Executive Licensing Panel Minutes

Centre 0021 (Hull IVF Unit)

Research Project Number R0067

Variation of Licenced Premises

Change of Centre Name

Date:	7 September 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Richard Sydee (Chair) Dina Halai Helen Crutcher	Director of Finance and Resources Acting Head of Policy Risk and Business Planning Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Annabel Salisbury	Licensing Manager Policy Officer - Induction

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 that Hull IVF Unit is licensed to provide treatment and storage services and is also licensed for research project R0067 entitled 'Biochemistry of early human embryos'. Project R0067 was first licensed in 1995.

1.2. The panel noted that the variation to change the premises, and centre name, for the treatment and storage licence, is also for consideration at the meeting.

1.3. 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.

1.4. The panel noted that licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. Inspections are also conducted 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). 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.

1.5. The panel noted that project R0067 was last inspected, on-site, in August 2019; no non-compliances were identified. As the licence for this project expires in January 2022, a renewal inspection is due to be conducted in the next two months.

1.6. The Person Responsible (PR) submitted a licence variation application on 1 July 2021 to change the address of the licenced premises to the following:

Hesslewood Business Park
Ferriby Road
Hessle
East Yorkshire
HU13 0JA

1.7. The panel noted that, following a DBA, an on-site inspection occurred at the centre on 5 August 2021, during which the PR confirmed that they will be changing the centre's name and making a small amendment to the new premises address. These changes are not correctly documented on the licence variation application form, initially submitted by the clinic and provided with the report, but have been confirmed by the centre on the email provided in the papers.

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, at the time of inspection, two major areas of non-compliance were identified concerning the suitability of premises and equipment. There were also two 'other' areas of non-compliance regarding staff and the Quality Management System (QMS). Since the inspection, the PR has implemented the recommendations concerning staff. The PR has provided a commitment to implementing the recommendations surrounding the suitability of premises, equipment and the QMS.

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 the inspectorate recommends the approval of the application to vary the licence to reflect the change of premises to the following address, subject to the recommendations in the report being implemented before any licenced activity commences:

Hesslewood Business Park
Ferriby Road
Hessle
East Yorkshire
HU13 0JA

2.5. The panel noted that should the application for a change of premises be approved, it is requested that the new licence should be deferred to commence on 27 September 2021.

2.6. The panel noted that, assuming this application is approved, there will be a period of time after the licence is varied, when the centre will need to store research embryos at the centre's 'old' premises at Hull and East Yorkshire Women and Children's Hospital, Hull Royal Infirmary, Anlaby Road, Hull, HU3 2JZ. A Special Direction has therefore been requested by the PR, to be in force from the 27 September 2021, for three months; this will allow storage of research embryos at the 'old' premises until they are moved to the new premises. The executive considered the storage facilities at the 'old' premises to be suitable at the last inspection and note that satisfactory arrangements have been made by the PR for their on-going security and suitability during the term of the Special Direction. It is recommended therefore that the Executive Licensing Panel (ELP) approve this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended).

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 premises are suitable for the conduct of licensed activities.

3.3. The panel endorsed the inspectorate's recommendation to change the centre's licensed premises, subject to the recommendations made in the report being implemented, to:

Hesslewood Business Park
Ferriby Road
Hessle
East Yorkshire
HU13 0JA

3.4. The panel endorsed the inspectorate's recommendation to issue a Special Direction, commencing from 27 September 2021, for a period of three months, to enable research embryos to be to be stored at the centre's old premises at Hull and East Yorkshire Women and Children's Hospital, Hull Royal Infirmary, Anlaby Road, Hull, HU3 2JZ.

4. Change of Centre Name - Consideration of Application

4.1. The panel noted that the name is presently **Hull IVF Unit** and the centre now wishes to be known as **Hull & East Riding Fertility.** The PR has therefore submitted a confirmation email, clarifying the centre's new name.

4.2. The panel noted the inspectorate's recommendation to approve the variation of licence to change the centre's name.

5. Decision

5.1. After considering the recommendation of the inspectorate and all supporting documentation, the panel changed the name of the centre to **Hull & East Riding Fertility**.

