

Executive Licensing Panel Minutes

Centre 0086 (BMI Chelsfield Park ACU)

Variation to Change Person Responsible (PR)

Date: 1 June 2021

Venue: HFEA Teleconference Meeting

Attendees:	Helen Crutcher (Chair)	Risk and Business Planning Manager
	Anna Coundley	Policy Manager
	Niamh Marren	Regulatory Policy Manager

Executive:	Bernice Ash	Secretary
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Observers:	Catherine Burwood	Licensing Manager
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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:

- 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 BMI Chelsfield Park ACU had been received by the HFEA on 19 May 2021 and it is requested to be considered, as a matter of urgency, by the Executive Licensing Panel (ELP).
- 1.3.** The panel noted that the current PR, Ms Sarah Pallett, resigned from her position on 13 April 2021. The HFEA were made aware of this on the same date and confirmed she would remain in position to supervise licensed activities until a new PR had been approved.
- 1.4.** The panel noted that Ms Pallett contacted the HFEA on 14 May 2021, stating that after a meeting with her employer, she had been given one week's notice to leave and 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. Following this, the HFEA's Chief Inspector and the executive met via videoconferencing with the Licence Holder (LH) and senior management of The Hospital Fertility Group (THFG). 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 appoint a new PR.
- 1.5.** The panel noted that on 22 April 2021, the centre notified the HFEA that they were liaising with the current PR, Ms Pallett, to resume her duties until the end of her notice period. The outcome of these discussions was not confirmed to the HFEA until 29 April 2021, which meant that there was effectively no PR in post to discharge their duties from 14 April to 29 April 2021.
- 1.6.** The panel noted that the proposed PR, Mr David Chui, is the Medical Director and PR at Sussex Downs Fertility Centre (centre 0015). He has academic qualifications in the field of medicine and has 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). Mr David Chui has provided email confirmation that he is willing to assume the role until another PR has been approved to fill this position.
- 1.7.** 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).
- 1.8.** The panel noted there are no outstanding issues relating to this centre. However, the proposed PR is aware that a renewal inspection is scheduled for 10 June 2021, agreeing to take responsibility in ensuring the centre's readiness for this.
- 1.9.** The panel noted that, in 2019, at the Sussex Downs Fertility Centre's (centre 0015) last renewal inspection, concerns were raised relating to the proposed PR's leadership at the centre (when he was the PR at the 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.
- 1.10.** 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. The executive noted that such a recommendation had already been made at the time of the last change of PR application, which was also requested to be considered as a matter of urgency by ELP on 2 November 2020. The report requested was not provided to the executive. Therefore, the centre is also required to undertake a root cause analysis into the circumstances which led to the recurrence of this situation and include it in the report. This report is to be provided to the HFEA by 1 September 2021

- 1.11.** The panel noted that inspectorate's recommendation to vary the centre's licence to Mr David Chui as the PR.
- 1.12.** The panel noted that, as a result of the UK's departure from the EU, a relicensing exercise is currently under way. This follows approval by the Licence Committee (LC) of a variation without application on 4 March 2021, meaning 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 2021, after the transition period ends on 30 June 2021.
- 1.13.** Due to the relicensing exercise, 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.
- 1.14.** The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) importing certificate, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. If this application is approved, the centre's ITE certificate should be amended to reflect the new PR's details.

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 particular concern that there had been a previous incident, in November 2020, whereby the ELP was also requested to consider a change to PR as a matter of urgency. The panel endorsed the executive's recommendation, requiring the centre to review procedures to ensure that in future, sufficient notification is provided to the HFEA to prevent the clinic being in breach of the conditions of the Act. The centre is also required to conduct a root cause analysis into the circumstances, which led to another urgent change of PR, and include this in the report. The report must be provided to the HFEA by 1 September 2021.
- 2.3.** The panel endorsed the inspectorate's recommendation and agreed to vary the licence of BMI Chelsfield Park ACU (centre 0086) 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 licence for 1 July 2021 onwards, also reflecting the approved variation of PR.

- 2.4.** The panel agreed that the centre's ITE import certificate should be amended to reflect the new PR's details.

3. Chair's signature

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

Signature



Name

Helen Crutcher

Date

7 June 2021