

Executive Licensing Panel - minutes

Centre 0086 (BMI Chelsfield Park ACU)

Variation Change of Person Responsible (PR)

Monday, 2 November

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Dina Halai Yvonne Akinmodun	Director of Strategy and Corporate Affairs Scientific Policy Manager Head of Human Resources
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

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.

1. Consideration of application

- 1.1. The panel considered the papers, which included an 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 the current PR resigned from BMI Chelsfield Park ACU on 26 October 2020, notifying his employer and the HFEA that he would be unable to fulfil his duties after 31 October 2020. The centre has recently changed ownership and it was envisaged that the current PR would remain in position until the transition had been completed.
- 1.3. The panel noted that the current PR had informed BMI Chelsfield ACU that the clinic should cease all activity until there have been discussions with the executive. The Chief Inspector of the HFEA wrote to the Licence Holder (LH) on 27 October 2020, to inform them of their legal responsibilities and the requirement to appoint another PR as soon as possible.
- 1.4. The centre was informed that, if an application to appoint a new PR had not been received by 1 November 2020, the clinic must cease all licensed activity. In this event, the clinic must also make an application for Special Direction to allow the continued storage of gametes and embryos at the clinic.
- 1.5. The panel noted that an application to change the PR for centre 0086, BMI Chelsfield Park ACU, was received by the HFEA on 27 October 2020 and it is requested to be considered by the Executive Licensing Panel (ELP) as a matter of urgency.
- 1.6. The panel noted that the proposed PR, Ms Sarah Pallett, is the recently appointed Clinical Lead for The Hospital Fertility Group. Prior to this, she was the PR of Bourne Hall Clinic (HFEA licensed centre 0188). The proposed PR has academic qualifications in nursing and management 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/1090/7).
- 1.7. The panel noted that assurances have been provided, that the recommendations for improvement, made at the time of the last inspection, have been fully implemented.
- 1.8. The panel noted that, from the information provided, that the character, qualifications and experience of the proposed PR, Ms Sarah Pallett, are suitable to carry out a PR's duties under section 17 of the HFE Act 1990 (as amended).
- 1.9. The panel noted that all information required under General Directions 0008 has been provided.
- 1.10. The panel noted the inspectorate's recommendation to vary the centre's licence to Ms Sarah Pallett as the PR.
- 1.11. 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.
- 1.12. The panel noted that, should the application for a change of PR be declined or adjourned at the meeting, it is recommended that the licensing committee considers the issue of Special Directions under the terms of Sections 24(5) of the 1990 Human Fertilisation and Embryology Act (as amended) for the following:
 - The completion of treatment of patients who have commenced drug therapy;
 - The storage of cryopreserved gametes and embryos.
- 1.13. The panel noted that the issue of these Special Directions should be contingent on the identification of a person suitable to assume responsibility for compliance with the Act (Steven

Fuller, laboratory manager). Any provision of treatment should only be carried out if the person to whom Directions are issued is able to confirm that it is safe for this treatment to be provided. In the absence of such confirmation then the person to whom Directions are issued should invoke a contingency plan for the completion of treatment and storage of gametes and embryos.

- 1.14.** It is recommended 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 27 January 2021.

2. Decision

- 2.1.** The panel agreed 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 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 Ms Sarah Pallett, in accordance with Section 18A of the HFE Act 1990 (as amended).
- 2.3.** The panel agreed that the centre's ITE certificate should be amended to reflect the new PR's details.
- 2.4.** The panel noted that the centre has been 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 27 January 2021.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

2 November 2020