

HFEA Statutory Approvals Committee

28 August 2014

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

Minutes – Item 1

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

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair	Lauren Crawford
Sue Price (professional)	
Rebekah Dundas (lay) (videoconference)	Legal Adviser:
Jane Dibblin (lay)	Sarah Ellson, Fieldfisher
Apologies:	Legal observer:
Debbie Barber (professional)	Shelley Edwards, Fieldfisher
Hossam Abdalla (professional)	

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:

- Tab 1. Executive Summary
- Tab 2. Application Form for Special Directions to Export
- Tab 3. Letter from PR dated 09-10-2013
- Tab 4. Emails from PR dated 18-11-2013
- Tab 5. Letter from New York Fertility Services undated
- Tab 6. Emails between NGA and Lister Fertility Clinic dated 16-04-2013
- Tab 7. Minutes of SAC meetings on 28-11-2013 and 27-03-2014

Submissions and supporting documents on behalf of IM and MM:

- Tab 8 Submissions of Jenni Richards QC dated 01-08-2014
- Tab 8.1 Letter from NGA dated 15-10-2013
- Tab 8.2 Letter from NGA dated 11-02-2014
- Tab 8.3 Witness statement of IM dated 23-06-2014 and exhibits
- Tab 8.4 Witness statement of MM undated
- Tab 9. Emails from PR dated 04-08-2014
- Tab 10. Supplementary Submissions of Jenni Richards QC dated 15-08-2014
- Tab 11. Executive Comments on Supplementary Submissions dated 20-08-2014
- Tab 12. General Direction 0006

Law Reports:

- Tab 13 Centre for Reproductive Medicine v U [2002] EWCA Civ 565
- Tab 13.1 R v HFEA ex parte Blood [1997] 2 All ER 687

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 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 from a deceased patient (‘A’) to New York Fertility Services, for the purpose of donation of the gametes to be used in treatment by A’s mother (‘IM’).
2. The Committee noted that previous applications by this centre for a Special Direction to export the same oocytes were refused on 28 November 2013 (minutes dated 04 December 2013) (Tab 7) and 27 March 2014 (minutes dated 2 April 2014) (Tab 7). IM and A’s father (‘MM’) have applied for permission to proceed with an application for Judicial Review in relation to the decision made on 27 March 2014. This Judicial Review application has been stayed by agreement of the parties until 19 September 2014 pending consideration of the application by the Statutory Approvals Committee (‘SAC’) on 28 August 2014. In agreeing to the application being considered by the SAC, the HFEA has confirmed to Natalie Gamble Associates (‘NGA’), the legal representatives of IM and MM, that a further application is not required from Centre 0078, the centre currently storing A’s gametes, but that

submissions on behalf of IM and MM and any additional material relied upon will be considered.

3. A was diagnosed with bowel cancer in November 2005 when she was 23 years old. A stored three eggs at IVF Hammersmith in 2008. At the time, A signed forms which can be found within exhibit IM2 attached to the statement of IM (tab 8.3). These forms included:
 - A form devised by IVF Hammersmith entitled "Consent to treatment involving egg retrieval and/or embryo replacement"
 - HFEA form 'WS Form' (consent to the storage of eggs)
 - A form devised by IVF Hammersmith entitled "Agreement to oocyte freezing"
4. In completing the WS form, A consented to her eggs being stored for later use in the event of her death (see section 3 of WS form). Section 3 of the WS form states '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'. A did not complete a form relating to the use of her gametes, such as a WD form.
5. A died on 12 June 2011. At the time of storage and at the time of her death A was single. IM and MM wish to use their daughter's eggs for the creation of an embryo(s) using donor sperm (see paragraphs 26 to 31 of the statement of IM) for use in IM's own treatment. Although it is stated that the chances of IM becoming pregnant are 'very small' and that 'any complications could be life threatening,' IM and MM say that they are determined to 'honour (A's) wishes.'
6. IM and MM state that they wish to export the gametes to New York Fertility Services. A letter from the proposed receiving centre is attached within the bundle of documents previously provided by the Centre which is at Tab 5. IM and MM state that the US clinic has provided details of two sperm bank websites with donor profiles from which they would select a donor who is as close to A's origins as possible.
7. 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 a Special Direction.
8. The Committee noted that this application for a Special Direction is being made because the centre is unable to export the sperm under the auspices of General Directions 0006 because the Executive suggests that the application

does not meet the requirements of sections 1(d), (e) and (h) of schedule 4 of General Directions 0006.

