

Licence Committee Meeting

**19 December 2005
21 Bloomsbury Street London WC1B 3HF**

MINUTES Item 17

Centre: Reproductive Genetics Institute (0206) Licence Renewal

Members:

Walter Merricks, Lay Member – Chair
Simon Jenkins, Lay Member
Neva Haites, Professor of Medical
Genetics, University of Aberdeen

In Attendance:

Frances Clift, Legal Adviser
Trish Davies, Director of Regulation
Chris Stark, Head of Business Systems,
Information and Support
Claudia Lally, Secretary to the
Committee

Providing Legal Advice:

Graham Miles, Morgan Cole Solicitors

Conflicts of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (40 pages)
- the following papers were tabled:
 - recent correspondence with Bevan Brittan (13 pages)
 - Licence Committee papers from 16 November 2005 (80 pages)
 - bundle of documents from centre 0157 (276 pages).

1. The papers for this item were presented by Debra Bloor, HFEA Inspector. Dr Bloor introduced the item by referring to her Summary Report for Licence Committee 19 December 2004, contained in the Licence Committee papers. She described the outcome of recent Licence Committee decisions. Frances Clift summarised for members of the Committee all the matters raised in communication with the centre between herself and Bevan Brittan, solicitors for the centre, since 16 November 2005.

2. The Committee asked the Executive to clarify whether the original requests for supporting information were usual. The Executive replied that the centre was only requested to submit the same documentation required of all centres to

support licence renewal applications. The only exception to this had been the counselling audit and the three embryo transfer log which the Licence Committee of 16 November had specifically asked should be submitted.

3. The Committee concurred with one of the conclusions of the Licence Committee on 16 November: in the absence of current staff CVs and treatment outcome data they could not be confident that they had a sufficiently comprehensive picture of the centre to make a judgement about whether to renew the licence.

4. The Committee was very concerned that after repeated requests this information had not been forthcoming, particularly in the light of the fact that a letter from Bevan Brittan to Frances Clift dated 15 December 2005 indicated that the centre would be submitting current CV's for staff members, outcome data and also data on the practice of clinical ICSI and embryo biopsy for each practitioner and data on three embryo transfers.

5. The Committee noted that the Licence Committee on 16 November decided to grant a storage only licence to centre 0206. The Executive informed the Committee that an offer of a storage licence had been drawn up and sent to the centre on 24 November. However, the centre had not acknowledged or accepted the licence. Furthermore, the letter from Bevan Brittan of 15 December states: "Our client only applied for a treatment and storage licence and if he is not granted a treatment and storage licence he does not wish to maintain premises such as those licensed as Centre 0206 solely for the purpose of storage". In effect this amounted to a rejection of the offer of a storage only licence.

6. The Committee noted with concern the persistent failure by the Person Responsible at the centre to submit the appropriate documentation supporting his licence application. Members of the Committee agreed that the Person Responsible seemed to be highly reluctant to comply with the requests for information. They agreed that it would not be appropriate to issue a licence before this information had been received. In the continuing absence of this information the Committee did not consider themselves to be in the position of being able to grant a new treatment and storage licence for the centre.

7. In addition to the failure to supply information in support of the licence application, the centre was regularly overdue in supplying treatment forms to the HFEA.


8. The Committee was concerned to act a proportionate way in the face of the clear evidence of a persistent failure to cooperate with the regulator. While there was no evidence of imminent danger to patients, nor had there been submitted the evidence on which the Committee could normally be expected and entitled to rely that the centre had operated to proper standards. It would therefore not be right to issue a licence for the future treatment of patients. However the interests

both of those patients already in the course of treatment during the currency of the existing licence, and of those with material in storage, could be protected by the issue of appropriate directions. Any inconvenience to the owner, staff and patients of the centre occasioned by the non-renewal of the licence had been brought about by the actions of the centre itself.

8. The Committee decided that it should issue a notice of proposal to refuse a licence and provide the centre with an opportunity to make representations. Although there would be insufficient time before expiry of the licence on 31 December 2005 for representations to be made and considered, the Committee would make Directions under section 24(7) of the Human Fertilisation and Embryology Act 1990 to apply on expiry of the licence. Such directions would be for the purpose of securing the continued discharge of certain of the duties of the Person Responsible. These would be limited to:

- storage of embryos and gametes at the centre, and
- treatment of patients currently receiving treatment, defined as those having commenced drug treatment prior to 1 January 2006

10. The Committee noted that under usual circumstances Special Directions would not come into force until they had been acknowledged in writing by the Person Responsible to whom they are addressed. However, in this circumstance the Committee treated Mr Taranissi's signed application form as written consent to continue to discharge the duties of a Person Responsible.

