

HFEA Executive Licensing Panel Meeting

9 June 2014

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

Minutes – Item 1

Centre 0198 (St. Jude’s Women’s Hospital) – Consideration of Special Directions

Members of the Panel: Juliet Tizzard (Chair) Rachel Hopkins Paula Robinson	Legal Adviser: Catherine Callaghan, Blackstone Chambers
Panel Secretary: Lauren Crawford	

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

The following papers were considered by the Panel:

- Cover sheet
- Exec summary
- PR response
- Annex A – papers put before the LC on 8 May 2014
- Annex B – minutes of 8 May LC meeting
- Annex C – Special Directions which came into force on 1 May 2014
- Annex D – Special Directions which came into force on 22 May 2014
- Annex E – Pre-action letter from LDD dated 28 May 2014
- Annex F – letter of response from Field Fisher dated 30 May 2014
- Annex G – letter from LDD dated 2 June 2014

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)
- 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

Background

1. St Jude's Women's Hospital ('the Clinic') has been licensed by the HFEA since 2002. A renewal inspection took place in June 2013, the report of which was subsequently presented to a Licence Committee ('LC'). The matter came before successive LC meetings over the course of a number of months and the LC adjourned consideration of the renewal application in November 2013, January and March 2014 so that further information on the Clinic's practices could be obtained and made available to the LC in due course. Following its meeting on 8 May 2014, the LC reached a proposed decision to refuse the application for the renewal of the licence of St Jude's Women's Hospital (Centre 0198).
2. The Clinic's previous licence expired on 31 January 2014 and since then it has been operating under successive Special Directions. The LC on 8 May 2014 issued more restrictive Special Directions than those under which the Clinic had been operating immediately prior to 8 May 2014. The most recent Special Directions revoked the previous Special Directions and came into force on 22 May 2014 (when the minutes of the meeting were signed by the Chair of LC).
3. The Executive received a pre-action letter dated 28 May 2014 from Lawford Davies Denoon, solicitors acting for the Person Responsible at the Clinic, challenging the decision to issue these more restrictive Special Directions on the basis set out in that letter. The pre-action letter evidenced an intention on the part of the Person Responsible to make

representations about the proposal to refuse the licence. That proposal is likely to be the subject of a representations hearing before the LC in due course.

4. The Authority replied to the pre-action letter on 30 May 2014. As that letter explained, the Authority agreed that it would be willing to reconsider the terms of the Special Directions applicable to the Clinic.
5. The solicitors acting for the Clinic have agreed to the terms of the Special Directions being re-considered by whichever of the LC or the Executive Licensing Panel ('ELP') could convene first. The ELP was able to convene earlier than the LC.
6. The executive summary invited the ELP to consider whether and if so on what terms to issue Special Directions which would permit the Clinic to operate pending the completion of the statutory process for applications for renewal. The executive summary noted that the ELP was not directly concerned with the question of the application for renewal.

Advice received from Counsel

7. The ELP received the following advice (orally and in writing) from its legal adviser:
 - a. The only task of the ELP today is to determine whether or not to issue Special Directions in respect of St Jude's Women's Hospital (Centre 0198), and if so, to determine the content and duration of those Special Directions. This matter arises in the context of an application by the centre for the renewal of its licence. Following a number of adjournments by the Licence Committee of consideration of the renewal application, on 8 May 2014, the Licence Committee reached a proposed decision to refuse the application for renewal of the centre's licence. The Person Responsible is entitled under section 19 of the Human Fertilisation and Embryology Act 1990 to make representations about the proposed decision not to renew the licence, and has

indicated an intention to do so. There is therefore likely to be a representations hearing before the Licence Committee, at which the Committee will make a concluded decision on the renewal application. If the proposed decision is maintained, then the Person Responsible is further entitled under section 20 of the Act to require the Authority to reconsider the decision afresh in an appeal to the Appeal Committee.

- b. The ELP is not concerned with the application for renewal, except to this extent: when determining what, if any, Special Directions to issue, it should bear in mind that the statutory process for determination of the renewal application is not yet complete, and that the Licence Committee has not yet reached a concluded decision. That means it is foreseeable that either the Licence Committee or an Appeal Committee may decide that the centre's licence should be renewed.
- c. The Authority has the power to issue directions under sections 23 and 24 of the Act. In particular, directions may make provision for the purpose of dealing with a situation arising in consequence of a licence ceasing to have effect: section 24(5A). Under section 9A of the Act, and the Authority's Standing Orders, the Authority has delegated to the ELP the power to issue Directions.
- d. When reaching a decision, the ELP will need to ensure that it acts in accordance with the 1990 Act. In particular, the ELP is reminded that, in carrying out its functions, the Authority (and therefore the ELP itself) is under a statutory duty set out in section 8ZA of the Act:
 - To carry out its functions effectively, efficiently and economically;
 - To have regard to the principles of best regulatory practice, including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed.
- e. A 'proportionate' decision is one which goes no further than is necessary to address the problem or mischief in question. In the

criminal law context, the concept of proportionality is used to convey the idea that the 'punishment must fit the crime'.

