

# Statutory Approvals Committee – minutes

## Item 4

### Centre 0148 (Shropshire and Mid-Wales Fertility Centre)

### Special Direction application to export sperm to Ukraine for posthumous use in treatment with donor eggs

Thursday, 27 June 2019

HFEA, Medway Meeting Room 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe Rachel Cutting Ruth Wilde	
Members of the Executive	Moya Berry Catherine Burwood	Committee Secretary Licensing Manager (Observer)
Legal Adviser	Sarah Ellson	Fieldfisher - LLP
Observers	Dee Knoyle Vicky Brown	Committee Secretary Inspector

## Declarations of interest

- Members of the committee declared that they had no conflicts of interest in relation to this item.

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## The committee had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members
- General Directions 0001 (2015)
- General Directions 0006 (2018)
- General Directions 0013 (2018)
- HFEA Standing Orders (2018)
- Special Directions Decision Tree (2018)

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## The following papers were considered by the committee:

- Executive Summary
  - Special Directions Application Form
  - Further information form
  - Letter from the receiving clinic confirming that they are willing to accept the sperm and treat the patient (redacted)
  - Patient statement (redacted)
  - GP letter dated 29 March 2019 (redacted)
  - GP letter dated 22 October 2018 (redacted)
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## 1. Background

- 1.1. The Person Responsible (PR) at Centre 0148 (the applicant) has applied for a Special Direction for the export of sperm from Shropshire and Mid-Wales Fertility Centre to Intersono Medical Centre in Lviv, Ukraine.
- 1.2. The committee noted the sperm provider is deceased, but if exported his sperm will be used to fertilise donor oocytes to produce embryos for use in his partner's treatment.
- 1.3. The committee noted that although there was no written consent from the deceased to export his sperm abroad, there was evidence of verbal consent as provided in by the couple's General Practitioner's (GP) written statements.
- 1.4. The committee noted that prior to the sperm provider's death the couple had planned to be treated outside of the UK due to the expense of treatment and also the lack of availability of donor eggs and difficulties in finding a clinic to treat the female partner due to her age.

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## 2. Consideration of application

### Application

- 2.1. The committee considered the application, which included an executive summary, a Special Direction application form and Further Information form.
- 2.2. The committee noted that the Human Fertilisation and Embryology Act (as amended) permits the Authority to issue directions to allow exports of gametes or embryos from countries outside of the United Kingdom. Furthermore, the committee noted that in relation to the import and export of gametes and embryos outside of the European Economic Area and Gibraltar, movement can be permitted without the need for a Special Direction if the conditions outlined in General Directions 0006 are satisfied.
- 2.3. The committee noted that this application for a Special Direction is being made as the centre is unable to export sperm to Intersono Medical Centre in Ukraine under General Directions 0006, since the following requirements of Schedule 4 are not met:
  - (d) 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;
  - (e) 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
- 2.4. The committee noted the information that had been provided to support the Special Direction application. This included letters from the couple's fertility consultant who discussed fertility options available to the couple, with one option being the use of donated eggs. The couple's GP also provided a statement stating that he specifically noted during a consultation with the couple on the 26 May 2017 that the couple were going to try and obtain IVF treatment in Poland. Treatment using the male partner's sperm and donor eggs at a clinic in Poland had been initiated by the couple. The female partner has stated to centre 0148 that her partner was fully involved in the decision to pursue donor egg IVF treatment abroad and wished for her to continue following his death.
- 2.5. In considering the application, the committee had regard to the principles (tests) derived from the decision of the Court of Appeal in R v HFEA ex parte Blood [1997] 2 All ER 687 and from rights arising under the Human Rights Act 1998.

## 2.6. Principle 1

The committee recognised that the centre is unable to export the gametes under General Directions 0006 because the gamete provider did not provide consent to export his gametes to another country before he died. It is also not documented that he was provided with information about, or was aware that, the laws in the country that his gametes will be exported to (Ukraine), may be different to those in the UK. The Committee noted that, except for section 1(d) and (e) of Schedule 1, all other requirements of General Directions 0006 were satisfied. The Committee also discussed compliance with section 1(h) of Schedule 1 of the General Directions 0006 which requires that 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. In particular it considered the requirements in UK treatment services in relation to payment to donors and the right of donor conceived children to obtain identifying information about the donor once they are 18.

## 2.7. Principle 2

The committee considered whether a refusal would amount to an interference with the patient's rights under the EC Treaty to obtain medical treatment services in another member state. The committee noted that the patient wishes to export her deceased partner's sperm to a centre outside of the EU/EEA.

## 2.8. Principle 3

The committee recognised that rights under the European Convention on Human Rights (ECHR) are separate and distinct from those arising under the EC Treaty. The couple's intention had been to travel to Poland for affordable IVF treatment where the advancing age of the female partner was not a barrier to her receiving treatment, using the male partner's frozen sperm and donor eggs. However, since the death of her husband the patient cannot be treated in Poland as a single woman, and therefore plans to be treated in Ukraine. The committee accepted that a refusal to allow the sperm to be exported could amount to an interference with the patient's rights to respect her private and family life under Article 8 and to found a family under Article 12 of the ECHR and that a refusal to grant the application would need to be justified.

