testing.
<b>Organisational risk</b>	Medium
<b>Recommendation to the committee:</b>	The Authority is asked to review the list of activities in Table 1, and decide whether the use of embryos for these training purposes is necessary.  The Committee is asked to authorise publication of the approved list of activities on the HFEA website.
<b>Evaluation</b>	Review as part of the inspection process

### **Approval of the activities for which embryos may be used in training persons**

#### **1. Introduction**

- 1.1 The Human Fertilisation and Embryology Act 2008 amended the Human Fertilisation and Embryology Act 1990, to introduce new activities for which human embryos may be used.
- 1.2 Schedule 2 to the 1990 Act was amended to permit the use of embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques. Section 1 of schedule 2 states the following:

- A licence under this paragraph may authorise any of the following in the course of providing treatment services (ca) using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques.
- 1.3 A Licence Committee, at its meeting on 22 July 2009, agreed to vary all IVF treatment licences to include the following activity:
- the use of embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques
- 1.4 The same Licence Committee also agreed to vary all licences to include new standard licence conditions. One of these conditions provides that centres may only use embryos for the purpose of training for those activities authorised by the Authority.
- 1.5 The Authority is asked to approve a list of activities for which the use of embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques will be permitted.
- 1.6 Paragraph 4A of Schedule 2 to the HF&E Act 1990 (as amended) provides that: **“A licence under this paragraph cannot authorise the use of embryos for the purpose mentioned in sub-paragraph (1)(ca) unless the Authority is satisfied that the proposed use of embryos is necessary for that purpose.”** Therefore, the Authority has to be satisfied that the use of human embryos is necessary for training staff in any particular laboratory procedure/technique.

## 2. Embryology Training

- 2.1 At present Clinical Embryologists are expected to undergo a formal nationally recognised training scheme e.g. the Association of Clinical Embryologist (ACE) Certificate Programme, which will enable them to become State Registered. The Certificate of Embryology enables new clinical embryologists to complete their training and to demonstrate competence. It is a practical based qualification that documents the development of the candidate's skills and is comparable to other branches of clinical science. The qualification is gained whilst employed as a clinical embryologist and takes a minimum of two years to complete. All tasks are performed under the supervision of a suitably trained embryologist who fulfils the criteria set out by the Training Committee. On completion of the Certificate, a further two years will be spent working towards State Registration.

### 3. Training Purposes

- 3.1 The HFEA sent a questionnaire to 15 embryologists asking them to identify activities for which human embryos might be used for training purposes. We received 14 completed questionnaires.
- 3.2 The activities (purposes) for which embryos could be used to train persons suggested by representatives of the sector are listed in Table 1. This list also includes records why the use of human embryos is necessary for training staff in each particular laboratory procedure/technique.

**NOTE: The HF&E Act 1990 (as amended) prohibits the creation of embryos for use in training. Therefore, the Authority can not lawfully authorise the training of persons to perform intra-cytoplasmic sperm injection (ICSI) as this would involve the creation of embryos**

Table 1: Procedures/techniques for which the approval of the Authority is sought for human embryos to be used for training purposes

Procedure / Technique	Reason(s) why the use of human embryos is necessary	Additional Issues to be considered
1. Embryo biopsy	<p>The use of animal embryos is not appropriate because of the differences between mouse and human embryos. For example:</p> <ul style="list-style-type: none"> <li>• substantial difference in size of mouse embryos compared to human embryos thus there is a difference in the biopsy tools required;</li> <li>• difference in the zona pellucida of human embryos compared to mouse embryos – the zona pellicuda of human embryos is extremely variable whereas the zona pellucida of mouse embryos is more</li> </ul>	<p>The use of human embryos for training biopsy practitioners would also allow the biopsied cells to be used to train practitioners to place these cells in the tubes needed for some genetic analysis and for allowing the practitioners to practice the manipulation of different sized blastomeres. Furthermore, the biopsied cells could also be used to work up different genetic tests prior to the application of these tests for patients undergoing treatment.</p>

