

Statutory Approvals Committee – minutes

Item 7

Centre 0328 (GCRM - Belfast)

Application for Special Directions to

- export donor eggs back to the Ukraine
- simultaneously export to the Ukraine and import back to the UK embryos created using donor eggs

Thursday, 29 November 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe Anthony Rutherford Ruth Wilde Emma Cave
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Members of the Executive	Dee Knoyle Catherine Burwood Paula Robinson Victoria Askew	Committee Secretary Senior Governance Manager (Observer) Head of Planning and Governance (Observer) Inspections & Logistics Officer (Observer)
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Specialist Adviser

Legal Adviser	Ros Foster	Browne Jacobson LLP
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Observers	Rachel Cutting (New Member Induction - Observer)
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Declarations of interest

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

The committee had before it:

- 8th 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)

The following papers were considered by the committee:

- Executive summary.
- Application 6090 for a Special Direction for the export of donor eggs to ManorIVF operating from Reproductive Genetics Clinic 'Victoria' Clinic, Kiev, Ukraine:
 - i. Application form.
 - ii. Further information form.
 - iii. Letter from proposed receiving centre confirming acceptance of eggs.
- Application 6093 for a Special Direction to export embryos created with donor eggs to ManorIVF operating from Reproductive Genetics Clinic 'Victoria' Clinic, Kiev, Ukraine:
 - i. Application form.
 - ii. List of embryos to be exported.
 - iii. Further information forms (three) combined for export and re-import of embryos.
 - iv. Letter from proposed receiving centre confirming acceptance of embryos (as provided above).
- Application 6263 for a Special Direction to re-import embryos created with donor eggs from ManorIVF operating from Reproductive Genetics Clinic 'Victoria' Clinic, Kiev, Ukraine:
 - i. Application form.
 - ii. List of embryos to be imported (as provided above).
 - iii. Further information forms (three) combined for export and re-import of embryos (as provided above).
- For the committee's reference: minutes of the Statutory Approvals Committee meeting of 22 March 2018 relating to centre 0338 (Reproductive Health Group), applications for Special Directions for the export of donor eggs to Ukraine and (virtual) export and re-import of embryos created with donor eggs from Ukraine.

1. Background

- 1.1. The Person Responsible (PR) at GCRM - Belfast, centre 0328 has applied for Special Directions to export donor eggs back to ManorIVF operating from Reproductive Genetics Clinic 'Victoria' Clinic, Kiev, Ukraine, and to also export embryos created in the UK using some imported donor eggs from ManorIVF and simultaneously import the embryos back to the UK. The simultaneous export and import of the embryos is a paper exercise that does not require the actual movement of the embryos but is necessary to ensure that they can continue to be stored and used on a lawful basis. The centre is unable to complete these transactions under the auspices of General Direction 0006 because the following requirements are not satisfied:

Schedule 3 – Import of gametes and embryos from outside of the European Economic Area (EEA)

Part 1

(h) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with the Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits.

Schedule 4 - Export of gametes and embryos outside of the European Economic Area (EEA)

Part 1

(f) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with the Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving of money or other benefits.

(h) 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.

2. Consideration of application

Application

- 2.1. The committee noted that the PR at centre 0328 has applied for Special Directions to export donor eggs back to ManorIVF operating from Reproductive Genetics Clinic 'Victoria' Clinic, Kiev, Ukraine, and export some embryos created in the UK using donor eggs from ManorIVF and simultaneously import the embryos back to the UK. Three suitably completed application forms and further information forms were received by the HFEA Executive.

Human Fertilisation and Embryology Act 1990 (as amended) Section 24

General Directions 0006, Schedule 4, Part 1(f)

- 2.2. The committee noted that Section 24(4) of the 1990 Act provides a power to make Directions and confers a broad power on the Authority to permit the import and export of a person's gametes. Pursuant to this power the Authority has issued General Direction 0006 ('the General Direction'). However, these applications have arisen because not all of the requirements of the General Direction can be met and therefore the committee is asked to consider whether, in the particular circumstances of this case, there are grounds to exercise the power under section 24(4) to issue Special Directions so as to permit the transactions to which the applications before the committee relate.

Money and benefits paid to egg donors – the centre has exceeded the limit

- 2.3. The committee noted that the centre is unable to complete these transactions pursuant to General Direction 0006 because the following requirements are not satisfied:

Schedule 3 – Import of gametes and embryos from outside of the European Economic Area (EEA)

Part 1

- (h) *no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with the Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits.*

Schedule 4 - Export of gametes and embryos outside of the European Economic Area (EEA)

Part 1

- (f) *no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with the Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving of money or other benefits.*
- (h) *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.*

- 2.4. The committee noted that the HFEA's requirements on donor compensation aim to balance the desire to treat donors fairly with the need to avoid a financial inducement to donate. The fundamental principle is that donation must be altruistic in nature. Donor compensation limits for UK donors are different from those that apply in respect of overseas donors. General Direction 0006 sets out the requirements that must be met before gametes can be imported into the UK. Schedule 3 relates to the import of gametes and embryos from outside of the European Economic Areas (EEA) and Gibraltar.

