Statutory Approvals Committee – minutes

Centre 0017 (Newcastle Fertility Centre at LIFE)

Special Directions application to import embryos from the United States of America (USA) for research purposes for Research Project R0152

Thursday, 31 August 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Bobbie Farsides	
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Legal Adviser	Sarah Ellson	Fieldfisher LLP
Observers		

Declarations of interest

- Members of the panel 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.

The following papers were considered by the committee:

- Executive Summary
- Special Directions Application Form
- Further Information Form
- General Direction 0006
- Statutory Approvals Committee minutes - 24 April 2014

- HFEA Standing Orders 2016

1. Background

1.1. Newcastle Fertility Centre at LIFE, centre 0017 holds a research licence for project R0152 entitled 'Towards improving assisted reproductive technologies for the treatment of infertility and prevention of disease'. The centre also hold a treatment and storage Licence and provides a full range of fertility services including embryo testing.

1.2. A couple who are carriers of mitochondrial disease wish to donate embryos currently stored at the Fertility Specialists Clinic, Texas, United States of America (USA), to research specifically undertaken at centre 0017 for research project R0152. The couple completed a cycle of pre-implantation genetic diagnosis (PGD) and have nine embryos in storage that are not suitable for use in treatment. The couple wish for these remaining embryos to be donated to research project R0152.

2. Consideration of application

2.1. The committee considered the application which included an executive summary, Special Directions application form, further information form, General Direction 0006, Statutory Approvals Committee minutes of a previous meeting and HFEA Standing Orders 2016.

2.2. The committee noted that centre 0017 has applied for Special Directions to import nine embryos from the Fertility Specialists Clinic, Texas, United States of America, under its research licence for use in research project R0152. A suitably completed application form and further information form was received by the Executive.

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

General Directions 0006, Schedule 3, Paragraphs 1 (g) and (i)

Purpose of importing the gametes or embryos – in this case for research rather than treatment

2.3. The committee noted that under General Direction 0006 Schedule 3, Paragraphs 1 (g) the purpose of importing the gametes or embryos concerned is anticipated to be to enable them to be used to provide treatment services, namely medical, surgical or obstetric services for the purpose of assisting a woman to carry a child or to be stored for such a purpose in the future. However, in this case, the purpose of importing the embryos is for them to be used at centre 0017 for research project R0152 and as such, the importing centre is unable to comply with the requirements of General Direction 0006 and requires Special Direction permitting the import.

Law outside the United Kingdom - the use of gametes and/or embryos and the parentage of any resulting child – in this case the purpose is for research and there is no resulting child

2.4. The committee also noted that under General Direction 0006 Schedule 3, Paragraphs 1 (i), before giving consent, the person(s) providing consent is required to have 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 United Kingdom as in the country from which the gametes or embryos are to be imported, and have been given further information which they may require. The importing centre cannot comply with this requirement as the embryos are to be imported for the purpose of research and as such there will be no resulting child.

2.5. Under Section 24 of the Human Fertilisation and Embryology Act 1990 (as amended), the Authority has the power to make directions as to particular matters and the Authority has issued General Direction 0006 which set out the circumstances under which the import and export of embryos intended for treatment purposes can take place.

2.6. Where centres are unable to comply with the requirements of Direction 0006, under sections 24(3A), the Authority has the power to issue Special Directions that allows the import of gametes and/or embryos intended for human application (intended for treatment for example) and under Section 24(3) for the import of gametes and/or embryos not intended for human application (intended for research for example).

2.7. Section 24(4) of the Act gives the Authority the power to modify sections 12 to 14 of the Act (the sections which set out the general conditions of every licence and the specific conditions of licences for treatment and for storage). This power allows the Authority to modify a centre's licence conditions to permit the use of imported material for treatment purposes if it would otherwise not be possible for the centre to comply with the terms of their licence. There is, however, no equivalent provision in section 24(4) in relation to material not intended for human application (intended for research for example) and this means that there is no power for the Authority to modify the standard licence conditions to permit the use of imported material for use in research where it is not possible for the centre to comply with the terms of their research licence. Therefore compliance with the terms of the research licence is an important issue in considering this application.

Previous application import for the purposes of research – case study

2.8. The Statutory Approvals Committee considered an application to import for the purposes of research at its meeting on 24 April 2014. The application was declined on the basis that the centre could not demonstrate compliance with research licence conditions R19 and R20, However, it is evident from those minutes that the committee reached the view that it had the necessary power to issue Special Directions to import for research purposes. The minutes make reference to the Authority's Standing Orders dated 1 April 2014, specifically paragraph 3.2 of Annex A. Paragraph 3.2 of Annex A remains unchanged in the most recent Standing Orders, dated 1 April 2016.

2.9. The committee noted that it is the Executive's view that consideration should be given to whether the standard licence conditions relevant to the research licence can be met if Special Directions are issued to allow the import of embryos for research.

Legal Advice

2.10. The Legal Adviser indicated that this was an unusual application and confirmed that she agreed with the approach suggested by the Executive and the advice previously given in a similar application.

2.11. General Direction 0006 which usually governs import and export, is based on the presumption that import and export of gametes and embryos will be for treatment services. There are, as would be expected, a number of specific measures which must be taken when gametes and embryos are for human application. These are included not least because Section 24(4A) of the HFE Act 1990 (as amended) sets out measures which the Authority had to include, when making directions relating to import or export of gametes or embryos intended for human application.