9. Paragraph 1(d) of Schedule 4 requires that: 'the person who provided the gametes has given and has not withdrawn consent in writing to the oocytes being exported to the country in which the receiving centre is situated'.
10. Paragraph 1(e) of Schedule 4 requires that before giving consent, the person who provided the gametes was given a written notice stating that the law governing the use of gametes and 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.
11. Paragraph 1(h) of Schedule 4 requires 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'.
12. The Committee noted a suitably completed application form for Special Directions and additional information, provided by the Centre 0078 previously, was available (Tab 2).
13. The Committee also noted that the penultimate exhibit to the Witness Statement of IM (Tab 8.3) was an email from the Person Responsible to NGA dated 18 December 2012 indicating that the case had been referred to the relevant ethics committee for assessment. As at the date of the email, a decision had not been reached. The Person Responsible ('PR') at Centre 0078 has since confirmed that the ethics committee could not reach a consensus or a considered view (page 23) and that this is one of the reasons that treatment at the clinic was declined.
14. The Committee noted that the application form records that export is necessary 'because only an overseas centre has agreed to provide treatment'.

Legal Advice

15. The Legal Adviser gave the following advice:
 16. The Committee should make a fresh decision as to whether Special Directions should be issued in this case. The Committee should not feel bound by any previous decision and should not

approach the decision as a "review" or "appeal" of the earlier decisions. There are new materials in the bundle, including submissions on behalf of the family and more detailed executive summary documents; the Committee should consider these carefully; it would be open to the Committee to make the same decision as before or to make a different decision and to make Special Directions. Whatever decision it reached the Committee should give reasons.

17. It had been agreed that today's decision should be based on original application plus the substantial additional documents provided in advance of today's meeting.
18. Para 8(1) of Schedule 3 of the Act requires that a person's gametes may not be kept in storage unless there is an effective consent by that person to their storage (and they are stored in accordance with that consent). It is agreed that there are currently no issues with the storage in the United Kingdom of these gametes: A gave consent to posthumous storage for later use. This consent remains valid until 17 February 2018 as "10 years" was selected on the WS form
19. Great emphasis on consent is imposed by the Act and recognised in the case of U (tab 13). "Effective" consent usually needs to be signed and set out in writing, and should be informed consent which implicitly requires the patient to be properly informed.
20. The areas where effective consent is said to be absent by the Executive are in relation to exporting the gametes, mixing the oocytes with sperm, (donor sperm), surrogacy and the use of gametes in treatment of another. The Executive indicates that the areas where A was not fully informed and able to give proper consent are the same.
21. The primary submission on behalf of the parents (page 47) is that the evidence plainly and unequivocally establishes that A did consent to the use of her embryos posthumously and that all other evidence points cumulatively to the posthumous use now sought by her parents. The parents submit that there is sufficient evidence to establish A's wishes and/or consent.
22. The absence of effective consent is not decisive of the issue. Had all the required effective consents been in place the export could

have proceeded without an application for Special Directions. Special Directions clearly provide for modification of s 12 of the Act (12(1)(c) without modification requires compliance with Schedule 3 on consent). S24(4) allows for modification of sections 12-14 of the Act in the case of imports and exports. This Committee would be familiar with its ability to modify the requirements by SD to allow import and export.

23. However when undertaking this exercise the Committee should only use the power to modify in ways that serve and promote the objects of the HFEA's legislation which clearly attaches great importance to consent, the quality of it and the certainty of it.
24. On the previous occasion the Committee, gave the word "sufficient" (as in "sufficient evidence") its ordinary meaning and drew on terms such as "ample, overwhelming or substantial evidence". It is suggested this is too high a bar and the Committee was again advised to give the word an ordinary meaning and to consider simply whether there is "sufficient" evidence to establish A's wishes. The Committee might decide this was synonymous with words such as "adequate" or "enough".
25. In relation to the submission on the engagement of human rights (paragraph 20 page 48) it is not entirely clear whose rights under Article 8 are being asserted (because of the redaction). The quote from *Evans* refers to a living partner's rights to become or not become a parent. The Legal Adviser had not been able to identify case law or any other authority to support an assertion (if that is what is being made) that a right, such as a right to be a parent when living would continue to be a "human right" posthumously (or indeed that any human rights not sought/asserted during life can be asserted after death). Existing rights attaching to a living person can be pursued after death by others on behalf of deceased. In the alternative, if it is being asserted that the human rights are those of the parents of A they do not (appropriately) appear to be claiming that the would-be "grandparents" have a right to a grandchild or to be grandparents.
26. In the Legal Adviser's view there was no interference with the daughter's right to be a parent while she was alive – it now appears to be suggested that the refusal to export could be a disproportionate interference with her rights under Article 8 but this has only arisen posthumously.

Discussion

27. The Committee noted there were two main issues to be discussed in this case:

- Whether in their previous discussions of the case the Committee's interpretation of the term 'sufficient evidence' was too restrictive and whether in fact the evidence points cumulatively to the posthumous use of A's eggs in the way being sought being exactly what she wished for;
- Whether the Committee in making its decision had to address human rights issues given the submissions that Article 8 of the ECHR is engaged by this decision.

