Executive Licensing Panel - minutes

Centre 0098 (Lanarkshire Acute Hospital NHS Trust)

Variation of Licensed Premises

Tuesday, 7 April 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Helen Crutcher	Director of Strategy and Corporate Affairs Communications Manager Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
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. Background

1.1. The panel noted that Lanarkshire Acute Hospital NHS Trust is located in Airdrie and has held a licence with the HFEA since 1992. The centre provides basic fertility services and long-term sperm storage facilities, holding a treatment (insemination using partner/donor sperm) and storage licence. The centre currently does not provide treatments with donor sperm; however, this licence type is the most suitable for the centre's range of activities.

1.2. The panel noted that in 2019, the centre had provided 109 cycles of partner insemination, with five pregnancies. This represents a clinical pregnancy rate of 5%, which is likely to be in line with the national average.

1.3. The panel noted that the centre was last inspected on 12 March 2020 when a renewal inspection was performed. The report of this inspection is due to be considered by the Executive Licensing Panel (ELP) on 21 May 2020.

1.4. The panel noted that on 19 March 2020, a variation of licensed premises application was made by the Person Responsible (PR). The centre needs to move their storage facilities to a new area within the hospital. The current cryostore has been deemed to be inappropriate due to access difficulties for the delivery of liquid nitrogen. The new cryostore is located at ground level, away from clinical areas, as recommended by health and safety guidelines and is close to the stores area of the hospital and the dedicated drop off point for liquid nitrogen deliveries.

1.5. The panel noted that the inspector considered they have sufficient information drawn from documentation submitted by the centre, and further assurances from the PR regarding the safety and suitability of the premises, that the new cryostore room is suitable for the storage of gametes.

2. Consideration of application

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

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

2.3. The panel noted the inspectorate recommends the approval of the application to reflect a change of existing premises to incorporate a new cryostore.

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.

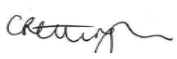
3.3. The panel was satisfied that the premises are suitable for the conduct of licensed activities.

3.4. The panel endorsed the inspectorate's recommendation to vary the centre's licence to reflect a change of existing premises, to incorporate a new cryostore.

4. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

16 April 2020

Licence Variation Application Report

Inspectors: Louise Winstone
Date of assessment: 19 March 2020
Date of Executive Licensing Panel: 7 April 2020
Purpose of report: Assessment of the centre's application to vary its licence to add another room to the licensed premises for use as a cryostore.

Centre details

Centre name	Lanarkshire Acute Hospital NHS Trust
Centre number	0098
Licence number	L/0098/16/a
Centre address	Infertility Department, Monklands Hospital, Monkscourt Avenue, Airdrie, Lanarkshire, ML6 0JS, United Kingdom.
Person Responsible (PR)	Seema Jain
Licence Holder (LH)	Iain Wallace (application to change LH currently in progress)
Date licence issued	1 July 2016
Licence expiry date	30 June 2020
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Lanarkshire Acute Hospital NHS Trust is in Airdrie and has held a licence with the HFEA since 1992.

The centre provides basic fertility services and long-term sperm storage facilities. The centre holds a treatment (insemination using partner/donor sperm) and storage licence. The centre currently does not provide treatments with donor sperm, however, this licence type is the most suitable for the centre's range of activities.

In 2019, the centre reported 109 cycles of partner insemination with five pregnancies. This represents a clinical pregnancy rate of 5%, which is likely to be in line with the national average.

The centre was last inspected on 12 March 2020 when a renewal inspection was performed. The report of this inspection is due to be considered at the ELP meeting on 21 May 2020.

On 19 March 2020, a variation of licensed premises application was made by the PR. The centre needs to move their storage facilities to a new area within the hospital. The current cryostore has been deemed to be inappropriate due to access difficulties for the delivery of liquid nitrogen. The new cryostore is located at ground level, away from clinical areas as recommended by Health & Safety guidelines and is close to the stores area of the hospital and the dedicated drop off point for liquid nitrogen deliveries.

On 2 February 2020, the centre submitted an application to change the Licence Holder from Dr Iain Wallace to Dr Jane Burns. This application will be considered as part of the licence renewal process.

Summary for licensing decision

In considering overall compliance, the inspector considers that they have sufficient information drawn from documentation submitted by the centre and further assurances from the PR regarding the safety and suitability of the premises to conclude that:

- the new cryostorage room is suitable for storing gametes;
- the practices used for storing gametes are suitable;
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, for variation of their licensed premises.

The ELP is asked to note that there are no areas of practice that require improvement.

Recommendation to the Executive Licensing Panel

The executive recommends that the application to vary the licence to reflect a change of existing premises to incorporate a new cryostore is approved.

Details of assessment findings

The licence variation application

An application was submitted by the PR at centre 0098 on 19 March 2020 to vary the centre's licence to reflect a change of premises, specifically the addition of a new cryostore.

The new cryostore room is needed because the centre's current cryostore has been deemed unsuitable for use due to the difficulties with delivering liquid nitrogen.

The applicant has complied with all the requirements of General Direction 0008 H (14) in submitting at the time of application or on request thereafter:

- an application form;
- a floor plan showing the new cryostore;
- confirmation that once the dewars have been moved, evidence will be provided that the equipment used to provide gamete storage in the room has been validated.

Details of the inspection findings

1. Key documents were provided by the centre in support of the change of premises application, 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)).

2. On the basis of the submitted application and supporting information, it was concluded that the new cryostore is compliant with requirements because:
    - A floor plan has been provided detailing the room's location.
    - The room is secure and access to it is limited to specific members of the laboratory team authorised by the PR.
    - The room has been refurbished to meet the requirements of the relevant health technical memoranda and health building notes.
    - The room has been fitted with appropriate safety signage.
    - The room has been equipped with an appropriate and validated oxygen monitoring system, with displays and alarms inside and outside the room, and a boosted extraction system to clear any nitrogen spillages.
    - The dewars and dewar temperature monitoring system have been validated and will be re-validated when the move has taken place.
    - The centre's critical processes related to cryopreservation are not affected by the introduction of this new cryostore to the licensed premises.
    - The PR has advised that standard operating procedures have been reviewed and updated where necessary.
    - Staff using the new cryostore room have had appropriate induction and training to allow them to use the room safely.

3. In summary, based on the inspector's assessment of the application and as detailed above, the inspector concludes that the centre's new cryostore is suitable for the conduct of licensed activities, specifically gamete storage.

4. No areas of practice required improvement.

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, 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 to a 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 to a 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

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