HFEA Statutory Approvals Committee

27 March 2014

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

Minutes – Item 4

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

Members of the Committee: David Archard (lay) Chair Sue Price (professional) Rebekah Dundas (lay) (video) Jane Dibblin (lay)	Committee Secretary: Lauren Crawford Legal Adviser: Sarah Ellson, Field Fisher Waterhouse Observing: Sam Hartley, Head of Governance and Licensing, HFEA Dawn Braithwaite, Mills and Reeve

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 application form for a Special Direction
- Supporting documents been submitted by the centre:
    - Letter from Natalie Gamble Associates to the HFEA dated 11 Feb 2014.
    - Statement with exhibits 1 – 6 received 12 Feb 2014.
    - Email from the Deputy Director Lister Fertility Clinic.
    - A copy of the letter from the intended export destination centre confirming that they are willing to accept the gametes for the purpose specified in the application form.

On the advice of its Legal Adviser, the Committee also agreed to consider:

- Minutes of the Statutory Approvals Committee Meeting 28 November 2013
- Committee Papers from 28 November 2013:
    - Executive Summary

- The online application form for a Special Direction;
- 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;
- Updated 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

Background

1. The Committee noted that this is an application for a Special Direction (under section 24(4) of the Human Fertilisation and Embryology Act 1990 (as amended) ('the Act')) to export three cryopreserved oocytes of a deceased patient to New York Fertility Services, for the purpose of donation of the gametes to be used in treatment by the deceased patient's mother.

2. The Committee noted that it had previously considered and refused an application for a Special Direction to export the same oocytes on the 28 November 2013.

3. The Committee noted that additional information from the patient's mother's solicitors has now been submitted and that the centre has made a fresh application for a Special Direction.

Discussion

4. The Committee noted that this was a new application and accepted the advice of its Legal Adviser that this could not be a review or an appeal against the previous decision.

5. The Committee noted that the HFE 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 is able to satisfy the conditions set out by General Directions 0006, of which there are nine, export is permitted without the need for a Special Direction.

6. The Committee noted that this application for a Special Direction is being made because the centre is unable to export the gametes 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.'

7. The Committee also noted that Executive consider 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'.

8. The specific issue is that the patient did not sign the necessary consent form for the use of her eggs posthumously in the manner proposed.

9. 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.

10. 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.

11. The Committee considered the new evidence provided within this application in turn, starting with the letter from the patient's mother's solicitors and the points raised in the request for the consideration of this application. In particular, the Committee noted that the submissions stated:

    - the patient gave effective consent to the use of her eggs in treatment after her death;
    - previous HFEA decisions have allowed the export of gametes for use in posthumous treatment without the consent of the gamete provider, notwithstanding the policy on consent in the Act – the HFEA must take a consistent approach;

- the patient's mother's age and her family connection with the prospective child are issues which should not be given undue weight in this decision; the Committee should bear in mind that age discrimination is unlawful and that any concerns about the welfare of any child should be framed within the risk-based approach guidance given by the HFEA.

12. The Committee was clear that in its consideration of this case it did not need to have regard to the patient's mother's age and/ or family connection with the prospective child.

13. The Committee considered that although applications for Special Directions for export for use in posthumous treatment may have been granted in the past, each application for a Special Direction is specific and considered individually and on its own merits.

14. The Committee took advice from its Legal Adviser regarding the cases mentioned within the Executive Summary. It noted that the cases of *"Blood"*, *"L"* and *"ZH"* related to the rights of a surviving partner who wished to make use of gametes stored from their deceased partner. In such cases the surviving partner's rights (particularly rights to family life) under the ECHR and the Human Rights Act had to be a factor in the decision about granting a Special Direction (and the justification for any interference in such rights). In the current case the submissions did not include any suggestion that the surviving parents have similar rights. The Legal Adviser also indicated that in this application (to transfer to the USA) additional European Convention rights did not apply. If, as indicated in the letter from Natalie Gamble Associates the centre considered applying to export to an accredited centre in the EEA or Gibraltar rights under Article 49 and 50 of the Treaty establishing the European Community right to the provision of medical services across member states, this additional right would need to be considered. However it would not be an absolute right for the mother to have such treatment but an additional circumstance in which any interference would need to be justified.