28. The Committee noted that in the minutes of the 27 March 2014 the Committee stated that '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'.

29. The Committee determined that it would look again at all the evidence to see whether there was simply enough evidence as to A's wishes and consent.

30. The Committee considered all of the evidence before it and in particular gave careful consideration to the "cumulative evidence" highlighted at paragraph 18 of the submissions at page 47. It noted that the strongest and only statement of A's wishes apparently applying to the posthumous use now being sought, was her statement to her mother about her mother carrying her babies and her parents bringing them up, in the context of her not expecting to leave hospital alive. Details of this conversation with IM were set out in IM's witness statement.

31. The Committee accepted the advice of its Legal Adviser and noted the case does not seem to interfere with IM's right to family life unless it was being asserted that A's parents had a right to be grandparents – which there was no case law to support. If the rights are those of A it was unclear how these could persist in the event of her death.

32. The Committee noted the submission that A's wishes would be frustrated if her eggs were allowed to perish and not be exported for use as proposed. It recognised a number of circumstances, as set out in the Executive summary

in which eggs will perish. It noted that in the absence of a clear indication of A's wishes, under the Act and associated regulations, her eggs could not be stored and would perish after 18 Feb 2016.

Decision

33. As previously the Committee was clear that its consideration of this case did not require it to have regard to the mother's age or family connection with the prospective child.

34. The Committee considered all the evidence before them and in particular the forms that were completed (and the consent to research form which was not completed) at the time of egg collection and storage, and all the reported discussions and conversations with IA, a friend and a cousin. The Committee concluded that it did not have evidence to support the view that:

- A had tried to seek out more information about this treatment for herself before her death;
- A had explicitly expressed a wish for her mother to carry her child as a surrogate in the event of her death, with the possible exception of the comments made in about January 2010;
- A had or would have consented to the use of an anonymous sperm donor;
- A consented to the use of her eggs after her death.

35. In relation to the comments made in January 2010 (set out at paragraph 22 of IA's statement) the Committee was of the view that this expression of wishes was made without sufficient information for A to fully understand the implications of such a statement and the issues involved, particularly the risks for IA in relation to surrogacy and the legal implications of such arrangements.

36. The Committee noted that the suggested "cumulative evidence" referred to in this case, emerged over a number of years and the Committee was concerned that A had had ample time, for example between the conversation in about January 2010 and June 2011 to put in place clearer instructions, or discuss with others, any wishes for her mother to carry her embryos (fertilised by donor sperm). None of the conversations contemplated or considered the use of donor sperm outside the UK and the particular implications of such arrangements.

37. The Committee noted that these steps could have included:

- Signing the necessary consent forms;
- Undergoing counselling in relation to any of these treatments;

- Seeking more information from others about what might be involved in such arrangements;
- Speaking to others about her wishes and intentions
- Having others witness her wishes and intentions
- Leaving something as a token to the anticipated "baby";
- A having formal discussions with the doctors involved in her treatment;
- A requesting information about what might be involved in donor insemination, surrogacy, the implications for parental status;
- A formally noting her wishes.

38. The Committee concluded that, contrary to the submissions, it did not accept the proposed posthumous use of her eggs was exactly what A had wished for. It considered that a number of the statements contemplated IA potentially acting as a surrogate in the event A was unable to carry a child, but that the context was whilst A was still alive. In the Committee's assessment nearly all of the evidence supported an understanding of A's wishes during her life but it did not make clear her intentions in the event of her death.

39. The Committee read the cases included in the bundle but considered them of limited assistance given that the circumstances of this application were very different from the situations in each of the reported cases. It was however assisted by the comments of Hale LJ in the case of *Centre for Reproductive Medicine v U* [EWCA Civ 565] at paragraph 24 that "The whole scheme of the 1990 Act lays great emphasis upon consent.... Parliament had 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 concerns. Centres, the HFEA and the courts have to respect that scheme, however great their sympathy for the plight of the particular individuals caught up in it."

40. The Committee did not consider that Article 8 rights relating to A (who is deceased) or her parents were engaged in this case. The Committee did not consider that a refusal to allow export in this case would amount to a disproportionate interference in any individual's human rights.

41. The Committee was extremely sympathetic to the views of A's parents and understood that in seeking this export the parents believed that they were trying to fulfil the wishes of A, but in light of everything considered the Committee still did not find they had evidence to support the issuing of the Special Direction for the export of gametes in this case. The Committee was not satisfied that there were exceptional circumstances that could justify the issue of Special Directions in this case and refused the application.

Signed:

Date: 3 September 2014

A handwritten signature in black ink, appearing to read 'DWA' followed by a stylized flourish that loops back under the letters.

David Archard (Chair)