Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
24 April 2015

Minutes – item no. 1

Centre 0206 (Reproductive Genetics Institute) – Renewal Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Joanne Anton Policy Manager Ian Peacock Analyst Programmer
Legal Adviser:	Dawn Brathwaite Mills & Reeve
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing Dee Knoyle Committee Secretary

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:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to Licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of application

1. The panel considered the papers, which included an application form, executive update, inspection report and licensing minutes for the past three years.

2. The panel noted that this is a treatment (including embryo testing) and storage centre which provides a full range of fertility services. The panel noted that in relation to activity levels this is a medium-sized centre.

3. The panel noted that the centre has been licensed by the HFEA since 2003 and is on a four-year licence due to expire on 3 May 2015.

4. The panel noted that in the 12 months to 30 September 2014, the centre provided 832 cycles of treatment (excluding partner intrauterine insemination).

5. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 July 2013 to 30 June 2014 showed the centre's success rates were in line with national averages.

6. The panel noted that in 2013, the centre did not perform any cycles of partner insemination. This information was confirmed during inspection as the centre did not notify the HFEA.

7. Between 1 July 2013 and 30 June 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 20%: this represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

8. The panel noted that at the time of the inspection on 25 and 26 November 2014, the Inspectorate identified one critical, four major and five other areas of non-compliance. The panel noted that no response was given by the PR in relation to the recommendations made in the renewal report.

9. The panel noted that the centre had delayed submitting an application form to the Inspectorate. However, on 13 February 2015 the PR communicated to the Inspectorate that he had no intention of closing the centre and a suitable treatment (including embryo testing) and storage application form was created by the centre via the clinic portal on 18 February 2015 but not submitted. The panel noted that the Inspectorate was concerned not to delay consideration of the centre's licence renewal to minimise any potential disruption or uncertainty in relation to patient treatment. The Inspectorate therefore extracted the application form from the clinic portal to submit to a licensing committee.

10. The panel noted that a copy of the application form was first sent to the PR to provide him with an opportunity to approve the form in lieu of accepting the standard declaration via the clinic portal. The PR was informed that the renewal application would be submitted to a licensing committee together with the renewal inspection report, and that it would be assumed that the PR was satisfied with the contents of the renewal application form if he did not indicate otherwise by 8 April 2015. The panel noted that no response was received from the PR following this correspondence but an application fee was later submitted. The panel noted that due to a delay in the production of an application form an invoice was not generated until 23 March 2015, but that confirmation had been tabled by the Inspectorate that the fee had been paid.

11. The panel noted that some improvement is required in order for the centre to reflect suitable practices and that the Inspectorate will continue to monitor the centre's performance.

12. The panel noted that the Inspectorate recommends the renewal of the centre's

treatment and storage licence for a period of three years without additional conditions.

Decision

13. The panel had regard to its decision tree and was satisfied that the appropriate fee and supporting information required by General Directions 0008 had been submitted.

14. The panel considered whether an application for the grant of a licence had been submitted, in light of the lack of co-operation from the PR throughout the process. The panel's legal adviser advised that the fact that a) the centre had created an application form in the HFEA's online clinic portal; b) the Executive had written to the PR on the basis that they would assume that he was satisfied with the contents of the renewal application form if he did not indicate otherwise by the 8 April 2015, (c) the PR had not taken positive action to suggest that he was not content with the application form being put to a licensing committee; and d) he had paid the application fee, was all evidence to suggest that application for the grant of a licence had been submitted. The panel accepted the advice of its legal adviser and agreed that an application had been submitted for a licence.

15. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities, and the PR has discharged their duty under section 17 of the HF&E Act 1990 (as amended). The panel further noted that the premises to be licensed are suitable for the conduct of the licensed activities.

