Executive Licensing Panel Minutes

Centre 0382 (Aria Fertility)

Initial Inspection Report – Treatment (including embryo testing) and Storage Licence

Date:	9 February 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Laura Riley Anna Coundley	Director of Strategy and Corporate Affairs Head of Regulatory Policy Policy Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Nora Cooke-O'Dowd	Licensing Manager Head of Intelligence

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. Aria Fertility is located at:

8 Welbeck Way
Marylebone
London
W1G 9YL

1.2. The proposed Person Responsible (PR), Dr Cristina Hickman, submitted an application for a treatment and storage licence in October 2020: since this time, the proposed PR has confirmed that she meant to apply for a treatment (including embryo testing) and storage licence.

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, a decision was taken by the HFEA to suspend all inspections at least until November 2020, after which prevailing circumstances will be reviewed on a case by case basis before a decision is taken with regard to inspection activities.

1.4. The panel noted that a revised inspection methodology was subsequently adopted to take into consideration measures to contain and mitigate the spread of the virus. These methods enable compliance to be reviewed through desk-based assessment (DBA) of documents submitted by the centre as well as the use of live video technology where available and appropriate. A risk-based approach (RBA) is then applied, balancing the risks of on-site inspection against those resulting from potential non compliances, identified during DBA, not being adequately investigated.

1.5. The panel noted that an on-site inspection was planned for January 2021, but in view of the ongoing Covid-19 pandemic the executive determined that for this proposed new centre, issues identified during the DBA/RBA were of relatively low risk and could be effectively reviewed using videoconferencing technologies rather than an on-site inspection. This is in keeping with the requirements of the HF&E Act 1990 (as amended) and removed potential risks to staff and patients associated with HFEA inspectors attending the clinic for an on-site inspection during the Covid-19 pandemic. The proposed PR agreed with this decision.

1.6. The panel noted that the DBA and videoconference call with key staff, for this application, was conducted on 8 January 2021. An on-site inspection will be performed when current restrictions relating to the pandemic have been eased.

2. Consideration of Application

2.1. The panel noted that at the time of the virtual inspection, the centre had five ‘other’ areas of non-compliance in relation to screening of donors, premises and facilities, laboratory accreditation, egg sharing arrangements and pre-operative assessment and the surgical pathway.

2.2. The panel noted that the inspection report was provided to the proposed PR on 25 January 2021 and she provided her responses on 26 January 2021; the non-compliances concerning premises and facilities, alongside the pre-operative assessment and the surgical pathway have been fully addressed. The proposed PR committed to fully implementing the remaining non-compliances regarding the screening of donors, laboratory accreditation and egg sharing

arrangements, providing additional evidence to the centre's inspector. Further information was provided by the PR, on the outstanding actions, on 26 January 2021; due to the timescales for submission of papers to this meeting, the executive has been unable to review this information provided and will liaise with the proposed PR once this evidence has been assessed.

2.3. The panel noted that the proposed PR, Dr Cristina Hickman, has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HFE Act 1990 (as amended) section 16(2)(c)(i) and (ii) (including acting in the capacity of PR). The proposed PR has successfully completed the HFEA PR Entry Programme.

2.4. The panel noted the suitability of the proposed Licence Holder (LH), Mr Stuart Lavery.

2.5. The panel noted the suitability of the premises for the conduct of licensed activities.

2.6. The panel noted that the inspectorate considered that there is sufficient information available to recommend:

- the appointment of the proposed PR;
- the appointment of the proposed LH;
- the grant of a treatment (including embryo testing) and storage licence for a period of two years, with an interim inspection in one year, subject to the implementation of the recommendations made in the report.

3. Decision

3.1. The panel referred to its decision tree.

3.2. The panel was satisfied that the appropriate application form was submitted.

3.3. The panel noted that the inspectorate had received the supporting information required by General Directions 0008 and was satisfied that the fee had been paid.

3.4. The panel was satisfied that the proposed PR, Dr Cristina Hickman, will discharge her duty under section 17 of the HFE Act 1990 (as amended). The panel agreed to appoint Dr Cristina Hickman as the Person Responsible when the new licence comes into effect, in accordance with section 18A of the HFE Act 1990 (as amended).

3.5. The panel was satisfied with the suitability of the proposed LH, Mr Stuart Lavery. The panel agreed to appoint Mr Stuart Lavery as the Licence Holder when the new licence comes into effect.

