HFEA Statutory Approvals Committee

28 November 2013

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 4

Centre 0078 (IVF Hammersmith) – Application for a Special Direction to export eggs to the USA

Members of the Committee: David Archard (lay) Chair Sue Price (professional) Rebekah Dundas (lay) (video) Debbie Barber (professional) Hossam Abdalla (professional) Apologies: Jane Dibblin (lay)	Committee Secretary: Lauren Crawford Legal Adviser: Graham Miles, Morgan Cole Observing: Sam Hartley, Head of Governance and Licensing, HFEA Matthew Watts, Policy Manager

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- Executive Summary
- The applicant centre has submitted the online application form for a Special Direction and a number of additional documents have been submitted both by the centre and by the solicitor acting for the couple which includes:
    - Letter from Stuart Lavery, Person Responsible ('PR'), dated 9 October 2013;
    - Licence for Tissue Bank Operation valid from 9 March 2012 to 1 April 2016;
    - Certificate of Compliance valid from 02 September 2013 until 02 August 2015 issued by centre for Medicaid and State Operations;
    - Certificate of Participation for 2013 issued by the American Association of Bioanalysts;
    - Letter dated 17 February 2012 addressed to Joel Batzofin by the Membership Committee Chair of The Society for Assisted Reproductive Technology;
    - Certificate of Accreditation dated 16 July 2011 issued by The Joint Commission;

- Consent to Storage of Eggs (WS Consent) Form signed by the gamete provider on 18 February 2008;
- IVF Hammersmith Consent to Treatment Involving Egg Retrieval and/or Embryo Replacement form signed by gamete provider on 18 February 2008;
- A blank IVF Hammersmith Consent to Research form;
- Consent to Disclosure of Identifying Information about Fertility Treatment to Another Person who is not covered by a Licence (CD) Form signed by gamete provider on 25 January 2008;
- IVF Hammersmith Agreement to Oocyte Freezing form signed by gamete provider on 18 February 2008;
- Letter from Natalie Gamble Associates to the HFEA dated 15 October 2003;
- Undated submissions of gamete provider's parents titled "Ethics Committee – blank Eggs".

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA General Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers
- HFEA Pre-Implantation Diagnostic Testing ("PGD") Explanatory Note For Licence Committee

Discussion

1. The Committee noted that this centre has applied for a Special Direction to export three cryopreserved oocytes to New York Fertility Services, 16 E. 40th Street, 2nd Floor, New York, NY 10016, USA.

2. The Committee noted that the HFEA Act 1990 (as amended) permits the Authority to issue directions to allow the export of gametes or embryos to countries outside the United Kingdom. Furthermore, the Committee noted that if a licensed centre meets all requirements set out by General Directions 0006, of which there are nine, export is permitted without the need for Special Directions.

3. The Committee noted that this application for Special Directions is being made because the centre is unable to export the eggs under the auspices of General Directions because they are not able to meet the requirements of section (d) of the Schedule 4 of General Directions 0006: that 'the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being exported to the country in which the receiving centre is situated' and section (e) of the Schedule 4 of General Directions 0006: that 'before giving consent, the person(s) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country in which the receiving centre is situated as it is in the United Kingdom, and they have been given any further information which they may require.'

4. The Committee also noted that the centre is also unable to comply with section (h) of Schedule 4 of General Directions 0006 that 'the gametes or embryos are not exported if they could not lawfully be used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre'.

5. The specific issue is that the patient (who is deceased) did not sign the necessary consent form for the use of her eggs.

6. The Committee noted that the patient stored three eggs at IVF Hammersmith in 2008. The patient completed a WS (consent to the storage of eggs) consent form. The patient consented to her eggs being stored in the event of her death and provided consent for her eggs to continue in storage for 'later use' in the event of her death.

7. The Committee noted that Section 3 of the WS Form states, in the case of patients who have consented to later use of their eggs in the event of their death or mental incapacity, that 'There is a separate form on which you can say how you want your eggs to be used. Your eggs can only be used if you have also completed the other form'. The patient however did not complete any further consent forms recording her consent to the use of her gametes or

any embryos that might be created using her gametes as required by paragraphs 5(1) and/or 6(1) of Schedule 3 to the HFE Act.