16. The panel was deeply concerned to learn of the lack of engagement from the PR throughout this inspection process to renew the licence, giving no response to the report or the recommendations made within it. The PR did not give any indication that he was committed to implementing the recommendations, or confirmation that the non-compliances due to be completed by 26 February 2015 had been addressed. The panel noted with concern that the PR had not submitted a self-assessment questionnaire (SAQ) despite several reminders. The issue had been escalated to 'critical' as failure to submit a SAQ and an annual return were issues raised at the previous inspection. The panel agreed that failure to implement the recommendations relating to the areas of non-compliance may result in the submission of a further report to a licensing committee with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

17. The panel further observed that, had the HFEA not taken steps to ensure that an application was made, the centre's licence would have expired. It was the panel's view that the HFEA's inspectorate had taken the initiative to take all steps necessary to ensure the continued activity of this centre with the best interests of the centre's patients at heart, and that the inspectorate should be commended for this. The panel noted that this was in stark contrast to the behaviour of and engagement from the centre's PR: current patients at the centre would have, by necessity, had their treatment stopped on expiration of the licence had the inspectorate not taken such proactive steps. The panel further noted that the history of the centre suggest that the PR is unlikely to comply with two of the recommendations in the report in a timely manner. It further noted that, in light of the factors outlined above and in the report, the Inspectorate recommends granting a licence for three years, rather than the usual four.

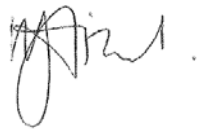
18. The panel had regard to its '*Guidance on periods for which new or renewed licences should be granted*'. In considering the recommendation before it, the panel considered the criteria it may take into account when deciding on the length of a licence, in particular:

- information provided with the licence application, and any response from the person making the application to the recommendation in the inspection report (paragraph 4.1 (c));
- co-operation by the centre/PR with… routine inspections (table at 4.3); and
- timely provision of accurate Register data to the Authority (table at 4.3).

It was also noted by the panel that the list of factors to take into account when deciding on the length of a licence was not meant to be exhaustive. Further, paragraph 4.5 of the *Guidance* stipulates that the panel may grant a treatment/storage/non-medical fertility services renewal licence for a period of up to three years where the evidence before it reveals concerns in any matters specified in the table at paragraph 4.3 of the *Guidance*.

19. The panel agreed that, in light of the lack of co-operation and response from the PR, it did have such concerns. Therefore, it endorsed the Inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of three years without additional conditions. It noted that the Inspectorate will continue to monitor the centre's performance and urged the centre to comply with all recommendations within the report to the timescales outlined. Failure to do so may lead to formal enforcement action being taken.

20. The panel noted that the centre's licence is due to expire on 3 May 2015. The panel further noted that a Person Responsible has 28 days in which to accept the offer of a licence (or exercise his right to make representations against the proposed decision to grant a licence). As the existing licence would expire during the course of this time, the panel agreed to issue Special Directions under Section 24(5A)(b) to allow for the continuation of licensed activity at the clinic. The Special Directions would come into force on 4 May 2015 and would remain in force until the new licence comes into effect, or 1 June 2015, whichever is sooner.



Signed: Date: 30 April 2015
Juliet Tizzard (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. 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: 25 and 26 November 2014

Purpose of inspection: Renewal of a licence to carry out treatment (including embryo testing) and storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Vicki Lamb (lead), Sara Parlett, Heidi Birch, Chris Hall and Zakia Ezzouyar.

Date of Executive Licensing Panel: 24 April 2015

Centre name	Reproductive Genetics Institute
Centre number	0206
Licence number	L/0206/10/c
Centre address	32A, Weymouth Street, London, W1G 7BX, UK
Person Responsible	Mr Mohamed Taranissi
Licence Holder	Mr Mohamed Taranissi
Date licence issued	4 May 2011
Licence expiry date	3 May 2015
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

The Reproductive Genetics Institute has held a treatment (including embryo testing) and storage licence with the HFEA since 2003 and provides a full range of fertility services. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The centre provided 832 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2014. In relation to activity levels this is a medium-sized centre.

Other licensed activities of the centre include storage of gametes and embryos.

Centre 0206 operates in the same way as the Assisted Reproduction and Gynaecology Centre (centre 0157). The Person Responsible (PR), staff and standard operating procedures (SOPs) are the same at both centres.

The report of the interim inspection conducted in February 2013 identified two 'critical' and four 'major' non-compliances. Since that time the PR had not updated the inspector on progress in addressing these non-compliances. During this renewal inspection it was possible to ascertain that the two 'critical' non-compliances relating to storage had been resolved. One of the 'major' issues relating to register submissions is routinely addressed during the data validation process and although the three other 'major' issues from the interim inspection had not been completely resolved, it is acknowledged that these issues: the failure to submit an SAQ; failure to submit an annual return; and failure to accurately record consent to disclosure to researchers, are not direct risks to the safety of gametes, embryos or patients. The failure to accurately record consent to disclosure to researchers is not a direct risk as, whilst the patients may have consented to disclosure to researchers, the centre always reports to the HFEA that no consent has been given.

