

# Executive Licensing Panel - minutes

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**Centre 0070 (The Bridge Centre)**

**Licence Extension Application**

**Variation of Licenced Activities**

Tuesday, 16 June 2020

HFEA Teleconference Meeting

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Panel members	Clare Ettinghausen (Chair) Joanne Anton Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Regulatory Policy Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
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 Bridge Centre is located in London and has held a licence with the HFEA since 1992.
- 1.3. In response to UK measures to contain and mitigate the spread of the Covid-19, a decision was taken by the HFEA to suspend all inspections of licensed premises until at least 31 August 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 taken with the agreement of the Department of Health and Social Care and is in line with other national regulators.
- 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 0070 has applied to extend their licence by one year; the current licence expires on 30 September 2020.
- 1.7. The panel noted that the centre was last inspected on 10 April 2018 and recommendations were made in relation to two 'other' areas of non-compliance. The Person Responsible (PR) subsequently provided evidence that all of the recommendations were implemented.
- 1.8. 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'.
- 1.9. 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 have been no serious (Grade A) incidents since the last inspection;
  - the centre has suitable procedures in place to continue to support patients.
- 1.10. The executive recommends the approval of the application to vary the centre's treatment and storage licence, extending the duration to 30 September 2021.
- 1.11. Centre 0070 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 panel noted that the executive also 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 treatments in response to Covid-19;
  - 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 licence, extending its duration to 30 September 2021, 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.

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### **3. Variation of Licensed Activities**

**3.1.** The panel noted that, until January 2015, the centre provided a full range of fertility services, including embryo testing. In 2016, the Person Responsible (PR) informed the HFEA that treatments offered at the centre were limited to partner insemination treatment.

**3.2.** The panel noted that the centre had been extensively refurbished, and the embryology laboratory decommissioned, albeit retaining embryo cryostorage facilities. Patients requiring treatment, involving the creation of embryos or the use of donor sperm, were to be treated at the London Women's Clinic, centre 0105, under a satellite agreement.

**3.3.** On 9 September 2016, the Executive Licensing Panel (ELP) agreed to the renewal of the centre's treatment and storage licence, but applied an additional condition to the licence issued, removing the licensing of activities involving the creation of embryos. It permitted storage and distribution - to allow embryo cryostorage and transport to centre 0105 for use in treatment to continue.

**3.4.** The panel noted that, on 9 March 2020, the PR submitted an application to vary the centre's licence to a treatment (insemination using partner / donor sperm) and storage licence. The PR has confirmed that all frozen embryos have now been transferred to centre 0105.

**3.5.** The panel noted that the centre currently undertakes the following activities:

- Sperm donor recruitment and selection
- Donor sperm procurement, processing, cryostorage and distribution
- Partner and donor insemination
- Egg donor recruitment and selection
- Satellite service with centre 0105 as the primary centre for all aspects of fertility treatment and egg donation.

**3.6.** The panel noted that, the PR has provided clarification, via email, to correct the errors noted in the submitted variation of licence application form. He has confirmed the centre will not be undertaking egg collections or egg freezing and they will be operating as a satellite centre to centre 0105.

**3.7.** The panel noted the inspectorate's recommendation to vary the centre's licence to a treatment (insemination using partner/donor sperm) and storage licence. If the ELP agree the licence variation, the inspectorate requested that the following additional condition is removed, as this type of licence does not allow these activities to be conducted:

a) The centre is not permitted to carry out the following activities

- Creation of embryos in vitro
- Procuring embryos
- Keeping embryos
- Processing embryos
- Placing any permitted embryo in a woman
- using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques.

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## 4. Decision

- 4.1.** The panel had regard to its decision tree. It was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.
- 4.2.** The panel endorsed the inspectorate's recommendation to vary the centre's licence to a treatment (insemination using partner/donor sperm) and storage, in accordance with Section 18A of the HFE Act 1990 (as amended). The panel also agreed to remove the additional condition, on the centre's current licence, as a treatment (insemination using partner/donor sperm) and storage licence does not allow these activities to be conducted.