3.6. The panel was satisfied that the premises to be licensed are suitable for the conduct of licensed activities based on the evidence provided within the report.

3.7. The panel was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

3.8. The panel referred to 'guidance on periods for which new or renewed licences can be granted' which states that an initial treatment/storage/non-medical fertility services licence would normally be granted for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence.

3.9. The panel agreed to grant the licence for treatment (including embryo testing) and storage for a period of two years with no additional conditions, subject to all the recommendations made in the report being fully addressed. The panel agreed that if no representations or any other information is received within 28 days, the final licence should be issued.

4. Chairs signature

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

Signature

Name

Clare Ettinghausen

Date

15 February 2021

Initial Licence Report

Purpose of the Inspection Report

This is a report of an assessment and inspection, carried out to determine whether an application for a new licence will meet essential requirements. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 8 January 2021

Purpose of inspection: Application for a new 'Treatment (including embryo testing) and storage' licence.

Inspection details: The report covers the findings from a desk-based assessment of submitted documentation, the inspection (via videoconferencing) and communications received from the centre.

Inspectors: Grace Lyndon (lead) and Karen Conyers

Date of ELP: 9 February 2021

Centre name	Aria Fertility
Centre number	0382
Centre address	8 Welbeck Way, Marylebone, London W1G 9YL
Proposed Person Responsible	Dr Cristina Hickman
Proposed Licence Holder	Stuart Lavery

Contents

Section 1: Summary report

Brief description of the centre:
Aria Fertility clinic is a private centre located in Marylebone, London. The proposed Person Responsible (PR) has submitted an application for an initial licence for 'Treatment and storage', however she has confirmed that this was an error and that she wishes to apply for a licence to carry out 'Treatment (including embryo testing) and storage'.

The centre will provide a full range of fertility services.

Centre's anticipated activity levels:

Type of treatment	Maximum number of proposed treatment cycles
In vitro fertilisation (IVF)	1500
Intracytoplasmic sperm injection (ICSI)	
Frozen embryo transfer (FET)	
Donor insemination (DI) and Partner insemination IUI(P)	500
Pre-implantation genetic diagnosis / screening (PGD/S)	300

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

Summary for licensing decision

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, a decision was taken by the HFEA to suspend all inspections at least until November 2020, after which prevailing circumstances will be reviewed on a case by case basis before a decision is taken with regard to inspection activities. A revised inspection methodology was subsequently adopted to take into consideration measures to contain and mitigate the spread of the virus. These methods enable compliance to be reviewed through desk-based assessment (DBA) of documents submitted by the centre as well as the use of live video technology where available and appropriate. A risk-based approach (RBA) is then applied, balancing the risks of on-site inspection against those resulting from potential non compliances, identified during DBA, not being adequately investigated.

This application was received in October 2020. As on-site inspections were not taking place at that time, a DBA was initiated, and evidence (document and photographs) was provided by the centre over an extended period. An on-site inspection was planned for 8 January 2021.

Paragraph 2(1) of Schedule 3B of the HF&E Act 1990 (as amended) provides that:
'*Where a person –*

> *(a) makes an enquiry to the Authority which concerns the making of a relevant application by that person, or*
> *(b) has made a relevant application to the Authority which the Authority has not yet considered,*
> *the Authority may arrange for a duly authorised person to inspect any of the premises mentioned in sub-paragraph (3).*'

The use of the word 'may' indicates that it is at the Authority's discretion whether to perform an on-site inspection.

In view of the ongoing Covid-19 pandemic the executive determined that for this proposed new centre, issues identified during the DBA/RBA were of relatively low risk and could be effectively reviewed using videoconferencing technologies rather than an on-site inspection. This is in keeping with the requirements of the HF&E Act 1990 (as amended) and removed potential risks to staff and patients associated with HFEA inspectors attending the clinic for an on-site inspection during the Covid-19 pandemic. The proposed PR agreed with this decision.

In summary, the inspection of this new centre licence application was carried out by DBA and a videoconference call with key staff which took place on 8 January 2021. An on-site inspection can be performed when current restrictions have been eased.

