

# Executive Licensing Panel Minutes

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## Centre 0170 (The Gateshead Fertility Unit)

### Licence Extension Application

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Date:	1 June 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Helen Crutcher (Chair) Anna Coundley Niamh Marren	Risk and Business Planning Manager Policy Manager Regulatory Policy Manager
Executive:	Bernice Ash	Secretary
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.

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### 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 The Gateshead Fertility Centre is located within the Queen Elizabeth Hospital part of Gateshead Health NHS Foundation Trust and has been licensed with the HFEA since 1996. The centre provides a full range of fertility services to NHS and self-funded patients, from a wide geographical area. Other licensed activities of the centre include storage of gametes and embryos.
- 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 0170 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 23 July 2019 and recommendations were made in relation to one major and one 'other' area of non-compliance. The Person Responsible (PR) has provided evidence that all the recommendations have been implemented.
- 1.10. The panel noted that the centre had a change of PR in April 2021; the previous PR has agreed to support the new PR for three months, working to prepare her for the role.
- 1.11. 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'.
- 1.12. 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.

- 1.13.** The executive recommends the approval of the application to vary the centre's treatment and storage licence, extending the duration to 31 December 2022, without additional conditions.
- 1.14.** The panel noted that as a result of the UK's departure from the EU, a relicensing project is currently under way. This follows approval by the Licence Committee of a variation without application on 4 March 2021. This means that new offer licenses are being sent to clinics, incorporating changes to some of the standard licence conditions. The varied licenses will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021.
- 1.15.** The panel noted that it is requested to approve this extension of licence for the centre's current licence and also for the new, varied, licence that will supersede it on 1 July. The Licensing team will send the centre a varied licence (if approved) for immediate use until 30 June, and an updated offer licence for 1 July onwards, also reflecting the extension of licence requested.
- 1.16.** The panel noted that centre 0170 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.
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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 endorsed the executive's recommendation to vary the centre's treatment and storage licence, extending the duration to 31 December 2022, without additional conditions, 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 licence for 1 July 2021 onwards, also reflecting the approved extension to the licence.
- 2.3.** The panel endorsed the executive's recommendation to renew the ITE's import certificate, in line with the centre's licence.

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### **3. Chair's signature**

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

#### **Signature**



#### **Name**

Helen Crutcher

#### **Date**

7 June 2021