Executive Licensing Panel Minutes

Centre 0037 (Glasgow Royal Infirmary)

Licence Extension Application

Date:	21 September 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Richard Sydee (Chair) Helen Crutcher Kathleen Sarsfield-Watson	Director of Finance and Resources Risk and Business Planning Manager Communications Manager
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.

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 fertility clinic at Glasgow Royal Infirmary has held a HFEA licence since 31 July 1992 and provides a full range of fertility services, including storage and embryo testing.

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)). Whilst the current Covid-19 restrictions do not prohibit an on-site inspection of the clinic's premises, the risks of doing so in some circumstances, outweigh the requirements to fulfil the Authority's legal duties to carry out its regulatory functions. This action has been taken with the agreement of 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 0037 has applied to extend their licence by one year; the current licence expires on 31 December 2021.

1.9. The panel noted that the centre was last inspected on 24 October 2019 and recommendations were made in relation to three major and four 'other' areas of non-compliance; the Person Responsible (PR) has provided evidence that all the recommendations were implemented.

1.10. 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'.

1.11. 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;
- there have been no serious (Grade A) incidents since the last inspection;
- the centre has suitable procedures in place to continue to support patients.

1.12. The executive recommends the approval of the application to vary the centre's treatment (including embryo testing) and storage licence, extending the duration to 31 December 2022, without additional conditions.

1.13. The panel noted that centre 0037 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to section 24(4AD). Such certificates are generally synchronised to the centre's HFEA licence. The executive therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

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;
- 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 endorsed the executive's recommendation to vary the centre's treatment (including embryo testing) and storage licence, extending the duration to 31 December 2022, without additional conditions.

2.3. The panel endorsed the executive's recommendation to renew the centre's ITE import certificate, in line with the centre's licence.

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

27 September 2021