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008, standard licence conditions (SLCs)and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has been submitted by the individual designated to act as the PR;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- subject to the proposed PR implementing the recommendations made in this report, it is considered likely that she will discharge her duty under section 17 of the HF&E Act 1990 (as amended);

- the premises (including those of relevant third parties) are suitable with the exception noted in the report;
- the centre's proposed practices are suitable with the exceptions noted in the report;
- the application contains the supporting information required by General Direction 0008, in application for an initial licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were five 'other' areas of non-compliance or poor practice that required improvement as follows.

'Other' areas of non-compliance:

- The proposed PR should ensure that the centre's donor recruitment, assessment, selection and screening procedures are compliant with all regulatory requirements and professional body guidance.
- The proposed PR should ensure that prior to undertaking diagnostic semen analyses the laboratory should be accredited by UKAS or to an equivalent standard.
- The proposed PR should ensure that egg sharing is not undertaken until the executive is assured that the centre's processes for these activities are compliant with regulatory requirements.

The inspection report was provided to the proposed PR on 25 January 2021 and she provided her responses on 26 January 2021 and the following non-compliance has been fully addressed.

'Other' areas of non-compliance:

- The proposed PR should ensure that the issues identified during the centre's fire safety risk assessment are actioned as a matter of urgency and before treatment services are commenced.
- The proposed PR should ensure the centre's resuscitation trolley, equipment, and requirements, comply with Resuscitation Council guidance and best practices.

The proposed PR has committed to fully implementing the remaining non-compliances and has provided further evidence to the centre's inspector. In view of the timescales for submission of papers to ELP the executive has not been able to review the information submitted on 26 January 2021 and will liaise with the proposed PR once the additional evidence has been reviewed.

Recommendation to the Executive Licensing Panel

The inspection team considers that there is sufficient information available to recommend:

- the appointment of the proposed Licence Holder;
- the appointment of the proposed Person Responsible;
- the granting of a 'Treatment (including embryo testing) and storage' licence for a period of two years, with an interim inspection in one year.

Centre 0382 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.

Following the suspension of all treatments during the Covid-19 pandemic, HFEA licensed 'Treatment and storage' centres were required to submit a self-assessment tool to the satisfaction of the executive before they could resume activities, in order to demonstrate that they would be able to do so safely. The proposed PR has completed and submitted this self-assessment tool to the satisfaction of the executive.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's proposed procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos. The centre will employ an electronic witnessing system with manual witnessing steps being performed where required.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's proposed procedures for screening donors are broadly compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's proposed procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment. Therefore, it is important that centres use donated gametes or embryos from identifiable donors. The

centre's proposed procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Screening of donors (Guidance note 11)
On the day of inspection the centre's standard operating procedure (SOP) for assessment and screening of donors (SOPCL13 Gamete and embryo donation version 1, October 2020) did not include requirements of the professional body guidelines introduced in 2019 (UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors (2019)). The centre's clinical team reviewed the SOP immediately after the inspection and submitted an updated document to the inspection team. Following further communications, and updates, version 4 was provided on 20 January 2021, however the following issues were noted (recommendation 1; SLC T53, CoP 11.3, 11.4 and 11.5, UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors (2019)).

- Whilst the document included reference to the 2019 professional body guidelines, it did not include reference to all aspects of this guidance, in particular the recommendations for a physical examination of donors or continued testing for syphilis, chlamydia and gonorrhoea during a course of donation.

- The SOP states 'All gamete donors will be screened as follows, prior to and within 3 months of the donation'. The proposed PR should ensure that the SOP makes it clear that where applicable testing of is carried out at the 'time of donation'.

- The SOP states that for egg donors repeat testing for HIV, hepatitis B, hepatitis C and syphilis will take place on the day of egg collection. However, given that results may take some time to be obtained it is not clear what steps will be taken if any of these tests are positive. Professional body guidelines recommend that when eggs are going to be used in a fresh treatment cycle (without cryopreservation), screening of egg donors should take place two months prior to donation and at the start of ovarian stimulation.

- The SOP states that that in the case of known donation and embryo donation 'age criteria will be assessed on a case by case basis.' This is not in accordance with code of practice guidance that age limits for donors should generally be observed unless there are exceptional reasons not to do so and should record any such reasons in the patient's medical records (CoP 11.3, 11.4 and 11.5).

