Executive Licensing Panel Minutes

Centre 0021 (Hull IVF Unit)

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 currently located in Hull Royal Infirmary and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services.

1.2. The panel noted that the centre also holds a research licence (R0067); the application to change the premises and name, for this licence, were also for consideration at the meeting.

1.3. The panel noted that, in the 12 months to 31 May 2021, the centre had provided 553 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium sized centre.

1.4. 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.

1.5. 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.

1.6. The panel noted that the centre was last inspected on 11 February 2021, when a renewal inspection was performed by DBA and the use of virtual technology. Recommendations were made to address two major and two 'other' non compliances; an application to change the Person Responsible (PR) was also considered by the Executive Licensing Panel (ELP) at this time. The newly appointed PR has provided evidence that all the recommendations have been implemented.

1.7. The PR submitted a licence variation application, on 9 June 2021, to change the address of the licenced premises to the following:

Hesslewood Business Park
Ferriby Road
Hessle
East Yorkshire
HU13 0JA

1.8. 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 this report, but have been confirmed by the centre on an 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, three major areas of non-compliance were identified concerning the suitability of premises, equipment and air quality. There were also two 'other' areas of non-compliance regarding staff and the Quality Management System (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 all 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. The recently approved renewal licence, commencing on 1 October, should also be amended to reflect the change of premises.

2.6. The panel noted that, if this application is approved, there will be a period of time after the licence is varied, when the centre will need to store gametes and 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; this will allow storage of gametes and 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 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 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 change the centre's licensed premises, with effect from 27 September 2021, subject to all the recommendations made in the report being implemented, to:

Hesslewood Business Park
Ferriby Road
Hessle
East Yorkshire
HU13 0JA

3.5. The panel endorsed the inspectorate's recommendation that the recently approved renewal licence, commencing on 1 October, should also be amended to reflect the change of premises.

3.6. 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 gametes and embryos 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 Premises Inspection Report

Centre name: Hull IVF Unit
Centre number: 0021
Date licence issued: 1 October 2017
Licence expiry date: 30 September 2021
Additional conditions applied to this licence: None
Date of inspection: 5 August 2021
Inspectors: Polly Todd (lead); Mhairi West (desk-based assessment (DBA)); Sara Parlett (onsite inspection)
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 currently located in Hull Royal Infirmary and has been licensed by the HFEA since 1992. The centre provides a full range of fertility services to patients.

The centre provided 553 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2021. In relation to activity levels this is a medium centre.

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 was last inspected on 11 February 2021 when a renewal inspection was performed by DBA and the use of virtual technology. Recommendations were made to address two major and two 'other' non compliances and at the same time an application to change the Person Responsible (PR) was considered by the committee. The newly appointed PR has provided evidence that all of these recommendations have been implemented.

The centre submitted an application on 9 June 2021 to vary its licence to change premises.

Following discussions at the onsite inspection, 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 documented on the licence 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.

Hull IVF Unit also holds a research licence (R0067) and the variation to change the premises for the research licence are also being considered by this ELP alongside this report.

Summary and recommendations for the Executive Licensing Panel

The ELP is asked to note that at the time of the inspection there were five areas of practice that required additional work to prevent three major and two 'other' areas of non-compliance should licensed activity commence without the work being undertaken. These have resulted in 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.
- The PR should ensure that the processing of gametes and embryos takes place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality.

'Other' areas of non-compliance:

- The PR should ensure that all staff complete an induction and relevant training for the new premises.
- 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 licence (L0021/14/c) and the centre's recently issued renewal licence (L0021/15/a) 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 licence (L0021/14/c) and the centre's recently issued renewal licence (L0021/15/a) 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 gametes and embryos at the centre's 'old' premises at Hull IVF Unit, 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 gametes and 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).

Centre 0021 has not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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 5.
    - 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 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 storage of gametes and embryos and confidential records were inspected during the visit and were considered to be suitable;
    - privacy, comfort and confidentiality for patients have been considered in the planning of the new premises. Designated counselling, scanning, consulting and male production rooms are available and appear fit for purpose.

