

# Executive Licensing Panel Minutes

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## Centre 0015 (Sussex Downs Fertility Centre)

### Variation to Change Person Responsible (PR)

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Date: 30 April 2021

Venue: HFEA Teleconference Meeting

Attendees: Clare Ettinghausen (Chair) Director of Strategy and Corporate Affairs  
Helen Crutcher Risk and Business Planning Manager  
Anna Coundley Policy Manager

Executive: Bernice Ash Secretary

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### Declarations of interest

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

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### The panel had before it:

- 9th edition of the HFEA Code of Practice.
  - Standard licensing and approvals pack for committee members.
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## **1. Consideration of Application**

- 1.1.** The panel considered the papers, which included a completed application form, an executive summary, previous licensing minutes, a CV and confirmation of acceptance from the proposed Person Responsible (PR).
- 1.2.** The panel noted that an application to change the PR for Sussex Downs Fertility Centre has been received by the HFEA on 21 April 2021 and it is requested to be considered by the Executive Licensing Panel (ELP) as a matter of urgency.
- 1.3.** The panel noted that, on 13 April 2021, the centre's current PR, Ms Pallett, resigned from her position, confirming with the HFEA that she would remain in position to supervise licensed activities until a new PR had been approved. Following a meeting with her employer, on 14 April 2021, Ms Pallett was given one weeks' notice to leave, but had been asked to relinquish her equipment that day. This meant that she would not be able to remain in post until a new PR had been appointed.
- 1.4.** The panel noted that, on 14 April 2021, the HFEA's Chief Inspector and the centre's inspector met via videoconferencing with the Licence Holder (LH) and senior management. The LH was reminded that if the PR is not able to carry out their duties, then the LH must inform the HFEA immediately and apply to the HFEA for a licence variation to nominate a new PR.
- 1.5.** The panel noted that after receipt of the application form, the centre notified the HFEA that they were liaising with the current PR to see if she could remain in post until a new PR was appointed. The outcome of these discussions was not confirmed to the HFEA until 27 April 2021, causing a delay in expediting this application.
- 1.6.** The panel noted that the proposed PR, Mr David Chui had previously been in this role at the centre until January 2021, has academic qualifications in medicine and more than two years of practical experience which are directly relevant to the activities to be authorised by the licence. The proposed PR has successfully completed the HFEA PR Entry Programme (T/1010/7).
- 1.7.** The panel noted there were two outstanding issues for this centre; a non-compliance, identified at the 2020 interim inspection, concerning medicines management, and a non-compliance regarding accreditation, noted at the 2019 renewal inspection.
- 1.8.** The panel noted that in 2019, during the centre's renewal inspection, concerns were raised relating to the proposed PR's leadership at the centre (when he was previously the PR at this centre). At a meeting in January 2020 with the Director of Compliance of the HFEA, Chief Inspector of the HFEA and the Executive, Mr Chui and his team provided assurances that the concerns raised would be addressed and it was agreed that no formal regulatory action would be taken.
- 1.9.** The panel noted that, from the information provided, that the character, qualifications and experience of the proposed PR, Mr David Chui, are suitable to carry out a PR's duties under section 17 of the HFE Act 1990 (as amended).
- 1.10.** The panel noted that inspectorate's recommendation to vary the centre's licence to appoint Mr David Chui as the PR.
- 1.11.** The panel noted that, as a result of the UK's departure from the EU, a relicensing project is currently underway. This follows approval by the Licence Committee (LC) of a variation without application on 4 March 2021. This means that new offer licences are being sent to all clinics,

incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July, after the transition period ends on 30 June.

- 1.12.** Due to the relicensing project, the panel is asked to approve this change of PR for the centre's current licence, and also for the new, varied, licence that will supersede it on 1 July 2021. The Licensing team will send the centre a varied licence (if approved) for immediate use until 30 June 2021, and an updated offer licence for 1 July 2021 onwards, also reflecting the variation of PR, as requested.
- 1.13.** The panel noted that the Executive recommends that the centre is required to review procedures to ensure that in future, sufficient notification is provided to the HFEA to prevent the clinic acting in breach of the conditions of the Act. The centre should be required to investigate the circumstances that led to this situation arising and submit a summary report to the HFEA documenting the findings of the investigation, any proposed corrective action and the timescale for implementation of any corrective actions. This report should be provided to the HFEA by 30 June 2021.

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## **2. Decision**

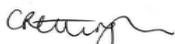
- 2.1.** The panel agreed that it was in receipt of the appropriate documentation as required by the HFE Act 1990 (as amended) in relation to Section 16(2), which sets out the requirements with regard to the role of Licence Holder and Person Responsible.
- 2.2.** The panel expressed concern regarding the late submission of this change of PR application to the HFEA, endorsing the inspectorate's recommendation that the centre is required to review procedures to ensure that in future, sufficient notification is provided to the HFEA to prevent the clinic acting in breach of the conditions of the Act. The centre is requested to investigate the circumstances that led to this situation arising and submit a summary report to the HFEA by 30 June 2021. In the event of the centre submitting an unsatisfactory report to the inspectorate, the item should be presented to a licensing meeting for consideration.
- 2.3.** The panel endorsed the inspectorate's recommendation and agreed to vary the licence of Sussex Downs Fertility Centre (centre 0015) with immediate effect to reflect the change of Person Responsible to Mr David Chui in accordance with Section 18A of the HFE Act 1990 (as amended), also approving this change for the new, varied, licence that will supersede it on 1 July 2021. The Licensing team will send the centre a varied licence for immediate use until 30 June 2021, and an updated offer licence for 1 July 2021 onwards, reflecting the approved variation of PR.

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### **3. Chair's signature**

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

#### **Signature**



#### **Name**

Clare Ettinghausen

#### **Date**

30 April 2021