## 2.9. Principles 4 and 5

The committee then considered whether interference with the patient's rights under the ECHR could be justified and whether a refusal to grant the application would be disproportionate. In doing so, the committee had regard to the fact that the centre acknowledged that written notice had not been given that the law governing the use of gametes and/or embryos and the parentage of any resulting child might be different in another country but considers that the couple would have been aware that there were differences in such laws, given their investigation of treatment in Poland. The sperm provider had no children of his own prior to his death and the female partner stated that it was her wish to give birth to his genetic offspring. This and further circumstantial evidence would suggest that had the sperm provider been alive he would have consented to the export of his sperm to allow his wife to be treated. The committee also considered the effect of a refusal on the patient and whether this represented an isolated case or an undesirable precedent.

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## 3. Decision

- 3.1. The committee considered that this is a rare and unique case where it had to consider whether consent had been given for fertility treatment involving the posthumous use of gametes outside the UK. The committee noted that the couple had been preparing for treatment abroad in Poland and as such the sperm provider had indicated that he would consent to the export of his sperm for use in fertility treatment.
- 3.2. In its consideration of the case, the committee was concerned as to the Ukrainian centre's compliance regarding section (h) of Schedule 4 of the General Direction 0006. The committee noted that for lawful use in the UK, egg donation treatment must comply with legal requirements both in

relation to using a donor who has consented to be identifiable to any donor conceived offspring over the age of 18 and who has received compensation which is compliant with UK Law. The committee felt there was a lack of certainty with regard to the egg donation arrangements and whether these would comply with the requirements for lawful use in the UK. In particular the committee noted that the couple did not want to consider "known egg donor" and that anonymity was important to them. It also noted the Executive Summary which explained that the centre has further clarified this and the female partner has confirmed in writing to them that her intention is to use an egg donor that is only anonymous to her and not one that would remain unidentifiable to any child born as a result of her treatment. The committee highlighted that it was the responsibility of the Person Responsible (PR) at Shropshire and Mid-Wales Fertility Centre to ensure section (h) of Schedule 4 of the General Direction 0006 could be complied with and to ensure that the arrangements in this case (notwithstanding usual arrangements in Ukraine) would comply with the requirements for lawful use in the UK in relation to the provision of identifying donor information to any resulting child born and how this could be obtained in the future.

- 3.3.** The committee also reminded the applicant that under the Human Fertilisation and Embryology (HFE) Act 1990 (as amended) S12(1)(e) lawful use in the UK would require that no money or other benefit shall be given or received in respect of any supply of gametes, embryos or human admixed embryos unless authorised by Directions. The committee considered that had a donor egg been imported for use in the UK General Directions 0001 paragraphs 12 and 13 would have applied and in particular:

*"....the centre should ensure the donor has not received compensation which exceeds:*

*(a) reasonable expenses incurred by the donor in connection with the donation of gametes provided to that centre; and*

*(b) loss of earnings (but not for other costs or inconveniences) incurred by the donor up to a daily maximum of £61.28 but with an overall limit of £250 for each course or cycle of donation (local currency equivalent).*

*.... the centre must keep a record (provided by the overseas centre) of:*

*(a) the actual expenses incurred by the donor;*

*(b) the amount reimbursed to the donor; and*

*(c) the receipts produced by the donor, and/or the steps taken by the person responsible to satisfy themselves that the excess expenses claimed by the donor have in fact been incurred.....*

Again, the committee highlighted that it was the responsibility of the Person Responsible (PR) at Shropshire and Mid-Wales Fertility Centre to ensure section (h) of Schedule 4 of the General Direction 0006 could be complied with in this respect.

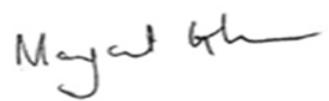
- 3.4.** The committee also strongly recommended that the patient receives appropriate counselling about the implications of treatment and reminded the centre of its obligation under the Code of Practice that it '*should keep a record that the implications discussion has taken place even if the patient declines to have this with the counsellor*'.
- 3.5.** Taking all of these circumstances into account, the committee concluded that a refusal could not be justified and/or would amount to a disproportionate interference with the rights of the patient. The committee was also satisfied that granting the application in the exceptional circumstances of this case would not set an undesirable precedent.
- 3.6.** The committee, therefore, agreed to issue a Special Direction in the case for Centre 0148, to export the sperm of the deceased partner from Shropshire and Mid Wales Fertility to Intersono Medical Centre, Lviv Ukraine of donor sperm for use in providing treatment services to the patient.

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## **4. Chairs signature**

- 4.1.** I confirm this is a true and accurate record of the meeting.

**Signature**

A handwritten signature in black ink, appearing to read "Margaret Gilmore", written on a light-colored background.

**Name**

Margaret Gilmore

**Date**

22 July 2019