6. Chair's signature

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

Signature

Name

Richard Sydee

Date

13 September 2021

Change of Research Premises Inspection Report

Centre name: Hull IVF Unit
Centre number: 0021
Date licence issued: 1 February 2019
License expiry date: 31 January 2022
Additional conditions applied to this licence: None
Date of Inspection: 5 August 2021
Inspectors: Sara Parlett (lead); Polly Todd; Mhairi West (desk-based assessment (DBA))
Date of Executive Licensing Panel: 7 September 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 and must, by law, be inspected every two years. 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 a combination of a desk based assessment and an on-site inspection.

Background

Hull IVF Unit is licensed to provide treatment and storage services and is also licensed for research project R0067: Biochemistry of early human embryos. The project was first licensed in 1995.

The project's licence was last renewed by licence committee in 2018, after a desk based assessment. The project was last inspected on site in August 2019 and no non compliances were noted. The licence is due to expire in January 2022 and therefore the clinic will be due a renewal inspection in the next two months.

The current licence has been varied to reflect the following change:

- 4 March 2021 - all centres: Variation of all licences without application (European Union (EU) Exit requirements).

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.

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). 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.

The centre submitted an application on 1 July 2021 to vary its licence to change premises.

Following discussions at the onsite inspection the centre also confirmed that they will be changing the centre's name and making a small amendment to the new premises address. These changes are not documented on the variation application form submitted by the clinic and provided with this report but have been confirmed by the centre. The email confirmation is included in the paper set.

An application to change the premises for the centre's treatment and storage licence is also being considered by this ELP alongside this application and report.

Summary and recommendations for the Executive Licensing Panel

The ELP is asked to note that at the time of the inspection there were four areas of practice that required additional work to avoid two major and two 'other' non compliances, should licence activity commence without correction.

The PR has implemented the following recommendation:

'Other' areas of non-compliance:

- The PR should ensure that all staff complete an induction and relevant training for the new premises.

The PR has committed to implementing the following recommendations:

Major areas of non-compliance:

- The PR must ensure that the premises are suitable for licensed activities.
- The PR must ensure that suitable equipment is in place.

'Other' areas of non-compliance:

- The PR should ensure that all relevant standard operating procedures (SOPs) are updated to reflect differences resulting in moving to new premises.

The executive recommends that the centre's request to vary the current research licence to reflect a change of the centre's name is approved.

The executive notes that the centre's new name will be:
Hull and East Riding Fertility.

The executive recommends that the application to vary the current research licence to reflect a change of premises is approved, subject to the recommendations made in this report being implemented before any licenced activities take place. The variation, if granted should be deferred until 27 September 2021 to align with the granting of the Special Direction.

The executive notes that the new address of the centre will be:
Hull and East Riding Fertility
Hesslewood Business Park
Ferriby Road
Hessle
East Yorkshire
HU13 0JA

Assuming the ELP approves this application, there will be a period of time after 27 September 2021 when the centre will need to store research embryos at the centre's 'old' premises at Hull and East Yorkshire Women and Children's Hospital, Hull Royal Infirmary, Anlaby Road, Hull, HU3 2JZ.

A Special Direction has therefore been requested by the PR to be in force from 27 September 2021 for three months, to allow storage of research embryos at Hull IVF Unit, Hull and East Yorkshire Women and Children's Hospital, Hull Royal Infirmary, Anlaby Road, Hull, HU3 2JZ. The executive considered the storage facilities at these premises to be suitable at the last inspection and note that satisfactory arrangements have been made by the PR for their on-going security and suitability during the term of the Special Direction. It is recommended therefore that the ELP approve this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended).

Details of Inspection 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 completion of the desk based assessment of these documents, a site visit was conducted on 5 August 2021. On the basis of these assessments, and as documented below, it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities, with exceptions noted at point 4.
    - Confirmation that the research spaces were designed to meet the requirements of the relevant health technical memoranda and health building notes has been provided.
    - Confirmation of the building completion certification/sign off issued by the contractor to the centre was provided.
    - confirmation of a fire safety inspection was provided and will be updated with a fire risk assessment once the new premises are in use (see recommendation 1);
    - security measures in place at the new premises, including those relating to stored research donated embryos and confidential research records were inspected during the visit and were considered to be suitable;

2. The centre does not yet have suitable equipment in situ. Some equipment has been purchased of which the centre is awaiting delivery and additional equipment will be moved from the current to the new premises by a specialist company on 26 September 2021. The PR has confirmed that all critical equipment will be fully tested and assessed as suitable before human embryo research takes place (see recommendation 2).

