

Executive Licensing Panel Minutes

Centre 0327 (Boston Place)

Variation to Change Person Responsible (PR)

Date: 15 June 2021

Venue: HFEA Teleconference Meeting

Attendees:	Clare Ettinghausen (Chair)	Director of Strategy and Corporate Affairs
	Joanne Anton	Head of Regulatory Policy
	Dan Howard	Chief Information Officer

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 Boston Place has been received by the HFEA on 10 March 2021 and it is requested to be considered by the Executive Licensing Panel (ELP).
- 1.3. The panel noted that the proposed PR, Ms Hannah Smyth, has academic qualifications in the field of biomedical science 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/1384/82).
- 1.4. The panel noted that, from the information provided, that the character, qualifications and experience of the proposed PR, Ms Hannah Smyth, are suitable to carry out a PR's duties under section 17 of the HFE Act 1990 (as amended).
- 1.5. The panel noted that inspectorate's recommendation to vary the centre's licence to Ms Hannah Smyth as the PR.
- 1.6. The panel noted that assurances have provided that the recommendations for improvement, made at the time of the last inspection, have been fully implemented.
- 1.7. The panel noted that, as a result of the UK's departure from the EU, a relicensing exercise is currently in progress. 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.
- 1.8. 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.
- 1.9. 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 endorsed the inspectorate's recommendation and agreed to vary the licence of Boston Place (centre 0327) with immediate effect to reflect the change of Person Responsible to Ms Hannah Smyth 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, also reflecting the approved variation of PR.

- 2.3.** 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

Clare Ettinghausen

Date

21 June 2021