At the time of the inspection and at the time of drafting this report, the PR had not submitted an application to the HFEA to renew the centre's licence or indicated an intention to close the centre. An inspection visit was conducted so that should a renewal application be submitted by the PR it could be processed with minimum disruption to patients undergoing treatment, and also in accordance with Section 4(1) of the 1990 Human Fertilisation and Embryology Act (as amended) which requires the premises to which a licence relates to be inspected at intervals not exceeding two years.

During the inspection the PR was reminded that a renewal application had not been submitted. The PR did not clearly indicate his intention to either submit a renewal application or close the centre when the licence expires or at any date prior to that. No renewal application had been initiated on the HFEA Portal.

When the draft report was sent to the PR on 8 January 2015 the PR had still not indicated his intention to either submit a renewal application or close the centre and no renewal application had been initiated on the HFEA Portal. The recommendation in that draft report was that the licence should continue until its expiry on 3 May 2015 and the PR should implement a plan of action for the closure of the clinic. No recommendation was made to renew the licence.

A treatment and storage licence renewal application (rather than a treatment (including embryo testing) and storage licence renewal application) was subsequently created by the centre on the clinic portal on 15 January 2015 but was not submitted.

No response was received from the PR regarding the inspection report, and a further request for a response to the report, or an indication of his intended actions, was sent on 10 February 2015.

On 13 February 2015, the PR called the inspector and stated that he had no intention of closing the centre.

Further correspondence to the PR on 17 February 2015 requested that a treatment (including embryo testing) and storage licence renewal application be submitted via the clinic portal. A suitable application form was created by the centre on 18 February 2015 but was not submitted. It should be noted that only the PR can submit an application and that submission indicates acceptance of a standard declaration by the PR. The HFEA Executive were concerned not to delay consideration of the clinic's licence renewal, to minimise any potential disruption or uncertainty in relation to patient treatment. For this reason, following correspondence to the PR on 12 March 2015, the form was extracted and a copy was sent to the PR to provide him with an opportunity to approve the form in lieu of accepting the standard declaration. In this correspondence the PR was informed that the renewal application would be submitted to a licensing committee together with the renewal inspection report, and that it would be assumed that the PR was satisfied with the contents of the renewal application form if he did not indicate otherwise by 8 April 2015.

No response was received from the PR following this correspondence.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 July 2013 – 30 June 2014 show the centre's success rates are in line with national averages.

In 2013, the centre did not provide notification of the number of cycles of partner insemination. During the inspection the PR confirmed that in 2013 the centre did not perform any cycles of partner insemination.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between 1 July 2013 and 30 June 2014 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 20%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing

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 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- an application has been provided;
- the application has designated an individual 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);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are broadly suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence.

The centre has not submitted an application fee to the HFEA in accordance with requirements. The generation of an invoice is triggered at the HFEA by submission of an application form: in the absence of submission of the application by the usual route, an invoice was not generated until 23 March 2015. This means that the payment terms will post date consideration of this application by the ELP.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical, four major and five 'other' areas of non-compliance which are subject to the following recommendations:

Critical areas of non compliance:

- **An appropriately completed self assessment questionnaire (SAQ) and annual return should be submitted.**

Major areas of non compliance:

- The PR should ensure that wherever possible CE marked equipment and reagents are used.
- The PR should ensure that the frequency and methodology for air quality testing is re-validated and the processes for embryo biopsy and use of vitrification kit are validated.
- The PR should implement suitable arrangements to ensure that those attending the centre are safeguarded against the risk of abuse, by ensuring that all staff have undertaken safeguarding training and know how to identify, report and respond appropriately to suspected or actual abuse.
- The PR should correct the register submissions that have been identified as being incorrect and review systems and processes to ensure that the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms

'Other' areas that require improvement:

- The PR should ensure that a fire evacuation drill is performed at the centre.
- The PR should ensure that appropriate hand-washing facilities are used.
- The PR should establish, and ensure the accurate use of, summary logs for treatment cycles involving, the placing in a woman of three embryos, and for cases in which

multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer.
- The PR should ensure the development of documented SOPs where these are missing or out of date.
- The PR should ensure that the systems and processes employed by the centre ensure that accurate donor information is submitted to the HFEA.

