HFEA Statutory Approvals Committee

24 April 2014

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

Minutes – Item 8

Centre 0102 (Guy's Hospital) – Application for a Special Direction to Import Embryos for Research

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair	Lauren Crawford
Rebekah Dundas (lay)	
Sue Price (professional)	Legal Adviser:
Jane Dibblin (lay)	Graham Miles, Morgan Cole
Debbie Barber (professional)	
	Also in attendance:
	Sam Hartley, Head of Governance and Licensing, HFEA

Declarations of Interest: The Members declared no conflicts in relation to this item.

The following papers were considered by the Committee:

- Executive Summary
- Application Form
- Supporting Letter
- Annex's 1 - 9
- Annex 10 Research Licence Conditions
- Annex 11 Supporting Information

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
- Application form to deposit a human stem cell line in the UK Stem Cell Bank.

The Application

1. The Committee noted that this centre has applied for a special direction to import 738 embryos from 77 patients who have had treatment at Nevada Centre for Reproductive Medicine, USA.

2. The Committee noted that Centre 0102, Guy's Hospital, currently holds research licences for two research projects:

   a) Licence R0075 "Improving methods for pre-implantation genetic diagnosis of inherited genetic disease and predicting embryo quality" (first licensed July 1994 and involving 'basic' research); and

   b) Licence R0133 "Developing criteria for estimating quality of stem cells derived from human embryos" (first licensed April 2002 and involving the derivation of stem cells intended for human application).

Legal Advice

3. The Legal Adviser provided the following legal advice to the Committee.

   a) Paragraph 7 of the Executive Summary refers to the power in section 24(4) to modify a centre's licence conditions to permit the use of imported material for treatment purposes. It suggests that there is no provision in section 24(4) in relation to material not intended for human application. This requires some clarification and refinement.

   b) Section 24(4) does not distinguish between embryos imported for treatment services and embryos not intended for human application. Therefore, section 24(4) gives the Authority discretion to make a special direction for the import of embryos for the purpose of research.

   c) Section 24(4) provides that directions may modify the conditions set out in sections 12 to 14 of the Act. It is notable that this power does not extend to conditions set out in section 15, which relate specifically to research licences. However, this does not mean that the Authority has no power to modify statutory licence conditions in the context of an application to

import for the purpose of research. It means that, in considering such an application, there is no power to amend those conditions in section 15 which relate exclusively to research.

d) Section 12 contains conditions that apply to all licences, including research licences. Significantly, section 12 imposes the requirement to comply with the effective consent provisions in schedule 3 to the Act. It follows that there is power under section 24(4) to modify statutory requirements relating to effective consent. Similarly, section 14 contains conditions that apply to all storage licences. Given that most research licences will also authorise the storage of embryos, the Authority's power to modify conditions in section 14 is also relevant to an application to import material for the purpose of research.

e) A distinction needs to be drawn between standard licence conditions imposed by sections 12 to 15 of the Act and those applied by the Authority to all licences, (or to all licences of a particular type). Section 24 (4) expressly refers to the power to modify conditions imposed by sections 12 to 14 only and not to variation of standard conditions applied by the Authority.

f) The Authority's Standing Orders dated 1 April 2014 set out at paragraph 3 of Annex A the powers delegated to the Statutory Approvals Committee. This includes at 3.2 'the issuing of Special Directions for the import/export of gametes or embryos (under section 24 of the Act)'. This power must be read as including the power to modify the statutory conditions in sections 12 to 14 of the Act as this is an integral part of the power under section 24(4). However, in the absence of any express reference in this part of the Standing Orders to a power to modify other standard conditions, the Committee should not assume that this power has been delegated.

g) In summary, therefore, in considering this application, the Committee has the discretion to modify any conditions imposed by sections 12 and 14 of the Act, but not any other standard condition. For these reasons, it is appropriate for the Committee to consider whether the centre can comply with all relevant standard conditions other that those in section 12 to 14 in relation to the material to be imported.

Discussion

4. The Committee accepted the legal advice given and considered whether the centre can comply with all relevant standard conditions in relation to the embryos concerned.

5. The Committee noted that standard licence conditions R19 and R20 specify information that is required to be provided to donors before they give consent to the use their embryos for research. The Committee noted that the issue that it had to determine was whether the donors had been given this information. It was not open to the Committee to speculate whether they

would have made a different decision if they had been provided with the information.

6. The Committee reviewed the consent form used by the Nevada Centre for Reproductive Medicine and noted the fact that the US gamete providers consented to any project of research involving embryos created using their gametes. However, there is no indication that the gamete providers were given the information specified in R19 and R20.

7. The Committee also noted that standard licence condition R30 requires that any licence authorising the derivation of human embryonic stem cell lines requires that a sample of all stem cell lines be deposited in the UK Stem Cell Bank in accordance with any relevant Bank guidelines. In this context, the Committee noted that the application form to deposit a human stem cell line in the UK Stem Cell Bank requires confirmation that the donor was given information comparable to that specified in R19 and R20. Consequently, in the absence of this information being given to the donor, the centre would not be able to comply with R30 in relation to any human embryonic stem cell line created under licence R0133.

8. The Committee concluded that it could not make a special direction under Section 24(4) in view of the centre's inability to satisfy the requirements of standard licence conditions R19 and/or R20 and/or R30 in relation to the embryos to be imported. Accordingly, the Committee determined that the application should be refused.

9. The Committee noted, however, that it would be open to the centre to request that the relevant gamete providers be given the information specified in R19 and R20 in relation to the embryos concerned. If the centre is able at a future date to provide evidence that the specified information has been given to the gamete providers and consent has been obtained following that information being given, a further application for special direction might be made.

10. In the event of such a further application, the Committee would also suggest that it would be helpful for the centre to provide further information as to the need for the numbers of embryos to be imported (738 embryos from 77 patients) in relation to each research project.

Signed: Date: 07/05/2014

David Archard (Chair)