Executive Licensing Panel Minutes

Centre 0105 (London Women's Clinic)

Variation of Licenced Premises

Date:	4 May 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Yvonne Akinmodun Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Human Resources Communications Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Niamh Marren	Licensing Manager Regulatory Policy 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. Background

1.1. The panel noted that the London Women's Clinic (LWC) is located in central London and has been licensed by the HFEA since 1992. The centre provides a full range of fertility services to patients, including embryo testing. LWC is part of a nationwide group of centres and has several satellite and transport centres.

1.2. The panel noted that, following a grade 'A' incident in 2012 a condition was placed on the centre's licence and remains in place today; the condition states 'To suspend the centre using donor sperm (this would apply to all clinics across the group) in relation to samples processed prior to the introduction of the electronic witnessing system in May 2010. If sibling stock is required and only available from sperm banked at that time (that is the donor cannot be contacted or declines to re-attend to provide further samples), the centre should document the risk analysis carried out (including verifying witnessing), provide careful counselling to the patient regarding the potential risk prior to obtaining the patient's consent and if the centre considers that these samples can be used safely then they could continue with that patient's treatment using those specific samples.'

1.3. The panel noted that, in the 12 months to 31 January 2021, the centre had provided 2554 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre. Closure of the fertility sector, in response to the Covid-19 pandemic, will have had an impact on activity levels.

1.4. The panel noted that the centre was due a renewal of licence inspection during the period of suspension of fertility treatments, due to Covid-19. In September 2020, the Person Responsible (PR) applied for a variation to extend the duration of the centre's current treatment (including embryo testing) and storage licence by one year. The centre's licence was initially issued for a period of three years; following the granting of the licence variation, the centre's licence duration was extended to four years.

1.5. The panel noted that the centre was last inspected on 18 February 2020 in response to an application made by the PR to vary the centre's premises; no recommendations were made in relation to areas of non-compliance at the inspection. The centre's last interim inspection was conducted on 29 January 2019 and recommendations were made to address three major non-compliances or areas of poor practice. The PR has provided evidence that all of those recommendations have been implemented.

1.6. The panel noted that the centre submitted an application, on 5 January 2021, to vary the centre's licence to reflect a change of premises as a major refurbishment of the centre's facilities was planned. The pre-implantation genetic screening (PGS) and andrology laboratory have been combined to make one larger laboratory, the current entrance to the cryo room has been replaced by a new entrance and a hatch has been opened between the andrology laboratory and andrology office with a view to converting the andrology office into a laboratory in the future. New equipment has also been installed.

1.7. The panel noted that in March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented. These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against

those resulting from potential non compliances, identified during DBA, if not adequately investigated.

1.8. The panel noted that, following the DBA/RBA for this centre, in February 2021, it was concluded that no items of concern were identified and the variation of premises inspection could be conducted by a DBA rather than an on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

2. Consideration of application

2.1. The panel considered the papers, which included an executive summary, application form and licensing minutes for the past four years.

2.2. The panel noted that, at the time of the of the DBA/RBA, conducted in February 2021, no areas of non-compliance were identified.

2.3. The panel noted that the information provided fulfils the requirements for this type of licence variation application, as defined in General Directions 0008.

2.4. The panel noted that, as a result of the UK's departure from the European Union (EU), a relicensing exercise 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 licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July, after the transition period ends on 30 June.

2.5. The panel noted that the inspectorate recommends the approval of the application to vary the centre's current licence, alongside the new varied licence that would supersede it on 1 July 2021, to reflect a change of premises due to a major refurbishment of the centre's facilities. The panel noted that the centre will be provided with a varied licence for immediate use until 30 June 2021, an updated EU exit licence will be sent to the centre, which will commence on 1 July 2021.

2.6. The panel noted that the existing condition on the licence, 'To suspend the centre using donor sperm (this would apply to all clinics across the group) in relation to samples processed prior to the introduction of the electronic witnessing system in May 2010. If sibling stock is required and only available from sperm banked at that time (that is the donor cannot be contacted or declines to re-attend to provide further samples), the centre should document the risk analysis carried out (including verifying witnessing), provide careful counselling to the patient regarding the potential risk prior to obtaining the patient's consent and if the centre considers that these samples can be used safely then they could continue with that patient's treatment using those specific samples' would remain.

3. Decision

3.1. The panel was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.

3.2. The panel was satisfied that the application fee was submitted to the HFEA in accordance with requirements.

3.3. The panel was satisfied that the premises are suitable for the conduct of licensed activities.

3.4. The panel endorsed the inspectorate's recommendation to vary the centre's licence to reflect a change of premises due to a major refurbishment of the centre's facilities; this licence will retain the existing condition and will be superseded from 1 July 2021, due to the relicensing exercise being conducted as a result of the UK's exit from the EU.

4. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

10 May 2021

Change of Premises Inspection Report

Centre name: London Women's Clinic
Centre number: 0105
Date licence issued: 29 March 2018
Licence expiry date: 28 March 2022
Additional conditions applied to this licence: To suspend the centre using donor sperm (this would apply to all clinics across the group) in relation to samples processed prior to the introduction of the electronic witnessing system in May 2010. If sibling stock is required and only available from sperm banked at that time (that is the donor cannot be contacted or declines to re-attend to provide further samples), the centre should document the risk analysis carried out (including verifying witnessing), provide careful counselling to the patient regarding the potential risk prior to obtaining the patient's consent and if the centre considers that these samples can be used safely then they could continue with that patient's treatment using those specific samples.

Date of inspection: February 2021
Inspectors: Polly Todd and Louise Winstone
Date of Executive Licensing Panel: 4 May 2021

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Inspections are also carried out when centres apply to vary their licence to change premises. The full inspection prior to a licence being granted, renewed or varied assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC)

This is a report of a change of premises inspection. The inspection was desk-based.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach

(RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

Following the DBA/RBA for this clinic, it was concluded that there were no items of concern and the inspection could be conducted via a desk-based assessment rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

Background

The London Women's Clinic (LWC) is located in central London and has been licensed by the HFEA since 1992. The centre provides a full range of fertility services to patients including embryo testing. LWC is part of a nationwide group of centres and has several satellite and transport centres.

Following a grade 'A' incident in 2012 a condition was placed on the centre's licence and remains in place today.

The centre provided 2554 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2021. Closure of the fertility sector in response to the Covid-19 pandemic will have had an impact on activity levels, but taking this into account, in relation to activity levels this is a large centre.

This centre was due a renewal of licence inspection during the period of suspension of fertility treatments. In September 2020, the Person Responsible (PR) applied for a variation to extend the duration of the centre's current Treatment (including embryo testing) and Storage licence by one year. The centre's current licence was issued for a period of three years and following the grant of the licence variation, the centre's licence duration was extended to four years.

The centre was last inspected on 18 February 2020 in response to an application made by the PR to vary the centre's premises. No recommendations were made in relation to areas of non compliance at that inspection. The centre's last interim inspection was on 29 January 2019. Recommendations were made to address three major non compliances or areas of poor practice. The PR has provided evidence that all of those recommendations have been implemented.

The centre submitted an application on 25 January 2021 to vary the centre's licence to reflect a change of premises as a major refurbishment of the centre's facilities was planned. The pre genetic screening (PGS) and andrology laboratory have been combined to make one larger laboratory, the current entrance to the cryo room has been replaced by a new entrance and a hatch has been opened between the Andrology laboratory and Andrology office with a view to converting the Andrology office into a laboratory in the future. New equipment has also been installed.

Summary for the Executive Licensing Panel

The inspection team considers that overall there is sufficient information available to recommend the variation of this centre's licence with the existing condition, to reflect the changes identified in this report.

As a result of the UK's departure from the EU, there is currently a relicensing exercise under way. This follows approval by the Licence Committee of a variation without application on 4 March 2021. This means that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July, after the transition period ends on 30 June.

Therefore, ELP is asked to approve this variation, for changes to the premises 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 variation requested in this paper set.

Details of desk-based assessment findings

1. Key documents were requested from the centre in support of the change of premises application assessment, to provide assurance that the premises and equipment in the proposed new facilities are suitable and satisfy the requirements of the Act in relation to the granting of a licence (HF&E Act 1990 (as amended) S16 (2)(d) and (e)). On the basis of this assessment, and as documented below, it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities.

    - Confirmation that the clinical spaces were designed to meet the requirements of the relevant health technical memoranda and health building notes has been provided.
    - Confirmation that planning permission or building regulations approval is not required for these alterations has been provided by the PR.
    - Confirmation of a fire safety risk assessment has been provided.
    - Confirmation that appropriate signage has been fitted at the entrances to the new room has been provided.
    - Security measures in place at the new premises, including those relating to storage of gametes and embryos and confidential records were considered to be suitable.
    - Documentation confirming that processing of gametes and embryos will take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality has been provided.
    - Confirmation of a deep clean of the laboratory has been provided.

2. The centre has suitable equipment. A full set of critical laboratory equipment sufficient to be able to perform licensed treatment is already in situ. Validation of this equipment was reviewed via a desk-based assessment and was considered complete.

3. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last interim inspection on 29 January 2019. The centre does not intend to change any activities or the type of licence and relevant standard operating procedures remain unchanged.

4. The centre has complied with the requirements of General Direction 0008 (section H 14) in submitting:
   - a relevant on-line application form;
   - a floor plan of the altered area to be referenced on the licence.

Areas of practice that require the attention of the Person Responsible

This section sets out matters which the inspection team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions (SLC), Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

‘Critical’ area of non compliance

A ‘critical’ area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A ‘critical’ area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
None identified.			

‘Major’ area of non compliance

A ‘major’ area of non compliance is a non-critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
None identified.			

‘Other’ areas of practice that requires improvement

Other areas of practice that requires improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
None identified.			

Additional information from the Person Responsible