No response has been received from the PR to indicate whether he will implement these recommendations.

Recommendation to the Executive Licensing Panel

When the report was drafted, in the absence of confirmation that the PR wished to renew the licence, the Executive recommended the continuation of the centre's licence until its expiry in May 2015.

When the PR confirmed he wished to renew the licence the PR was given a further opportunity to comment on his intentions with respect to the implementation of the recommendations in the report to enable the Executive to form a recommendation with respect to the renewal of the licence.

The centre has one critical, four major and five 'other' areas of concern. The inspection team notes that the success rates are consistent with the national average and the multiple pregnancy rates are not likely to be statistically different from the 10% multiple live birth rate target.

Some improvement is required in order for the centre to reflect suitable practices.

The licensing history of this centre suggests the PR is unlikely to comply with the following recommendations in a timely manner:
- The PR should correct the register submissions that have been identified as being incorrect and review systems and processes to ensure that the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms;
- The PR should ensure that the systems and processes employed by the centre ensure that accurate donor information is submitted to the HFEA.

Therefore, in consideration of the 'Guidance on periods for which new or renewed licences should be granted', the renewal report and the licensing history, the inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years without additional conditions. The ELP is asked to note that the renewal fee has not yet been paid, as the invoice was not generated until 23 March 2015.

The inspector will continue to monitor the centre's performance. Failure to implement the recommendations relating to these areas of non-compliance may result in the submission of a further report to a licensing committee with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

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 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.

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)
This is not applicable at centre 0206 as donor selection, assessment, consent and any diagnostic investigations are carried out at centre 0157 earlier in the donor pathway.

Payments for donors (Guidance note 13; Directions 0001)
This is not applicable at centre 0206 as egg donors are recruited at centre 0157 and donor sperm is purchased and stored at centre 0157.

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

What the centre could do better

Nothing identified at this inspection.

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 a suitable environment that is fit for purpose.

The centre has procedures in place that are broadly compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

Laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are accredited and therefore considered 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 third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed

from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

Medicines management
This is not applicable at centre 0206 as no medicines are held at this centre.

Pre-operative assessment and the surgical pathway
This is not applicable at centre 0206, as no surgical procedures are carried out at the centre.

Multiple births (Guidance note 7; Directions 0003)
The centre's procedures are broadly 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. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's 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. Sperm is processed at centre 0157 and if it is produced at home, this is recorded in the notes by staff at centre 0157.

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

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- 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;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's 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 the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

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

Traceability (Guidance note 19)
The centre's 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,
- to 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 broadly 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; Directions 0010)
The centre does not have any transport or satellite agreements, therefore this is not applicable at this centre.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. All of the equipment and materials used in licensed activity are 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 procedures are partially 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 procedures for reporting adverse incidents are compliant with HFEA requirements. The incidents log was reviewed during the inspection and showed that no adverse incidents had occurred since the last inspection. 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
Although centre staff undergo regular training in how to evacuate in the event of a fire, this is only done at centre 0157 and a fire evacuation drill has never been performed at centre 0206 (SLC T2). See recommendation 6.

Infection control
Although there is a hand washing basin in the theatre, the inspection team was informed that this is not used by the laboratory or clinical staff. The staff use the sink in the kitchen area to wash their hands prior to performing procedures. This could potentially pose an infection risk as the sink in the kitchen area is not dedicated for this purpose and does not have hands-free taps (SLC T2). See recommendation 7.

Multiple births
Centre staff were not able to provide summary logs for treatment cycles involving the placing in a woman of three embryos, or for cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer (General Directions 0003). See recommendation 8.

Quality management system (QMS)
SOPs are not in place for patients wishing to withdraw their consent to treatment, storage or legal parenthood and for dealing with unexpected medical, or other, emergencies. The SOP for testing laboratory air quality does not reflect the centre's own current practice (SLC T33b). See recommendation 9.