2. The centre does not yet have suitable equipment in situ. Some equipment has been purchased of which the centre is awaiting delivery. Additional equipment will be moved from the current to the new premises by a specialist company on 26 September 2021. External suppliers will re-validate this equipment in the week commencing 27 September 2021 (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 premises to the new premises (see recommendation 2).

4. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection on 11 February 2021. The centre does not intend to change any activities or the type of licence. Some of the relevant SOPs have yet to be updated to reflect physical differences in premises (see recommendation 5).

5. 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 activity commencing at the new premises, the PR has agreed to confirm the following;

- all impervious easy clean floors and walls are sealed in clinical areas (see recommendation 1);
- medical gases are moved to a secure location and the relevant change of location reflected on the floor plan (see recommendation 1);
- all safety signage, compliant with relevant Health Technical Memorandum (HTM) is in situ where medical and compressed gasses are being stored (see recommendation 1);
- sinks with taps and soap dispensers allowing hands free use are in situ in all clinical areas (see recommendation 1);
- suitable sedation equipment for the care of patients undergoing surgical procedures has been installed (see recommendation 2);
- suitable cupboards for the safe custody of controlled drugs have been installed (see recommendation 2);
- testing and re-validation of the dewars and the associated alarms has been undertaken once the cryostore has been moved to the new premises (see recommendation 2);
- emergency resuscitation equipment has been installed (see recommendation 2);
- 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 (see recommendation 3);
- confirmation of a deep clean prior to laboratory work starting will be provided before licensed activities start and is scheduled for the week commencing 30 August 2021 (see recommendation 3);
- staff induction to the new premises has been undertaken (see recommendation 4);
- all relevant standard operating procedures (SOPs) will be updated to reflect physical differences in premises (see recommendation 5).

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.
   - the centre has paid the required application fee to the HFEA

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 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	Inspection team’s response to the PR’s statement
None identified		n/a	

‘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	Inspection team’s response to the PR’s statement
1.Suitability of premises: The premises are not currently suitable for the proposed licensed activity because: • impervious, easy clean floors and walls in clinical areas are not yet sealed; • the medical gases storage area is a temporary location and is not suitably secure; • the medical and compressed gases storage areas have not yet been fitted with appropriate safety signage, compliant with relevant HTM; • sinks with taps and soap dispensers allowing hands	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 all impervious, easy clean floors and walls are sealed in clinical areas; • confirmation that medical 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 medical and	1. A full audit has been carried out and the areas identified have been sealed and checked. 2. Medical gases have been relocated. The architect has amended the floor plans. 3. 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 chained to the wall and protected from direct sunlight/ elements. The compound for storage of deliveries / returns has been fitted with a lock and has	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: • confirmation that sinks with taps allowing hands free use have been installed; • evidence confirming that medical gases have been moved to a more secure location and this has been reflected on the floor plan; • evidence confirming that floors and walls in

free use have yet to be installed in all clinical areas. • A fire safety inspection has been undertaken but a fire risk assessment has not yet been completed as the centre is not yet active. SLC T17.	compressed gases are being stored; • confirmation that sinks with taps and soap dispensers allowing hands free use are in situ in all clinical areas. Thereafter, the PR should undertake a fire risk assessment once the centre is occupied and in use. Evidence of this should be provided to the centre's inspector by 6 November 2021.	CCTV. 4. All relevant signage has been ordered. 5. Replacement taps have been ordered and soap dispensors ordered and due for delivery wk/c 31/08/21. 6. A general health & safety inspection and fire safety inspection have been booked for once the Unit is operational.	clinical areas have been sealed; the inspection team awaits confirmation of: • installation of appropriate safety signage; • installation of compliant soap dispensers; • completion of fire safety and general health and safety inspections. Further action required.
2. Equipment: The following issues were noted on inspection: • suitable sedation equipment for patients undergoing surgical procedures has not yet been installed; • a suitable cupboard for the safe custody of controlled drugs has not yet been installed; • emergency resuscitation equipment has not yet been installed at the centre.	The PR must ensure that suitable equipment is in place. The PR should provide confirmation to the centre's inspector, that emergency resuscitation equipment and all necessary equipment required to undertake safe sedation of patients is in place before any licensed activity takes place. The PR should ensure that a suitable cupboard is in place, compliant with Home Office requirements, for the safe	1. Equipment is due for delivery & installation wk/c 23/08/21 2. Resuscitation equipment is due for installation wk/c 27/09/21 3. Controlled drugs cupboard is being installed and home office inspection on 25/08/21. Details / evidence will be submitted accordingly. 4. The validation schedule includes testing and	The inspection team acknowledges the PR's response and commitment to implementing this recommendation and confirms receipt of: • evidence showing that a controlled drugs cupboard is in situ. The inspection team awaits confirmation of: • installation of suitable sedation and emergency resuscitation equipment; • that a Home Office