3. Testing and re-validation of the dewars and related monitoring alarms will be undertaken by the centre when they have been transferred from the current to the new premises (see recommendation 2)

4. Some evidence is still outstanding, as detailed below. This evidence will need to be provided before the proposed new premises can be deemed as suitable for the conduct of licensed activities. Following the move, and prior to licensed research activity commencing at the new premises, the PR has agreed to confirm the following that;
   - gases used during the culture of embryos for research purposes are moved to a more secure location and the relevant change of location is reflected on the floor plan (see recommendation 1);
   - all safety signage, compliant with relevant Health Technical Memorandum (HTM), is in situ where gases used during the culture of embryos for research purposes are stored (see recommendation 1);
   - all relevant research SOPs will be updated to reflect physical differences in premises (see recommendation 3).
   - staff induction to the new premises has been undertaken (see recommendation 4).

5. Embryonic stem cells for human application are not derived and therefore the relevant research licence conditions requiring equipment validation (R53-54) do not apply.

6. 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 premises to be referenced on the licence;
   - A fee was not required for this application.

Section 5: Areas of practice that require the attention of the person responsible

The 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 direct risk of causing harm to a patient, donor or to an embryo. 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 or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- 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" area 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
1.Suitability of premises: The premises were considered unsuitable because: • the compressed gas storage area is a temporary location and is not suitably secure; • the compressed gas storage areas have not yet been fitted with appropriate safety signage, compliant with relevant HTM. Once the new centre has been in operation for the required period, a fire risk assessment is required. SLC R10.	The PR must ensure that the premises are suitable for licensed activities and should provide the following to the centre's inspector before licensed activity commences: • confirmation that compressed gases have been moved to a more secure location and relevant floor plans have been changed to reflect the new location; • confirmation that all safety signage, compliant with relevant HTM, is in situ where compressed gases are being stored. The PR should undertake a fire risk assessment once the centre is occupied and in use. Evidence of this should be	Medical gases have been relocated. The architect has ammended the floor plans accordingly. Secure doors (wooden, bolted and padlocked, but with ventilation spaces at the top and bottom), sensor activated lighting and CCTV have been fitted. Bottles are secured to the wall and protected from direct sunlight/elements. The area/ compound for storage of deliveries / returns has been fitted with a lock and has CCTV. All relevant signage has been ordered. A general health & safety inspection and fire safety	The inspection team acknowledges the PR's response and prompt actions towards making the premises suitable for licenced activities. The inspection team confirms receipt of evidence confirming that medical gases have been moved to a more secure location and this has been reflected on the floor plan. The inspection team awaits confirmation of: • installation of appropriate safety signage; • completion of fire safety and general health and safety inspections. Further action required.

	provided to the centre's inspector by 6 November 2021.	inspection has been arranged and will be carried out when the Unit is operational.	
2. Equipment: The centre does not yet have suitable equipment in situ. SLC R10.	The PR must ensure that suitable equipment is in place. The PR should provide confirmation to the centre's inspector that all critical equipment has been fully tested and assessed as suitable before human embryo research takes place.	Equipment is due for delivery & installation w/c 23/08/21 The validation schedule includes testing and revalidation of critical equipment and monitoring devices - evidence will be provided once scheduled relocation has been completed.	The inspection team acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

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 good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Quality management system (QMS): Several research SOPs have not been updated to reflect physical differences in premises.	The PR should ensure that all relevant research SOPs are updated to reflect differences resulting in moving to new premises. The PR should provide confirmation that all relevant SOPs have been reviewed and amended as required by 6 November 2021.	SOPs have been updated with relevant information from the O&Ms. Information on changes in the flow of processes is still in draft format pending 'operation run throughs'/ senario testing with each team. SOPs will be submitted as requested.	The inspection team acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond a request by the centre's inspector for a selection of SOPs to be submitted by 6 November.
4. Staff: Staff induction to the new premises had not been undertaken at the time of the inspection.	The PR should ensure that all staff complete an induction and relevant training for the new premises. Evidence of this should be provided to the centre's inspector before any licensed activity takes place.	A staff induction checklist has been prepared to orientate staff with the new systems and SOPs have been updated with the relevant information from the building operation and maintenance manuals	The inspection team acknowledges the PR's response and confirms receipt of evidence that staff have had training and induction into the new premises. No further action required.

Additional information from the person responsible
Once the new preimises are opertaional, the existing PR and NL will undertake a full informal inspection to confirm that the Unit meets the expected requirements and suitable for activity.