	<p>homogenous and thus easier to drill;</p> <ul style="list-style-type: none"> <li>the biopsy of human embryos is more difficult than the biopsy of mouse embryos thus the overall skill of a biopsy practitioner could only be assessed using human material in a practice situation.</li> </ul>	
<b>2. Blastocyst biopsy</b>	<p>Blastocyst biopsy involves removal of cells from the trophectoderm for genetic diagnosis. Although mouse embryos could be used to gain the basic elements of the skill required to biopsy human blastocysts, due to differences between mouse and human embryos, practice using human embryos is essential to prepare the practitioner for the challenges of human blastocyst biopsy.</p>	As above.
<b>3. Cryopreservation and thawing techniques</b>	<p>Cryopreservation and thawing of embryos are basic techniques required in almost all embryological laboratories. The skills required for successful cryopreservation involve movement of embryos between different solutions, loading of embryos into cryopreservation vessels, freezing, thawing and removal from straws and successful manipulation through a range of solutions. These</p>	<p>This would also provide good training on the manipulation of embryos e.g. moving embryos between different culture dishes.</p>

	<p>techniques could be practiced using mouse embryos, but mouse embryos are extremely robust and often survive cryopreservation even when subjected to large fluctuations from the standard protocol. Human embryos are more susceptible to cryo-damage and therefore exposure to sub-optimal conditions may affect the outcome of any treatment cycle. It would, therefore, be greatly beneficial to be able to check the survival rate of human embryos following cryopreservation by a trainee embryologist before allowing them to carry out actual clinical practice.</p>	
<p><b>4. Vitrification</b></p>	<p>Vitrification has been proposed as beneficial for the cryopreservation of oocytes and blastocysts in particular, but it requires very different skills to those used for slow freezing procedures. The introduction of this technique into clinical practise would require substantial training, even for experienced embryologists, and as the survival rate of samples has been shown to be correlated to the skill of the embryologists the ability to demonstrate success on human embryos, donated for use for training purposes,</p>	

	would be beneficial before this technique is applied in clinical practice.	
<b>5.</b> Assisted hatching (all techniques: mechanical, chemical and laser)	Animal embryos are different than human embryos. In particular the zona pellicuda of animal embryos differs from the zona pellicuda of human embryos thus the techniques needed to make a whole or weaken the zona pelludia would be different depending on the source of the embryo.	Training persons in these techniques would also improve micromanipulation skills: these skills are also required to perform ICSI but assisted hatching is carried out on existing embryos therefore, embryologist could practice these skills without creating embryos.
<b>6.</b> Embryo handling and manipulation e.g. moving embryos between dishes; loading transfer catheters; loading freezing vials / straws	Animal embryos may not always approximate how human embryos behave when manipulated. Trainee embryologists need to get used to handling human embryos e.g. get used to drawing embryos into catheters or moving embryos between dishes before they apply these techniques in clinical practice. Furthermore, trainee embryologists need to get used to manipulating embryos in fine drawn pipettes.	
<b>7.</b> Morphological assessment of embryos	Embryos of other species do not respond in the same way as human embryos. Embryos of other species are visibly different in texture, size and other physical features than human embryos thus give a different experience during training. Plus animal embryos are more	

	or less sensitive than human embryos to whatever procedure is applied.	
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#### 4. Summary

- 4.1 Animal embryos and models do not provide equivalent experiences or results.
- 4.2 Most clinical IVF laboratories do not have access to animal embryos or have separate facilities necessary to deal with animal embryos.

#### 5. Conclusion

- 5.1 **The Authority is asked to review the list of activities in Table 1, and decide whether the use of embryos for these training purposes is necessary.**
- 5.2 **The Authority is asked to authorise publication of the approved list of activities on the HFEA website.**

## Control sheet

### Document control

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### Version/revision control

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1			

\* Excluding control sheet