

Executive Licensing Panel - minutes

Centre 0055 (The James Cook University Hospital)

Renewal Inspection Report

Tuesday, 11 December 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Lisa Whiting Helen Crutcher	Director of Strategy and Corporate Affairs Research Manager Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance Manager

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

- 1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.
- 1.2. The panel noted that The James Cook University Hospital has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.
- 1.3. The panel noted that the current licence was renewed for a period of three years, rather than the standard four, without additional conditions in October 2015, due to the number and type of non-compliances identified at the renewal inspection. These non-compliances were all fully implemented within the prescribed timescales.
- 1.4. The panel noted that the centre had not yet paid the licence renewal fee. On 4 December 2018, the centre's Quality Manager had informed the inspector that the fee should have been paid on 5 December 2018, but on 6 December 2018, the HFEA finance team confirmed to the centre's inspector that the renewal fee had still not been received at HFEA.
- 1.5. The panel noted that General Direction 0008 paragraphs 1 and 2 states the following:

Applications to the Authority relating to categories A-M must be made by completing and submitting the relevant on-line application, together with relevant supporting information detailed below, via the 'electronic portal' located on the Authority's website. An application fee (details of current fees payable are available on the Authority's website) must also be submitted.

Failure to submit a fully completed application form, pay the application fee or provide all the necessary information set out below will, in normal circumstances, result in the application not being considered until such times as these requirements have been satisfied.
- 1.6. The panel noted that the treatment and storage licence for the centre expires on 31 January 2019 and the next Executive Licensing Panel meeting will be on 15 January 2019. If the renewal of the licence is considered at that meeting, this will not allow sufficient time for the issue of minutes and for an offer licence to be accepted by the PR.
- 1.7. The inspectorate recommended the panel consider the renewal of this licence without the renewal fee having been received by the HFEA, or to issue Special Directions for the continued operation of this centre until such time as the renewal of the licence can be considered and any licence offered can be accepted by the PR within the standard timeframe.

2. Decision

- 2.1. The panel had regard to its decision tree. It was not satisfied that the appropriate application and fee had been submitted as required by General Directions 0008.
- 2.2. The panel decided to adjourn consideration of the renewal of the centre's licence until confirmation had been received that the fee had been submitted as required by General Directions 0008.
- 2.3. The panel agreed to issue Special Directions under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity upon expiry of the centre's current licence, to allow time for the required fee to be submitted, for the renewal to be considered by the Executive Licensing Panel and for the administration of the outcome of their consideration to be completed within the usual timeframe. These Special Directions would come into force on 1 February 2019 and would remain in force until any new licence comes into effect, or to 30 April 2019, whichever is sooner.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

14 December 2018