- The centre's SOP does not include any reference to assessment of donors in relation to coronavirus (Coronavirus (COVID-19) and gamete donation | HFEA). (Recommendation 1; T53, CoP 11.3, 11.4 and 11.5).

Suitable premises and suitable practices
Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway

Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in an appropriate environment that is fit for purpose.

The centre's proposed procedures are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm with the exception noted below.

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to processes gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which will undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are broadly compliant with HFEA requirements for accreditation by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. It is important to assure the quality of the services provided.

Infection control (Guidance note 25)
The centre's proposed systems to manage and monitor the prevention and control of infection are compliant with guidance.

Medicines management (Guidance note 25)
The centre's proposed arrangements for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines are compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. The centre does not propose to use intralipids, therefore this area of practice is not relevant to this inspection.

Pre-operative assessment and the surgical pathway (Guidance note 25)

It is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively. The centre's proposed policies and procedures are broadly compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's proposed procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

Procurement of gametes and embryos (Guidance note 15)
The centre's proposed procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre proposes to keep a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's proposed procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes and embryos sent to other licensed centres within or outside the UK are:

- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- shipped in a container/package which is validated, properly secured and ensures that the gametes or embryos are maintained in the specified conditions.

Receipt of gametes and embryos (Guidance note15)
The centre's proposed procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and have enough accompanying information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's proposed procedures for import and export of gametes and embryos are compliant with HFEA requirements.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has not yet been allocated an ITE import certificate.

Traceability (Guidance note 19)
The centre's proposed procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
- identify the donor and recipient of particular gametes or embryos,
- to identify any person who has carried out any activity in relation to particular gametes or embryos, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport and satellite arrangements therefore this area of practice is not relevant to this inspection.

Equipment and materials (Guidance note 26)
The centre proposes to use equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and will be appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's proposed procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's proposed procedures for reporting adverse incidents are compliant with HFEA requirements. The centre will report adverse incidents (including serious adverse events and reactions) to the HFEA and will investigate all incidents that occur. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
Five 'high priority' issues were noted in the centre's fire risk assessment provided to the centre's inspector on 11 January 2021. The assessment was completed on 30 December

2020 with dates for completion ranging from 4 to 30 January 2021. Two issues of particular concern were items to be cleared from the garage fire exit, and that security arrangements needed to be reviewed to ensure accessibility of all staff to the digital padlock sealing the inner door of the garage. These issues had the longest due dates for completion of 30 January 2021 and 29 January 2021, respectively. The inspection team had not reviewed this document prior to the inspection therefore were not able to discuss this on inspection to confirm if these high priority issues had been actioned and no update has been provided (recommendation 2; SLC T17).

Laboratory accreditation (Guidance note 25)
The centre will be undertaking diagnostic semen analyses however the laboratory is not accredited by UKAS or another accreditation body recognised as accrediting to an equivalent standard (recommendation 3; SLC T21).

The centre's SOP references protocols as set out in the World Health Organisation (WHO) manual for semen analysis fifth edition (2010). However, two protocols in use for assessing sperm concentration and morphology are not methods recommended in the WHO manual. This was discussed with the proposed PR on the day of inspection and in further correspondence after the inspection. In response the proposed PR provided previous reports of external proficiency testing National External Quality Assessment Scheme (NEQAS) performed by herself at a different centre 3-5 years previously as evidence of validation. The inspection team did not consider this was sufficient evidence to conclude that these processes had been suitably validated as they were from several years ago and performed in a different laboratory.

The inspection team considers that other requirements of accreditation to an equivalent standard are in place, namely appropriate premises to carry out the testing; a quality management system is in place; have staff who are suitably qualified to interpret the results, and have provided verbal assurance that the laboratory, when operational, will participate in the NEQAS for semen analysis.

Pre-operative assessment and the surgical pathway (Guidance note 25)
The resus trolley is stored in the recovery area, but the trolley does not provide the facility to lock the drawers to stop unauthorised access to needles and drugs (recommendation 4; T2).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The proposed PR has complied with HFEA requirements during the application process and in preparing the centre for licensed activity.

The proposed PR has academic qualifications in the field of biological sciences and more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The proposed PR has successfully completed the HFEA PR Entry Programme (T/1378/82).

Leadership

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

The inspection team considers that the centre is likely to be compliant with HFEA guidance regarding effective leadership.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements. The centre has suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities, respectively.