15. The Legal Adviser indicated that the Committee's task in considering this item was to make a reasonable decision. "Wednesbury" unreasonable decisions were decisions which no reasonable Committee/decision maker could make, recognising that there was often a range of decisions that might be considered reasonable. The Legal Adviser indicated that in determining whether to grant a special direction in this case the Committee should closely scrutinise the submissions and might want to consider whether there was ample, substantial or overwhelming evidence in relation to the deceased person's wishes sufficient to overcome the inability to comply with General

Direction 0006. In particular the Committee would need to determine whether in all the circumstances there was effective consent to the use of the deceased's eggs after her death.

16. The Committee carefully noted the evidence submitted by the patient's mother's solicitor to support the application. First they considered the in-patient clinical notes for the patient dated 10 January 2006 which state that 'the patient and mother want to know if there is a possibility that ovaries could be transplanted into mother and therefore allowing (mother) to take on the IVF procedure'.

17. The Committee noted the date of these notes and that this was some time before the storage of eggs in February 2008 and five years before her death in the summer of 2011. The Committee did not consider that the notes gave any clear indication of the patient's wishes in the event of her death.

18. The Committee next considered an email from a friend of the patient, outlining a conversation they had a few years ago when the patient was undergoing chemotherapy. The friend states '…[the patient] told me the reason she had IVF was to ensure she would be able to have a baby once her treatment was over' and that 'she had saved her eggs to use when she got better and if she was unable to carry the baby she would get you [the patient's mother] to be a surrogate for her'.

19. The Committee noted again that this item did not specifically state the patient's wishes in the event of her death. It further noted that the email confirmed the patient's views in respect of the use of her gametes whilst alive, but it did not, on its face, support the applicant's claims that the patient wished for her gametes to be used in this way in the event of her death.

20. The Committee next noted the statement from the patient's mother and took considerable time to discuss the points raised in the statement; in particular it gave attention to paragraphs 15 and 21. The Committee noted the patient's mother's recollection of the conversation had with the patient on the day she signed the consent forms and in January 2010. The Committee was sensitive to the views of the patient's mother and acknowledged her belief that in proceeding with this application she would be carrying out her daughter's wishes.

21. The Committee carefully considered the consent forms submitted. The Committee noted that the patient has clearly signed and agreed for her eggs to be frozen. The Committee noted that the patient did not sign the consent form for research and accepted the mother's statement that this was a deliberate decision. As referred to above the Committee noted the detailed

wording of the signed WS form. The Committee noted that the patient consented to the storage of her eggs for a period of ten years. The Committee noted that the form requires the patient to decide in advance of storage what should happen to her eggs posthumously.

22. The Committee noted that Section 2 of the "Consent to Treatment Involving Egg Retrieval and/or Embryo Replacement" states, 'We do not consent to the transfer of any eggs or embryos so produced into any female other than the above named unless specific surrogacy or donation consent has been agreed'. No evidence of consent to surrogacy had been provided.

23. Further to this the Committee also noted that the form implies that the only treatment options the patient had been informed of and consented to involved only the patient's eggs. The Patient specifically did not consent to the mixing of her eggs with donor sperm.

Decision

24. 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. The Committee reminded itself of the of the judgment of Lord Justice Hale who stated, in the Case of *U v Centre for Reproductive Medicine* [2002] that "*The whole scheme of the 1990 Act lays great emphasis upon consent… Parliament has devised a legislative scheme and a statutory authority for regulating assisted reproduction in a way which tries to strike a fair balance between the various interests and consent. Centres the HFEA and the Courts have to respect that scheme, however great their sympathy for the plight of particular individuals caught up in it"*

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

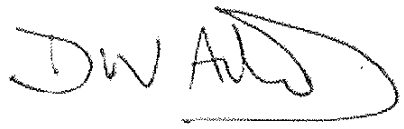
26. Although the Committee was sensitive to the views of the patient's mother, on the balance of the paperwork provided it was not satisfied that there is sufficient evidence to support the assertion that the patient expressed clear and explicit consent to the use of her gametes posthumously.

27. The Committee was therefore unable to satisfy itself that there was enough evidence to support the making of a Special Direction in the particular circumstances of this case, as it did not feel it had ample, overwhelming or substantial evidence that the patient consented or wished, in the event of her

death, for her eggs to be mixed with donor sperm and for her mother to act as a surrogate.

28. 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: 2 April 2014



David Archard (Chair)