Signed.......... Date.....20/12/05.....
Walter Merricks (Chair)

**DIRECTIONS GIVEN UNDER THE
HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990**

Ref: S.D. 2005/0206/1

These Directions are:

SPECIAL DIRECTIONS

These Directions are addressed to:

Mohammed Taranissi

Former Licensed Centre:

**REPRODUCTIVE
GENETICS INSTITUTE**

Sections of the Act providing these Directions:

Section 24 (5) – (9)

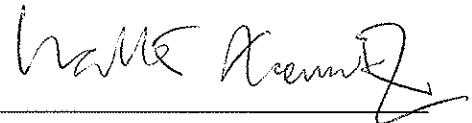
These Directions come into force on:

1 January 2006

These Directions remain in force:

Until 31 March 2006 or
the date on which a
final determination is made
by a Licence Committee,
whichever is the earlier

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1. On 31 December 2005, the treatment and storage licence ("the old licence") in respect of Centre 0206 at the Reproductive Genetics Institute ceases to have effect.
 2. These Directions are given for the purpose of securing the continued discharge of the duties of the Person Responsible under the old licence, but limited to the following:
 - storage of embryos and gametes at the centre, and
 - treatment of patients currently receiving treatment, defined as those having commenced drug treatment prior to 1 January 2006.
 3. You are to secure that the duties under section 17(1) of the Human Fertilisation & Embryology Act 1990 ("the 1990 Act") are complied with in relation to the storage of all gametes and embryos, and the treatment of those patients referred to in paragraph 2 above.



Walter Merricks

Chair of Licence Committee

Date 20/12/05

TO: THE PERSON RESPONSIBLE

NOTICE OF PROPOSAL TO REFUSE LICENCE

TAKE NOTICE that on 19th December 2005 a Licence Committee of the Human Fertilisation and Embryology Authority made a proposal to refuse to grant by way of renewal a treatment and storage licence for THE REPRODUCTIVE GENETICS INSTITUTE (centre 0206).

Pursuant to s.19 of the Human Fertilisation and Embryology Act 1990 (“the Act”) notice is hereby given of the reasons for the proposal:

1. It is a condition of the centre’s licence that, in support of an inspection, the Authority shall be provided, within 28 days of a request in writing being made with such information as specified in written request or in directions.

2. A written request that the centre should complete a licence renewal form was first made on 2 January 2005. The licence application at s.9 stated that, in order to process the application, it was essential for the Authority to be provided with a complete set of supporting documentation. The documents to be included were listed in the application form at paragraphs 9.1 to 9.6.

3. On 22 June 2005 a Licence Committee considered the information in the possession of the Authority at that time and regarded it as incomplete and out of date. Pending receipt of further information, it decided to renew the centre’s licence for a limited period of three months, expiring on 30 September.

4. On 22 September 2005, no further information having been submitted, a Licence Committee again considered the information available. Pending receipt of further information it agreed to renew the centre’s licence for a limited period of three months, expiring on 31 December.

5. On 16th November 2005, no further information having been submitted, a Licence Committee gave further consideration to the information available. It specifically requested that the centre should provide information required to accompany the renewal application form

as set out in s.9 of the renewal application form. The Committee was not satisfied that it had sufficient information to grant the treatment licence in accordance with s.16 (4). It decided to offer a 12 month storage licence. That offer has been rejected.

6. Despite further requests, the centre has failed to submit:

- Recent treatment outcome data;
- Data on the practice of clinical ICSI and embryo biopsy for each practitioner;
- CVs for key staff;
- Information relating to 3 embryo transfers;
- The centre's complaints and incidents procedure;
- A counselling audit.

7. On 19 December 2005, no further information having been submitted, the Committee concluded that the information available was insufficient to enable it to grant a licence. The Committee took note of the bundle of documentation relating to treatment and laboratory protocols, patient information and consent and treatment forms. The Committee noted that there was some documentation which was out of date and a lack of clarity as to which was currently applicable.

8. The Person Responsible has failed in his duty under s.17 (1) of the Act to secure that the conditions of the licence are complied with, in that the centre has failed to comply with the condition referred to in paragraph 1 above.

9. The Person Responsible has also failed to secure that directions are complied with in that:

- Directions 1999/1 require that treatment forms must be submitted to the Authority within two calendar months of the following:
 - the date intra uterine fetal pulsation seen, or if not seen,
 - date result of treatment known, or if treatment did not take place;
 - date treatment was abandoned and/or date embryos were put into storage, or if the treatment was not attempted,
 - date eggs were collected or collection was attempted or abandoned

- The centre submitted 33% of treatment forms more than 90 days after treatment had taken place during the period from April 2004/2005.

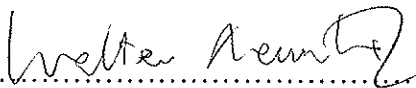
In accordance with Section 19(3) of the Act, if you wish to make representations to the Licence Committee about this proposal you must give notice to the Committee within 28 days beginning with the date of this Notice. Provided such notice is given by you within the period specified above, the Licence Committee will, before making its determination, consider any representations that you wish to make which may be:

- (a) Oral representations made by you or another acting on your behalf at a meeting of the Committee; and

- (b) Written representations made by you.

If you do not give notice within the period specified above, the Licence Committee will proceed to make its determination

^{20th}
Dated 19th December 2005



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Walter Merricks

Chairman of the Licence Committee