What the centre could do better
Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's proposed procedures to ensure that they take into account before treatment is provided, the welfare of any child who may be born as a result of the licensed treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding
The centre's proposed procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre's proposed procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information and opportunities to discuss the implications of their treatment, and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The centre's proposed procedures for seeking patient feedback are documented, and the proposed PR has provided assurance that this feedback will be reviewed regularly and, where necessary, actions will be taken to address problems in the service communicated via patient feedback.

On the basis of discussions with centre staff and a review of documents in the course of the inspection it was possible to assess that the centre:

- will have respect for the privacy and confidentiality of patients in the clinic;
- will give patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- will provide patients with satisfactory facilities for their care;
- will have a mechanism in place to effectively respond to patient calls and queries in a timely manner.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Patient Support
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's proposed procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's proposed procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Patient support (Guidance note 3)

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's proposed patient support procedures are compliant with HFEA guidance.

Counselling (Guidance note 3)
The centre's proposed counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent, including consent to legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's proposed procedures for egg sharing arrangements are broadly compliant with HFEA requirements. It is important to ensure that:

- care is taken when selecting egg and/or sperm providers donating for benefits in kind
- egg and/or sperm providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's proposed procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's proposed procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's proposed procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Egg sharing arrangements (Guidance note 12; General Direction 0001)
Egg share agreements for sharers or recipients were not in place at the time of inspection (recommendation 5; CoP guidance note 12).

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's proposed procedures for providing information to patients and donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's proposed procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

The centre's proposed processes for collecting legal parenthood consent at this centre are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's proposed procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consents, so that it only releases patient identifying information, to researchers, with the consent of the patient. Information can be used by researchers to improve knowledge about the health of patients undergoing licensed fertility treatment and those born as a result of it.

What the centre could do better
Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's proposed procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre's proposed procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's proposed procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre will only store gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's proposed procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better
Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
Good medical records are essential for the continuity of the patient's care. The centre's proposed procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

It is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors. The centre's proposed procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements.

What the centre could do better
Nothing identified at this inspection.

Areas of practice requiring action

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, General Directions or the Code of Practice, and the recommended improvement actions 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, or a significant shortcoming from the statutory requirements. 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	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 represent a major area of non-compliance.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
None identified			

‘Other’ areas of practice that require improvement

An ‘other’ area 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 constitutes a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
1. Screening of donors A number of issues were noted in the centre’s SOP for donor recruitment, assessment and screening (version 4) as described in the body of the report. SLC T53, CoP 11.3, 11.4 and 11.5, UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors (2019). As the centre is not yet undertaking donor recruitment assessment or screening this non-compliance has been graded as an ‘other’.	The proposed PR should ensure that no donor recruitment, assessment and screening activity is undertaken until the executive is assured that the centre’s processes for these activities are compliant with regulatory requirements and professional body guidance. The proposed PR should review all relevant regulatory requirements and professional body guidelines and ensure these are incorporated into the centre’s processes for donor recruitment, assessment, and screening. A copy of the updated SOP should be provided to the centre’s inspector upon completion. The proposed PR should also undertake further training and competency assessment of	SOPCL13 v5 is attached, and has been updated to reflect regulatory requirements and professional body guidance. Relevant clinical staff have been trained in these revised procedures and this is documented in FRMHR12 V3, also attached.	The executive acknowledges the proposed PR’s response, and for providing a revised SOP and competency assessments for clinical staff completed on 26 January 2021. In view of the timescales for submission of papers to ELP the executive has not been able to review the information submitted on 26 January 2021. The executive will liaise with the proposed PR to confirm that these activities can commence when it is assured that the centre’s processes for donor recruitment, assessment and screening are compliant with regulatory requirements. **Further action is required.**

