Statutory Approvals Committee – minutes

Centre 0199 (CARE London)

Special Direction application to export sperm and embryo to San Diego Fertility Centre, United States of America (USA)

Thursday, 26 November 2020

HFEA, 10 Spring Gardens, London, SW1A 2BU – Microsoft Teams Meeting

Committee members	Margaret Gilmore (Chair) Emma Cave Anne Lampe Ruth Wilde	
Members of the Executive	Moya Berry	Committee Officer
Legal Adviser	Eve Piffaretti	Blake Morgan LLP

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:

- 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)

The following papers were considered by the committee:

- Executive Summary

- Redacted application form (gametes)
- Redacted application form (embryo)
- Further information form
- Redacted letter from receiving centre confirming willingness to accept the gametes and embryo to be exported.
- Email from PR confirming address of receiving centre
- Email from PR reviewing the screening of the sperm provider
- Redacted statement from patient in support of the application including the following exhibits:
  - EX01 – copies of emails from November 2017 to February 2018.
  - EX02 – letter dated 14 February 2018.
  - EX03 – copies of emails from 6-7 May 2019.
  - EX04 – copies of emails May 2019 to August 2019.
  - EX05 – copies of emails confirming joint meeting on 7 April 2020.
- Redacted letter of support from patient's legal representative

1. Background

1.1. The Person Responsible (PR) at Centre 0199 (the applicant) has applied for a Special Direction to the export of four ampoules of frozen sperm and one embryo, from CARE London, United Kingdom (UK) to San Diego Fertility Center, San Diego, California, United States of America (USA) for use in surrogacy treatment.

1.2. The committee noted that the patient's husband is deceased. His sperm had been frozen prior to his chemotherapy treatment. The embryo had been created using his frozen sperm and a donor egg.

1.3. The patient now seeks to export her embryo and the sperm to California, where surrogacy (including commercial surrogacy) is well established and lawful. The patient is unable to carry a pregnancy herself due to her complex gynecological history and surrogacy is the only option available for her to have her late husband's child.

2. Consideration of application

Application

2.1. The committee considered the application, which included an executive summary, a Special Direction application form, and a Further Information form. The application also included a supporting statement from the patient and a letter of support from the patient's legal representative.

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 to countries outside of the United Kingdom. Furthermore, the committee noted that in relation to the import and export of gametes and embryos outside Gibraltar and the European Economic Area (EEA), 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 the sperm and embryo to San Diego Fertility Center, San Diego, California, United States of America (USA), under General Directions 0006, since the following requirements of schedule 4 are not met:

> d) The person who has 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.

h) The gametes or embryos are not to be exported if they could not be lawfully 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. In considering the application, the committee had regard to its decision tree and 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.

2.5. **Principle 1**

The committee recognised that the centre is unable to export the sperm and embryo under General Direction 0006 because the following requirements were not satisfied:

d) The person who has 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.

h) The gametes or embryos are not to be exported if they could not be lawfully 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.

2.6. The committee observed that, except for section 1(d) and (h) of Schedule 4, all other requirements of General Directions 0006 were satisfied.

2.7. The committee noted the couple had been preparing for treatment abroad in the USA and as such the sperm provider had indicated that he would consent to the export of the embryo and his sperm for the posthumous use in fertility treatment.

2.8. The committee also recognised that although the embryo was created using a UK egg donor, who has consented to identity release, laws in the USA do not ensure that this is supplied upon request to a child born following treatment with a donor gamete. The centre has confirmed that the patient is aware of this and believes that should any child born as a result of the proposed treatment seek information about the egg donor in the future, that this could be facilitated between the HFEA and the centre.

2.9. With regard to screening, the committee noted that the patient's husband had not undergone screening as a gamete donor at the time his sperm was frozen prior to chemotherapy. The centre has confirmed it has reviewed the husband's screening test results following a stem cell transplant and, together with his medical history, considers there is minimal risk to any surrogate who may have treatment using his sperm. In addition, the receiving clinic have confirmed that the surrogate would be counselled about the very small risk of infection prior to treatment with the sperm or embryos created with the sperm.

2.10. **Principle 2**

The committee noted the proposed export was to a country outside the EU and considered whether a refusal would amount to an interference with the patient couple's wishes to obtain medical treatment services because the embryos were essential for treatment. The committee noted that the patient wishes to export her deceased partner's sperm and the one embryo to a centre outside of the EU/EEA.

2.11. **Principle 3**

The committee recognised that rights under the European Convention on Human Rights (ECHR) are separate and distinct from those arising under the United Kingdom's previous membership of the EU. Prior to his death, the couple's intention had been to travel to the USA for surrogacy treatment, using the male partner's frozen sperm and one embryo created from a donor egg and the patient's husband's sperm. The committee accepted that a refusal to allow the sperm and embryo 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.

2.12. **Principle 4 & 5**

The committee 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 regarding the law governing the use of gametes and/or embryos, and that the parentage of any resulting child might be different in another country. However, the committee considers that the couple would have been aware that there were differences in such laws, given their investigation of treatment in the USA. In addition, further supporting evidence suggested that had the sperm provider been alive, he would have consented to the export of his sperm and the embryo to be used with a surrogate. The committee considered the effect of a refusal on the patient and whether this represented an isolated case or an undesirable precedent.

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 surrogacy involving the posthumous use of gametes and one embryo outside the UK. The committee noted that although there was no written consent from the woman's late husband, it had received considerable supporting information and noted that prior to his untimely death, the couple had been preparing for treatment abroad in the USA, indicating the husband's consent to the export of his sperm and the embryo for use in surrogacy treatment. The committee also noted that the couple had exhausted all attempts to conceive through IVF and surrogacy in the UK.

3.2. In consideration of this case the committee also 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 and to any donor conceived offspring over the age of 18 years. Therefore, the committee strongly recommend that the clinic makes explicit to the applicant, the pathway for identifying how donor information could be made available to any child born as a result of her treatment using the embryo.

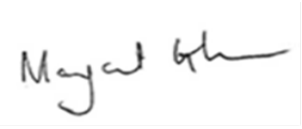
3.3. Taking all of these circumstances into account, the committee concluded that a refusal could not be justified and/or would amount to a disproportionate interference with the rights of the patient. The committee was also satisfied that granting the application in the exceptional circumstances of this particular case would not set an undesirable precedent.

3.4. The committee therefore agreed to issue a special direction in the case of CARE London, Park Lorne, 111 Park Road, London, NW8 7JL, United Kingdom (UK) to export four ampoules of sperm and one embryo to San Diego Fertility Center, 11425 El Camino Real, San Diego, California 82130, USA for use in treatment.

4. Chairs signature

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

Signature



Name

Margaret Gilmore

Date

23 December 2020