General Direction 0001

- 2.5. The committee noted that General Direction 0001 sets out the requirements for giving and receiving money or other benefits in respect to any import of gametes or embryos from outside the UK. Parts 12 and 13 provide as follows:

Part 12

When considering whether to import gametes donated overseas, 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).*

Part 13

When receiving donated gametes from overseas, the centre must keep a record (provided by the overseas centre) of:

- (c) *the actual expenses incurred by the donor;*
- (d) *the amount reimbursed to the donor; and*

- (e) *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.*

- 2.6. Following a HFEA review of activities across the fertility sector in relation to the importation of eggs, particularly donor eggs, for use in treatment in the UK, the PR of centre 0328 confirmed that his centre had imported donor eggs from Ukraine and was made aware of concerns the executive had regarding the level of compensation provided to donors in Ukraine.
- 2.7. The Committee noted that compensation of the Ukrainian donors was not authorised by directions, specifically General Direction 0006. As such, the use of the imported gametes would be in breach of section 12(1)(e) of the 1990 Act, and the storage and use of the gametes would not be in pursuance of the centre's licence. Section 4(1)(a) and (b) of the 1990 Act state that '*No person shall store any gametes, or – in the course of providing treatment services for any woman, use.... (iii) the eggs of any other woman.. except in pursuance of a licence*'.
- 2.8. The committee noted that the ongoing storage and use of these imported donor eggs and the embryos created using these gametes is currently not 'in pursuance of' the clinic's licence and as such cannot take place lawfully. Special Directions to enable the simultaneous import and export of the embryos was being sought in order to rectify the position.
- 2.9. The committee also noted that the PR of centre 0338 had confirmed that the centre had halted the import of donor eggs from Ukraine on 18 June 2018, and that it had not supplied donor eggs imported from Ukraine to any other centres in the UK.

Legal Advice

- 2.10. The committee was advised by its Legal Adviser that changes impacting the import of gametes and embryos from third countries outside the EEA, such as Ukraine, took effect on 1 April 2018 when the United Kingdom implemented the Human Fertilisation and Embryology (Amendment) Regulations. This involved implementation of the EU's Directive 2015/566 ("the Import Directive") implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells. In order to ensure these requirements are met centres must apply for and receive a certificate confirming their status as an Importing Tissue Establishment (ITE) before accepting the import of gametes from third countries.
- 2.11. The committee noted that GCRM – Belfast, centre 0328 had yet to receive an ITE certificate. As the physical import of donor eggs from ManorIVF had taken place prior to the regulatory changes on 1 April 2018, the committee decided that it would not be necessary for the 2018 Regulations to be met in order for a virtual export and re-import of embryos to take place, being satisfied that the relevant quality and safety standards in place prior to the 2018 Regulations were met at the time of the import and noting that no actual transfer of embryos was to take place.

3. Decision

- 3.1. The committee had regard to:

HFEA General Directions 0001

HFEA General Directions 0006

The Human Rights Act 1998:

- Article 8 – respect for a private and family life
- Article 12 – right to marry and found a family

- 3.2. The committee had regard to the Authority's statutory duty to promote, in relation to activities governed by the Act, compliance with requirements imposed by or under the Act.
- 3.3. In relation to the Special Direction for the export of the six remaining donor eggs from the Ukraine, the committee noted that the donors involved in producing these eggs for donation would have undergone an invasive procedure to extract these eggs in good faith that relevant regulations were being met. Although the committee agreed that they could not be lawfully used in the UK, they could be used for patients elsewhere and this was a more favourable option rather than allowing them to perish.
- 3.4. The committee considered whether a refusal to make Special Directions for the export and simultaneous import of the embryos would be an interference with the patients' rights under Articles 8 and/or 12 of the European Convention on Human Rights and whether such interference would be justified and proportionate. The committee decided that refusal is likely to amount to interference which is not justified or proportionate for the following reasons:

Embryos created using donor eggs from the Ukraine:

- patients have consented in good faith to treatment using donor eggs to create a family and it was presumably unknown to them that these eggs were imported unlawfully from the Ukraine. These embryos are essential to three couples' treatments. The committee considered that a refusal to allow these seven embryos to be simultaneously (but notionally) exported to the Ukraine and imported back to the UK for the patients' use would not be proportionate in this case and would have a huge impact on the patients concerned, causing distress as a result of the cessation of treatment. A refusal, which would impact on their rights to family life and to found a family, could not be justified in the circumstances.

- 3.5. The committee concluded that, taking all the factors into account, the current case involves a highly exceptional set of circumstances and agreed to issue Special Directions to allow:

Donor eggs:

- the export of donor eggs as soon as possible to:

ManorIVF – Reproductive Genetics Clinic
'Viktoria' 70 Pochayninska Street
Kiev 04070
Ukraine

Embryos created using donor eggs:

- the notional export of embryos created using donor eggs as soon as possible to:

ManorIVF – Reproductive Genetics Clinic
'Viktoria' 70 Pochayninska Street
Kiev, 04070
Ukraine

- the formal re-importation of embryos created using donor eggs as soon as possible to:

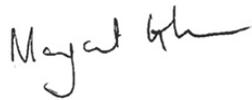
GCRM – Belfast
Edgewater Business Park
Edgewater House
Edgewater Road
Belfast, BT3 9JQ
United Kingdom

- 3.6. The committee noted that the provisions of paragraphs (f) and (g) of Schedule 3 and (d) and (e) of Schedule 4 refer to obtaining written consent to the embryos being imported/exported. Given that this is a notional exercise and the embryos will not actually be leaving their current place of storage, the committee agreed that compliance with these conditions was not required.
- 3.7. The committee considered that granting Special Directions for these applications, would be in the best interests of the patients affected in this exceptional case and would not set an undesirable precedent which would undermine the imperative requirements identified.
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4. Chairs signature

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

Signature



Name

Margaret Gilmore

Date

19 December 2018