	relevant staff in these revised procedures. The executive will confirm that these activities can commence when it is assured that the centre's processes for donor recruitment, assessment and screening are compliant with regulatory requirements and that staff training and competency assessments have been completed.		
2. Premises and facilities Five 'high priority' issues were noted in the centre's fire risk assessment provided to the centre's inspector on 11 January 2021 with timescales for completion as 29 and 30 January 2021. SLC T17.	The proposed PR should ensure that the issues identified during the centre's fire safety risk assessment are actioned as a matter of urgency and before treatment services are commenced.	Fire risk assessment (FRA) dated 30.12.20 identified 5 areas of non compliance. 4 areas of non compliance had been resolved by 04.01.2020. A typing error in the report stated 1 action date as 30.01.2020, rather than 30.12.2020 - this related to the removal of waste which occurred immediately at the time of inspection. The PR can confirm that the only outstanding risk in the FRA relating to the fire exit route through the garage has been actioned and the appropriate corrective action	The executive acknowledges the proposed PR's response, and updated fire risk assessment. The executive notes the PR's confirmation that all corrective actions identified have now been completed. **No further action is required.**

		to resolve the identified risk applied. FRA attached.	
3. Laboratory accreditation The centre's SOP references protocols as set out in the WHO manual for semen analysis fifth edition (2010). However, two protocols in use for assessing sperm concentration and morphology are not methods recommended in the WHO manual. SLC T21. WHO manual for semen analysis fifth edition (2010). As the centre is not yet undertaking diagnostic semen analyses this non-compliance has been graded as an 'other'.	The proposed PR should ensure that prior to undertaking diagnostic semen analyses the laboratory should be accredited by UKAS or to an equivalent standard. The proposed PR should ensure that a robust validation (such as using data from published studies) is completed for semen analysis methods to be used that are not recommended in the WHO manual (2010).	Equivalence to UKAS is demontrated in DATEM10 v3, Section 10 Validation of semen analysis procedures using Makler chamber for sperm concentration and TestSimplets for sperm morphology has been performed using samples provided by UK NEQAS, an independent QA body, relative to WHO 2010 (refer to process validation DATEM10 v3 Section 10). Results obtained are within the target scores set by NEQAS. Aria Fertility is registered with the NEQAS Scheme.	The executive acknowledges the proposed PR's response and updated process validation document provided. In view of the timescales for submission of papers to ELP the executive has not been able to review the information submitted on 26 January 2021. The executive will liaise with the proposed PR to confirm whether or not the validation satisfies the relevant requirements. **Further action is required.**
4. Pre-operative assessment and the surgical pathway The resus trolley is stored in the recovery area, but the trolley does not provide the facility to lock the drawers to stop	The proposed PR should ensure the centre's resuscitation trolley, equipment and requirements, comply with Resuscitation Council guidance and best practices.	Resuscitation guidance has been reviewed and a risk assessment of the resuscitation trolley has been performed and is attached. Actions detailed	The executive acknowledges the proposed PR's response and risk assessment provided. The executive notes the PR's confirmation that all the

unauthorised access to needles and drugs. SLC T2 Resuscitation Council (UK) – Quality standards for cardiopulmonary resuscitation practice and training (2016), section 2.1. Resuscitation trolley contents 1: cardiac arrest equipment to support airway 2014. Resuscitation Council UK; Quality Standards: Acute Care section 12 Resuscitation Council UK: Acute care equipment and drug lists Section 4.	The proposed PR should provide a risk assessment of resuscitation requirements including the location of the trolley. Evidence of actions implemented to mitigate any risks identified should be provided to the executive before treatment services commence.	in risk assessment have been incorporated.	additional equipment noted in the risk assessment and the corrective actions, have now been completed. **No further action is required.**
5. Egg sharing arrangements Egg share agreements for sharers or recipients were not in place at the time of inspection. CoP guidance note 12. As the centre is not yet undertaking egg sharing this	The proposed PR should ensure that egg sharing is not undertaken until the executive is assured that the centre's processes for these activities are compliant with regulatory requirements. The proposed PR should provide agreements sharing for	Egg sharing will not be undertaken until the inspector has received, reviewed and approved the relevant documentation.	The executive acknowledges the proposed PR's response and her commitment to implementing this recommendation before undertaking egg sharing treatments. The executive will liaise with the proposed PR to confirm

non-compliance has been graded as an 'other'.	egg sharers and recipients, and any other relevant documents for these activities to the centre's inspector upon completion. The executive will confirm that these activities can commence when it is assured that the centre's processes for egg sharing are compliant with regulatory requirements and that, where necessary, staff competency assessments have been completed.		that these activities can commence when it is assured that the centre's processes for egg sharing are compliant with regulatory requirements and that, where necessary, staff competency assessments have been completed. **Further action is required.**

Further response from the Person Responsible to this inspection report