- f. A 'consistent' decision will be one that is consistent with other decisions made by the Authority on the basis of similar facts and evidence.
- g. When reaching a decision, the ELP must also act in accordance with the HFEA's Standing Orders, in particular, section 6 and Annex C which contains the Protocol for the conduct of ELP meetings.
- h. The clinic's previous licence expired on 31 January 2014, and since then, it has been operating under successive Special Directions issued by the Licence Committee. The ELP will be aware that under section 23(3) of the Act, anything done by a person pursuant to directions is to be treated for the purposes of the Act as done pursuant to a licence.
 - At the Licence Committee meeting on 9 January 2014, the Committee agreed to issue a Special Direction for the continuation of the centre's current licensed activities for a period of 3 months from 1 February 2014 until 30 April 2014.
 - At the Licence Committee meeting on 13 March 2014, the Committee agreed to issue a further Special Direction for the continuation of the centre's current licensed activities for a period of 3 months from 1 May 2014 until 31 July 2014.
 - However, at the Licence Committee meeting on 8 May 2014, the Committee decided to impose more restrictive Special Directions. In particular, the directions specified that the PR must not:
 - Take on any new patients;
 - Initiate any new treatment cycles;
 - Undertake any new egg sharing;
 - Undertake any new altruistic egg donation.
- i. Solicitors acting for the centre and the PR, Mr Adeghe, have objected to those Special Directions. They have stated that the effect of these

Directions is to prevent the centre from continuing to operate and will almost certainly result in the closure of the clinic. The PR has argued that such restrictive Special Directions effectively circumvent the statutory process for determining renewal applications. The clinic intends to commence legal proceedings for judicial review unless the Authority issues new Special Directions which permit the centre to continue to operate as normal pending the conclusion of the statutory licensing process. The ELP will wish to consider carefully the submissions made on behalf of the centre.

- j. The ELP will also wish to consider the recommendations made by the Executive, and the reasons given by the Licence Committee for imposing the Special Directions. However, the ELP is an independent body and must reach its own decision, independently of any decision that has been previously reached by the Licence Committee and of any recommendation by the Executive.
- k. In deciding whether to issue Special Directions on the same or similar terms as those issued by the Licence Committee on 8 May 2014, the ELP will wish to consider:
 - The practical effect of any directions it issues;
 - If the directions would have the same practical effect as a suspension of a licence, then the ELP will wish to consider whether the statutory conditions for the exercise of power to suspend a licence (under section 19C) would be satisfied here, if the licence had continued in force. (Those conditions are that the Authority has reasonable grounds to suspect that there are grounds for revoking a licence under section 18, and that the Authority is of the opinion that the licence should be immediately suspended.)
 - To clarify: the ELP has no power to suspend the centre's licence because the licence expired in January 2014. However, if the effect of the ELP's decision today will be to prevent the centre from operating, then the ELP should satisfy itself that, if the

licence had continued in force, the statutory conditions for suspending a licence would be met.

- A suspension of a licence, or the issue of Special Directions which have the same practical effect, is plainly a very serious step to take.
- Parliament intended that suspension of an existing licence would be the only means by which a licensing decision could have immediate effect notwithstanding the statutory reconsideration process.
- The ELP will wish to consider whether the evidence before it is sufficient to reach a conclusion that the centre should be effectively shut down, and whether this is consistent with the Authority's previous decisions in relation to this centre, and other centres.

Discussion

8. The Panel considered that the questions to be decided were:
 - whether or not the Clinic should be issued with new Special Directions to operate, bearing in mind that its licence has expired;
 - Whether and if so what restrictions should be put in place;
 - What duration any Special Directions should have.
9. The Panel noted the Executive's concerns regarding the Clinic and noted the critical and major areas of non-compliance set out in the licence renewal update report for 13 March 2014. The Panel noted the LC's concerns regarding the Clinic's practices, and its reasons for the proposed decision to refuse the renewal application. The Panel noted all of the responses from the Clinic in relation to the areas of non-compliance. The Panel had serious concerns about the Clinic's practices relating to consent and donation, but was not in a position on the basis of the material before it to reach a concluded view about whether these

concerns would justify restrictive conditions on any Special Directions issued.

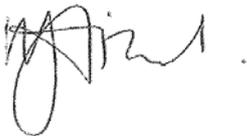
10. The Panel noted paragraph 4.9 of the Executive Summary for Licence Committee 8 May 2014, where the Executive sets out five possible options for Special Directions that were available to the LC on 8 May 2014. The Panel noted that the Executive did not recommend permitting the Special Directions to expire (option C) for the reasons set out in paragraph 4.10. The Panel noted that prior to the meeting on 8 May 2014, the Clinic had been granted successive Special Directions for the continuation of licensed activities. The Panel agreed that it would be neither reasonable nor proportionate not to issue any Special Directions or to permit them to expire.
11. The Panel considered the terms of the Special Directions which came into force on 22 May 2014, and LC's reasons for imposing the restrictions. The Panel considered that the restrictions set out in paragraph 4 of the Special Directions would probably have the effect of preventing the Clinic from continuing to operate, akin to suspension of the Clinic's licence (if it had not expired). It was not clear to the Panel that that was the LC's intention. The Panel considered that it was not in a position to reach a concluded view that the circumstances regarding the Clinic are such that it would have suspended the Clinic's licence had this not expired, and therefore that it would not impose restrictions which may have the same or similar effect to a suspension. The Panel was also mindful of the fact that the statutory representations and reconsideration process had not yet been completed.
12. The Panel was therefore satisfied that it was necessary to issue new Special Directions to enable the Clinic to continue to provide licensed treatment services.

Decision

13. The Panel agreed to issue Special Directions with immediate effect for the continuation of the Clinic's activities under its last licence (L0198-7-B).
14. The Panel was not minded to add any restrictions to the Special Directions at this time.
15. The Special Directions will be effective immediately, and shall remain in force until the earliest of either:
 - a. 12 December 2014; or
 - b. the conclusion of the statutory representations and reconsideration process.
16. The existing Special Directions in place until 21 November 2014 (S.D.2014/01/0198/c) will be revoked by these Special Directions.

Signed

Date 13/06/2014

A handwritten signature in black ink, appearing to be 'J. H. Smith', written in a cursive style.