8. The Committee was satisfied that, in the absence of such effective consent, the gametes could not be used in treatment services in the UK. Accordingly, the Committee agreed with the Inspectorate's conclusion that the proposed export of the gametes would not comply with paragraph 1(h) of Schedule 4 to GD0006, in addition to paragraphs 1(d) and 1(e) of the same schedule. Therefore, the gametes could only be exported as an exception to the Authority's policy reflected in General Directions 0006.

9. The Committee noted that the patient has since died and the patient's parents have approached the applicant clinic with a wish to use their daughter's eggs to create embryos for their own use using donor sperm. Using any embryos that are created, the patient's mother wishes to have treatment at a clinic in New York with the hope of having her daughter's child with the intention that she and her husband will raise the child as their grandchild.

10. The patient's parents made written submissions as to their intentions and their motivation for seeking treatment to an Ethics Committee of the Imperial College. The PR has informed the HFEA that the Imperial College Ethics Committee was unable to reach any consensus or any definitive conclusion and this was one of the reasons for declining treatment at the centre. The patient's parents' solicitors have confirmed that they have not been able to find another licensed centre in the UK which is prepared to offer treatment.

11. The Committee noted that the applicant centre cites lack of consent by the patient to export and the fact that written notice regarding the law and parentage of any child was not provided to the deceased patient, as a reason for making an application for a Special Direction.

12. The Committee noted receipt of a letter from the PR dated 9 October 2013 which states *"…At the time she consented to her eggs to continue in storage for later use in the event of her death. However, she never completed a WD form consenting to the use and storage of her donated eggs and therefore we don't have written confirmation of her wishes",* and further that having then referred to the wishes of the patient's mother and father to be the egg recipients, the PR goes on to say that *"As a unit we feel that this is beyond what the patient might have consented to and we cannot (sic) assume that these would have been her specific wishes, as there is no documented confirmation for them. This is the reason why we are applying for special directions to export to the New York Fertility Centre."*

13. The Committee considered very carefully all of the information presented, including the written submissions from the deceased patient's parents and their solicitors.

Decision

14. The Committee had regard to the statutory requirements in the UK for consent for use of gametes. Special Directions would not be granted routinely, or where the purpose or dominant effect appeared to be to circumvent those requirements.

15. The Committee noted that, in their statement, the patient's parents said: "..(the Person Responsible) may recall his first meeting with (the patient) when she asked him if women with stomas were able to carry a child. (The Person Responsible) confirmed that it was possible. It was then mentioned that should it become evident (the patient) would not be able to carry a child that we had agreed that I (her mother) would do it for her'.

16. The Committee considered that this reference to the possibility of the patient's mother carrying her child could not be regarded as a clear and unequivocal expression of the patient's wish that her mother would carry her child in the event of the patient's death as distinct from during her lifetime.

17. The Committee considered that although the patient had clearly consented to storage of her eggs in the event of her death she had not consented to the use of the stored eggs or the export of the stored eggs.

18. The Committee recognised that a refusal to make a Special Direction in this case will prevent the patient's parents from obtaining treatment services abroad. However, the Committee was satisfied that a refusal to make an export direction would not interfere with any rights under EU Law to obtain medical treatment services abroad as the intention is to transfer the gametes to a country outside of the EEA and Gibraltar. The Committee also noted that no case has been made out that a refusal would engage any rights arising under the Human Rights Act.

19. The Committee recognised that the HFEA has a duty to promote compliance with the provisions of the HFE Act and to uphold the general scheme of regulation and that one of the cornerstones of the scheme of regulation is the requirement in Schedule 3 to the Act for effective consent. The Committee agreed that making a Special Direction in the particular circumstances of this case would risk undermining the absolute nature of the consent provisions in the Act and might lead to uncertainty in the eyes of patients as to what might

happen to their gametes in the event of their death and in the absence of their consent.

20. In the light of all of these considerations, the Committee could not be satisfied that there were exceptional circumstances that would justify the issue of a Special Direction in this case and refused the application.

Signed: Date: 04/12/2013

David Archard (Chair)