

# Executive Licensing Panel - minutes

---

**Centre 0119 (Birmingham Women's Hospital)**

## **Licence Extension Application**

Wednesday, 7 October 2020

HFEA Teleconference Meeting

Panel members	Richard Sydee (Chair) Helen Crutcher Laura Riley	Director of Finance and Resources Risk and Business Planning Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Matthew Mudford	Licensing Manager Scientific Policy Officer (Induction)

---

## **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 a completed application form and Executive summary.
- 1.2. The panel noted that the Assisted Conception Unit at Birmingham Women's Hospital has held a licence with the HFEA since 1992. The centre currently holds a treatment (including embryo testing) and storage licence and provides a full range of fertility services.
- 1.3. In response to UK measures to contain and mitigate the spread of the Covid-19 coronavirus, a decision was taken by the HFEA to suspend all inspections of licensed premises until at least 1 November 2020.
- 1.4. The panel noted that HFEA licensed premises should be inspected every two years (Schedule 3B paragraph (4)(1)). The suspension of inspections impacts on the Authority's legal duties to carry out its regulatory functions. This action has been agreed with the Authority.
- 1.5. The panel noted that the HFEA normally issues licences for treatment and/or storage for a duration of up to four years but can issue a licence for five years (Schedule 2 paragraph 1(5) of the HF&E Act 1990).
- 1.6. In light of the current suspension of inspections, due to Covid-19, centre 0119 has applied to extend their licence by one year; the current licence expires on 30 November 2020.
- 1.7. The panel noted the centre was last inspected on 24 July 2018 and recommendations were made in relation to three major and two 'other' areas of non-compliance. The Person Responsible (PR) has provided evidence that all of the recommendation has been implemented.
- 1.8. The panel noted that the executive is satisfied that;
  - the PR has discharged their responsibility under section 17 of the Act;
  - the centre has followed professional body guidance to suspend all non-essential treatments in response to Covid-19;
  - the centre continues to manage the storage of gametes, embryos and patient records appropriately during this period;
  - there has been one serious (Grade A) incident since the last inspection which has been reported to the HFEA and investigated appropriately by the PR. The PR has taken suitable corrective actions;
  - the centre has suitable procedures in place to continue to support patients.
  - the PR's appointment was initially thought to be on a medium term basis. Unforeseen circumstances have dictated that he is unable to step down as PR at the treatment and storage centre;
  - as the PR is also the PR of research project R0173, an additional condition was added to the centre's licence by the Executive Licensing Panel (ELP), with regards to the recruitment of gamete and embryo donors for the research project R0173 from centre 0119;
  - the PR has confirmed that, since his appointment, he has fully complied with the additional licence condition and research project R0173 has not recruited gamete or embryo donors, from centre 0119 since his appointment;
  - an application by the Licence Holder of the research centre to appoint a suitable replacement to the current PR of research project R0173 has been hindered by the current pandemic.
- 1.9. The executive recommends the approval of the application to vary the centre's treatment (including embryo testing) and storage licence, extending the duration to 30 November 2021, with the additional licence condition to remain in place until such time that an application is made to have it removed.

---

## 2. Decision

### 2.1. The panel was satisfied that;

- the PR has discharged their responsibility under section 17 of the Act;
- the centre has followed professional body guidance to suspend all non-essential treatments in response to Covid-19;
- the centre continues to manage the storage of gametes, embryos and patient records appropriately during this period;
- there has been one serious (Grade A) incident since the last inspection which has been reported to the HFEA and investigated appropriately by the PR. The PR has taken suitable corrective actions;
- the centre has suitable procedures in place to continue to support patients;
- the PR's appointment was initially thought to be on a medium term basis. Unforeseen circumstances have dictated that he is unable to step down as PR at the treatment and storage centre;
- As the PR is also the PR of research project R0173, an additional condition was added to the centre's licence by ELP, with regards to the recruitment of gamete and embryo donors for the research project R0173 from centre 0119;
- The PR has confirmed that, since his appointment, he has fully complied with the additional licence condition and research project R0173 has not recruited gamete or embryo donors, from centre 0119 since his appointment;
- An application by the Licence Holder of the research centre to appoint a suitable replacement to the current PR of research project R0173 has been hindered by the current pandemic.

**2.2.** The panel noted that one serious (Grade A) incident has occurred at the centre, since the last inspection in 2018, but were reassured that this was thoroughly investigated by the PR and suitable corrective actions had been taken.

**2.3.** The panel endorsed the executive's recommendation to vary the centre's treatment (including embryo testing) and storage licence, extending the duration to 30 November 2021, with the additional licence condition to remain in place, until such time that an application is made to have it removed.

---

## 3. Chair's signature

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

### Signature



### Name

Richard Sydee

### Date

14 October 2020