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## 5. Chair's signature

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

### Signature



### Name

Clare Ettinghausen

### Date

22 June 2020

**Executive Summary for Executive Licensing Panel  
16 June 2020**

<b>Centre name</b>	The Bridge Centre
<b>Centre number</b>	0070
<b>Person Responsible</b>	Kamal Ahuja

**Licence variation to extend the duration of the centre's licence and the licence type**

**Background**

1. This is an application made by the Person Responsible (PR) under s18A(2)(a) of the HF&E Act 1990 for a variation to extend the duration of the centre's current Treatment and Storage licence (L/0070/20/b) by one year to expire on 30/09/2021. The clinic's licence was issued for a period of four years and if this variation is granted, the licence duration will be extended to five years. The background and reasons for this application are set out below.
2. In 2020 the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19).
3. In response to UK measures to contain and mitigate the spread of the virus, a decision was taken by the HFEA to suspend all inspections of licensed premises until 31 August 2020, at which point prevailing circumstances will need to be reviewed before a further decision is taken with regard to inspection activities. This is in line with other national regulators.
4. 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 taken with the agreement of the Authority.
5. 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).
6. The Bridge Centre was last inspected on 10 April 2018 and recommendations were made in relation to two 'other' areas of non-compliance.

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7. The PR provided evidence that the recommendations were implemented.
8. 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'.
9. The executive is satisfied that;
  - the PR has discharged his responsibility under section 17 of the Act;
  - the centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is in the process of applying to the executive to resume treatment services, in line with GD0014 Version 2;
  - the centre continues to manage the storage of gametes 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.
10. Until January 2015, the centre provided a full range of fertility services including embryo testing. In 2016, the PR informed the HFEA that treatments offered at the centre were limited to partner insemination treatment. The centre had been extensively refurbished, and the embryology laboratory decommissioned, albeit retaining embryo cryostorage facilities. Patients requiring treatment involving the creation of embryos or the use of donor sperm were to be treated at the London Women's Clinic, centre 0105, under a satellite agreement.
11. On 9 September 2016, the executive licensing panel agreed to the renewal of the centre's Treatment and Storage licence but applied an additional condition to the licence issued, removing the licensing of activities involving the creation of embryos. It permitted storage and distribution - to allow embryo cryostorage and transport to centre 0105 for use in treatment to continue.
12. On 9 March 2020, the PR submitted an application to vary the centre's licence to a Treatment (Insemination using partner / donor sperm) and Storage licence. The PR has confirmed that all frozen embryos have now been transferred to centre 0105.
13. The centre currently undertakes the following activities:
  - Sperm donor recruitment and selection

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- Donor sperm procurement, processing, cryostorage and distribution
- Partner and donor insemination
- Egg donor recruitment and selection
- Satellite service with centre 0105 as the primary centre, for all aspects of fertility treatment and egg donation.

14. The PR has provided clarification via email to correct the errors noted in the submitted variation of licence application form. He has confirmed that the centre will not be undertaking egg collections or egg freezing at The Bridge Centre and they will be operating as a satellite centre to centre 0105.

**Recommendation:**

The executive recommends the variation applications are granted to extend the duration of the centre's licence to 30/09/2021 and to vary the centre's licence to a Treatment (Insemination using partner / donor sperm) and Storage licence. If the licence type is varied, the executive requests that the additional condition **a)** The centre is not permitted to carry out the following activities:

- creation of embryos in vitro
- procuring embryos
- keeping embryos
- processing embryos
- placing any permitted embryo in a woman
- using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques.

is removed from the centre's licence. This is because a Treatment (Insemination using partner / donor sperm) and Storage licence does not allow for the licensed activities stated in the additional condition and therefore it would no longer be necessary.

Centre 0070 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.

Louise Winstone  
Inspector

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