2.12. General Direction 0006 is made pursuant to the powers given under Section 24 of the Act. Section 24(4) specifically refers to the Authority being able to make directions to authorise centres to receive embryos from outside the United Kingdom. It goes on to say "directions made by virtue of this subsection may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions." Sections 12 to 14 cover all licences, storage and treatment licences. There is no reference to modifying section 15 which refers to research licences.

2.13. The Legal Adviser confirmed that she considered that the Act allows the Authority to make directions for the import or export of gametes or embryos for research purposes. Section 24 does not distinguish between the potential purposes of importing or exporting gametes or embryos. The fact that there is no reference to modifying Section 15 does not mean the Authority has no power to make directions relating to research, just that it cannot modify or amend the conditions in section 15 (which relate to research licences).

2.14. The Legal Adviser suggested that first the committee should consider those parts of Schedule 3 to General Directions 0006 with which the centre could not comply and consider whether the committee was prepared to vary those General Directions to permit the import.

2.15. The committee should also consider whether the centre could comply with the relevant standard licence conditions that are attached to its research licence because there is no power to vary these. These were highlighted by the Executive as R18, R19, R21, R22 and R24.

2.16. The Legal Adviser agreed with the Executive that to grant Special Directions the committee should be satisfied that there are exceptional circumstances justifying the import other than in accordance with General Directions 0006.

2.17. The Legal Adviser confirmed that she did not think the case of Blood was of assistance when considering this case because the import for research purposes did not engage the same issues about a right to family life or rights to treatment.

2.18. The Legal Adviser indicated that, given that the requirements of Section 15(4) that "No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project" any directions which authorised the import of the embryos to research project R0152 at Newcastle Fertility Centre at LIFE, centre 0017 would ensure that the donors would be assured that their donated material could only be used for that research.

2.19. The Legal Adviser indicated her understanding that, whilst the HFEA asks centres, through the application/renewal process, about their source of embryos and gametes for research purposes, there is no guidance, standard licence condition or other requirement which mandates that the clinic must only use the source that they have advised the HFEA of and it is permitted for them to use a different source or add an additional source without having to advise the HFEA.

3. Decision

3.1. The committee had regard to General Direction 0006, HFEA Standing Orders 2016 and the Research Licence Conditions relevant to this case.

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

General Directions 0006, Schedule 3, Paragraphs 1 (g) and (i)

3.2. The committee noted that Special Directions have been applied for because the following conditions cannot be met by the applicant. The committee noted these were not relevant in this case since no pregnancy is anticipated:

g) Before giving consent, the person(s) referred to in paragraph 2 f. 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 United Kingdom as in the country from which the gametes or embryos are to be imported, and they have been given any further information which they may require.

i) The purpose of importing the gametes or embryos concerned is to enable them to be used to provide treatment services, namely medical, surgical or obstetric services for the purpose of assisting a woman to carry a child or to be stored for such a purpose in the future; and

Research Licence Conditions

Provision of information and consent

3.3. R18: The committee noted that under paragraph 2(1)(c) of schedule 3 of the Act a consent to the use of any embryo must specify whether the embryos can be used for the purposes of any project of research. The committee was satisfied that the PR has confirmed that each gamete provider has provided such consent.

3.4. R19: The committee was satisfied that the donating couple have been provided with copies of the research project information sheet and this information was assessed as compliant with R19 at the onsite research inspection on 23 January 2017. The committee was satisfied therefore that prior to giving consent to donate the couple had the necessary information.

3.5. R21 and R22: The committee was satisfied that the couple have had the opportunity to discuss the research and address any queries via email or skype with a trained member of Newcastle's research team, choosing to correspond via email. The PR has provided assurance that both gamete providers have individually confirmed their understanding of the research and decision to donate. This meets the requirements of R21 and R22.

No Money and Benefits exchanged

3.6. R24: The committee was satisfied that the centre has confirmed that the gamete providers have not been paid for donation of their embryos for research. The committee noted that the gamete providers have personal experience of mitochondrial disease and have lost a child to the disease. The couple actively sought out and approached Newcastle Fertility Centre to donate affected embryos after undergoing PGD in the USA.

3.7. The committee accepted that the clinic would not be in breach of any research licence condition if it accepted these embryos for use in research project 0152 notwithstanding it may not have anticipated the US centre would be a source of material.

3.8. The committee was satisfied that there are exceptional circumstances in this case to justify the import of the nine embryos for use in research. The committee was satisfied as to the value of the research, the couple's understanding and motivation for wishing to donate to this research project and the unsuitability of the embryos for any form of treatment.

3.9. The committee had regard to the advice given by its Legal Adviser. The committee agreed with the interpretation that there is discretion to grant Special Directions in this case and that it had the power under Standing Orders to make such Special Directions.

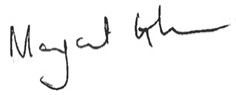
3.10. The committee agreed to grant Special Directions to import nine embryos from the Fertility Specialists Clinic, Texas, USA. for use in research project R0152 entitled 'Towards improving assisted reproductive technologies for the treatment of infertility and prevention of disease' at Newcastle Fertility Centre at LIFE, centre 0017.

3.11. The committee noted that none of the centre's research licence conditions are varied and therefore that the centre must continue in compliance with those, including any need to secure revised Ethics Committee approval if appropriate for use of embryos imported from the US.

4. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

2 October 2017