

HFEA Statutory Approvals Committee

28 August 2014

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

Minutes – Item 2

Centre 0293 (Andrology Solutions) – Application for a Special Direction to export patient sperm to Shady Grove Fertility, 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)	Shelley Edwards, FieldFisher

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
- Application form
- Further information form
- Agreement with receiving centre
- Letter from receiving centre
- Letter from patients
- Letter from referring centre
- Letter from USA embassy

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 centre had previously applied for a special direction to export an estimated six ampoules of a patient’s sperm to Shady Grove Fertility, USA.
2. The Committee Statutory Approvals Committee of 24 July 2014 considered that it did not have enough information to make an informed decision on whether to grant a Special Direction, and urged the centre to provide more information to show why the export is necessary. The Committee specifically wished to know:
 - what information the patient has received about donor availability in the UK;
 - whether the patient couple have tried to have treatment in the UK, and whether ethnicity is a factor;
 - further explanation of the reasons why treatment in the UK cannot be considered a realistic option, and why the centre in the USA is preferred (for example, success rates were mentioned by the centre);
 - any other reasons to support why this treatment abroad is necessary, including reference to the patient’s rights under Article 8 of the Human Rights Act 1998 if it is asserted that such rights would be engaged by a refusal to make a special direction in this case.
3. The Committee noted that these questions have now been addressed by the Centre.

Discussion

4. The Committee noted that the patient couple have investigated the options of treatment in the UK. However, they were informed they may need to wait years on the waiting list for an egg donor, which is too long for them given their age. They have not tried to have treatment in the UK because the waiting list is too long. Ethnicity is not a factor.
5. The Committee also noted that these patients are not UK nationals – they are Irish Nationals, and reside in Ireland. It is extremely difficult to carry out egg

donation in Ireland, as there is only one clinic which offers this and the waiting list is too long, there is a limited supply of donors and it's too expensive. The waiting list is also too long in the UK, and given their age, having treatment in the UK is not a feasible option.

6. The Committee noted that the patients are very happy with the treatment centre in the States having met the team at a seminar in Ireland. They have limited waiting times and excellent success rates. The clinic also offers a refund scheme in the programme that they have chosen. The couple have been stretched financially to their limits.
7. The Committee further noted that if the Special Direction is not approved, and the patient's sperm cannot be exported, the centre would class this as an unjustified interference with Article 12 of the Human Rights Act 1998 ('The right to [marry and] found a family') and 'the right to respect for [private and] family life' (under Article 8) as the patients would not be able to have fertility treatment at their chosen clinic in the USA and as they consider this to be their last chance to have a child of which is biologically that of the male partner, they would not be able to found a family.
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 they are not able to meet the requirements of section (h) of schedule 4 of General Directions 0006: '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.
9. The Committee noted specifically that the sperm will be used in the fertilisation of donor eggs that have been procured from an anonymous egg donor in the USA. Creating an embryo from sperm and an anonymously donated egg in the UK would not be lawful. The Committee regarded the UK requirements for identifying donors to be important. Special directions would not be granted routinely, or where the purpose or dominant effect appeared to be to circumvent those requirements.
10. The Committee further noted that the patient couple are intending to have donor egg treatment at Shady Grove Fertility, USA, but the male partner has been refused a visa to enter the country. The couple have undergone 4 previous cycles of egg donation, two in Czech Republic and two in Spain, all of which were unsuccessful.

Decision

11. The Committee concluded that, given that the patient is unable to travel to the USA, combined with the fact that donor eggs are necessary and that treatment services within their own country of residence are limited, a refusal to issue Special Directions would interfere with the right to respect for private and family life under Article 8 of the ECHR. In particular, the Committee noted the information as to the potential delay in receiving treatment services in the UK.

12. The Committee agreed to grant the Special Directions in this case for Centre 0293 to export six straws of this patient's sperm to Shady Grove Fertility, USA.

Signed:

Date: 17/09/2014

A handwritten signature in black ink, appearing to read 'DWA' followed by a stylized flourish.

David Archard (Chair)