The testing and re-validation of the dewars, relevant critical equipment and related monitoring alarms has yet to be undertaken as they have not yet been transferred from the current to the new premises. SLC T24; T25.	custody of controlled drugs. Evidence of this should be provided to the centre's inspector before any licensed activity takes place. The PR should provide confirmation that the testing and re-validation of the dewars, relevant critical equipment and related monitoring alarms has taken place once they have been transferred to the new premises. A sample of several validation documents will be requested for review by the centre's inspector. This must be provided to the centre's inspector before any licensed activity takes place.	revalidation of critical equipment and monitoring devices - evidence will be provided once scheduled relocation has been completed.	inspection has been completed; • evidence of testing and revalidation of critical equipment. Further action required.
3. Air quality: The centre has not yet assessed air quality in the critical work areas or backgrounds, so could not confirm that processing of gametes and embryos will take place in an environment of at least Grade C air quality,	The PR should ensure that the processing of gametes and embryos takes place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality. The PR should provide	1. The air handling unit (AHU) has been designed to meet all relevant HTMs. All commissioning certificates have been received and reviewed, including but not limited to duct volume and velocity testing, grille/ diffuser balance test, fan drive,	The inspection team acknowledges the PR's response and commitment to implementing this recommendation and confirms receipt of: • commissioning certificates for the air handling unit and Hepa

with a background of at least Grade D air quality. The laboratory and clinical areas have also not yet been deep cleaned to ensure air quality and infection control requirements can be met. SLCs T17 and T20.	evidence of this to the centre's inspector before any licensed activity takes place. The PR should provide confirmation to the centre's inspector that a deep clean has been completed before any licensed activity takes place.	pressue differentials between rooms, particle distribution and temperature. A certificate of pressure test has been provided. The ductwork supply and extract of the ventilation system have been inspected and cleaned to TR19/BS EN 15780 standard and certification provided. Validair and Stockton QC will each independently verify the air quality against GMP standards and EUTD requirements (on the 03/09 and 15/09 respectively after all equipment has been installed and the laboratory and clinical areas have been deep cleaned). Reports containing particle counts, VOC levels and microbial results from settle plates and active air will be submitted once available	Filter certificates. The inspection team awaits receipt of: • confirmation that a deep clean has taken place before any licensed activity takes place. 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 statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
4. Staff: Staff induction to the new premises had not been undertaken at the time of the inspection. SLC T15.	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.	Team leaders have received initial staff training for building operation including; local AC operation, location of distribution boards, emergency lighting, fire alarm, nurse call, disabled refuge, interlocking door system, Building Management System, plant room (gas, water, AHU), access control system, security alarm and panic alarm. 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 Operation and Maintenance manuals (O&Ms).	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.

5. Quality management system (QMS): Several SOPs have not been updated to reflect physical differences in premises. SLC T33(b).	The PR should ensure that all relevant 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. A sample of several SOPs will be requested by the centre's inspector for review and should be provided by 6 November 2021.	SOPs have been updated with relevant information from the O&Ms. Information on changes in process flow is still in draft format pending 'operation run throughs'/ scenario 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.

Additional information from the Person Responsible