

Executive Licensing Panel Minutes

Centre 0344 (Hewitt Fertility Centre, Knutsford)

Licence Extension Application

Date:	23 February 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Richard Sydee (Chair) Helen Crutcher Joanne Anton	Director of Finance and Resources Risk and Business Planning Manager Head of Policy
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood	Licensing Manager

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 and Executive summary.
- 1.2.** The panel noted that Hewitt Fertility Centre, Knutsford has held a treatment and storage licence with the HFEA since July 2015. The centre provides a full range of licensed fertility treatments (excluding embryo testing), to NHS and self-funded patients.
- 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, after which prevailing circumstances will be reviewed on a case by case basis before a decision is taken with regard to the inspection of the centre taking place.
- 1.4.** The panel noted that inspections resumed in November 2020 and had continued until a further national lockdown was implemented by the UK Government on 5 January 2021.
- 1.5.** The panel noted that new inspection methodology has enabled assessment of compliance against the requirements of the Act, Standard Licence Conditions and Code of Practice requirements through desk-based assessment and the use of virtual technology where available and appropriate.
- 1.6.** 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.
- 1.7.** 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).
- 1.8.** In light of current circumstances regarding inspections, due to Covid-19, centre 0344 has applied to extend their licence by one year; the current licence expires on 20 July 2021.
- 1.9.** The panel noted the centre was last inspected on 12 March 2019 and recommendations were made in relation to two major and one 'other' area of non-compliance. The Person Responsible (PR) has provided evidence that all the recommendations had been implemented.
- 1.10.** The panel noted that the centre's 12 March 2019 interim inspection report was considered by the Executive Licensing Panel (ELP) on 21 May 2019; the panel particularly noted the non-compliance relating to pregnancy success rates concerning IVF and FET in women aged under 38 years old, and looked forward to receiving a further progress update, following the renewal inspection to be conducted in 2021, encouraging the PR's continued engagement with the inspectorate on this issue.
- 1.11.** The panel noted that, since the March 2019 inspection, the centre had received four risk tool alerts for pregnancy success rates in relation to IVF and FET in women aged under 38 years old. The PR conducted an investigation into success rates and this report was provided to the centre's inspector in December 2020, giving assurance that she will continue to monitor these in this specific group of patients. The centre has not received any risk tool alerts since May 2020. The executive is satisfied that the PR has acted appropriately to investigate and improve pregnancy success rates in women aged under 38 years old.
- 1.12.** The panel noted that a desk-based assessment is not required for this application in line with the 'Procedure for risk-based inspection during the COVID- 19 pandemic: Licence Extension, Desk Based Assessment and postponement of inspections'.

- 1.13.** 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 activity in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services;
 - the centre continues to manage the storage of gametes, embryos and patient records appropriately during this period;
 - there have been no serious (Grade A) incidents since the last inspection;
 - the centre has suitable procedures in place to continue to support patients.
- 1.14.** The executive recommends the approval of the application to vary the centre's treatment and storage licence, extending the duration to 20 July 2022, without additional conditions.
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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 activity in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services
 - the centre continues to manage the storage of gametes, embryos and patient records appropriately during this period;
 - there have been no serious (Grade A) incidents since the last inspection;
 - the centre has suitable procedures in place to continue to support patients.
- 2.2.** The panel was satisfied that the issues regarding risk tool alerts, for pregnancy success rates concerning IVF and FET in women aged under 38 years old, had been addressed and endorsed the executive's recommendation to vary the centre's treatment and storage licence, extending the duration to 20 July 2022, without additional conditions.
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3. Chairs signature

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

Signature



Name

Richard Sydee

Date

26 February 2021