Equipment and materials
Some consumables and reagents, such as pipettes, hyaluronidase and the freezing kit, currently in use are not CE marked. Centre staff had been informed that the company that provided the hyaluronidase was permitted to continue to sell it pending the conclusion of the CE marking process, but no confirmation of this was provided during the inspection or afterwards. Centre staff provided evidence that they had been led to believe that the freezing kit was in fact CE marked and, but as there was no CE mark on the packaging the inspection team did not consider that the kit was CE marked (SLC T30). See recommendation 2.

Process validation
The frequency and methodology for air quality testing has changed, but this has not been validated. There is no process validation for the embryo biopsy procedure or vitrification (SLC T72). See recommendation 3.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of medicine and has more than two years

of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (T/1075/7).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has clearly defined 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)
This is not applicable at centre 0206 as patient selection, assessment, consent and any diagnostic investigations are carried out at centre 0157 earlier in the patient pathway.

Safeguarding
The centre's procedures are partially 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

Safeguarding
There was evidence that not all members of staff were fully aware of the requirements of safeguarding and their role in ensuring that patients, partners and staff are safeguarded (SLC T15). See recommendation 4.

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 procedures for performing embryo testing are partially 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, are given every opportunity 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

The embryo biopsy procedure has not been validated (SLC T72). See recommendation 3.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit no patients were available to speak to the inspectors. One patient had provided feedback directly to the HFEA about centre 0206 in the time since the last inspection and this individual appeared satisfied with the service received. Additionally, 18 patients had provided feedback directly to the HFEA about centre 0157 in the same time period. Twelve of these patients had compliments about the centre.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's 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 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.

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

Egg and sperm sharing arrangements (Guidance note 12; Direction 0001)
This is not applicable as it is not performed at this centre.

Surrogacy (Guidance note 14)
The centre's 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 procedures are compliant with HFEA requirements to be responsive to patient complaints. This is important to ensure that the centre uses any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's 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

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4;CH(11)02)
This is not applicable at centre 0206 as the regulatory requirements for the provision of information prior to consent are carried out at centre 0157 earlier in the treatment pathway.

What the centre could do better

Nothing identified at this inspection.

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

What the centre does well

Consent (Guidance note 5 and 6)
Consent is obtained at centre 0157 earlier in the treatment pathway. Appropriately completed consent forms were seen in all five sets of notes reviewed. Patients and donors provide all relevant consents before any licensed activity is carried out.

Legal parenthood
Where a couple are not married or in a civil partnership and the woman is to be treated with donated gametes or embryos and before licensed treatment is provided, both the woman to be treated and her partner must give consent in order that the partner may be legally recognised as the second parent of any child born as a result of that donation. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born in order to become the legal parent. The centre's procedures are broadly compliant with HFEA requirements.

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

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

What the centre could do better

Legal parenthood
In February 2014, the HFEA issued a Chief Executive's Letter (CE (14) 01) requiring all licensed clinics to carry out an audit of parenthood consent documented in the records of patients who received treatment using donor sperm or embryos on or after 6 April 2009, who were neither married nor in a civil partnership. The audit was to be completed by 10 May 2014 and the PR was asked to notify the centre's inspector on completion. The letter noted that failure to complete the audit would be considered as a critical non-compliance.

The PR has not submitted a report of the findings of the audit, nor was it clear during the inspection whether an audit had been undertaken however, information submitted to the HFEA's register indicates that this centre has performed no treatments where it would have been relevant to seek consent to parenthood in the relevant time period. As a result it is considered disproportionate to cite the failure to complete the audit as a critical non-compliance although it is recommended that the PR should assure himself that procedures for taking consent to parenthood are fully compliant with requirements before providing any relevant treatments in the future.

Disclosure of information, held on the HFEA Register, for use in research
Seven sets of patient notes were audited on inspection and two inconsistencies were noted between the patient files and the consent data held on the register where the completed patient and partner consent indicated that consent had been given while the information submitted to the HFEA register indicated that consent had been withheld (General Directions 0005 and SLC T9e). See recommendation 5.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's 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 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 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 only stores 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 procedures for using embryos for training staff are compliant with HFEA requirements. However, embryos have not been used for the purpose of training staff since the last renewal inspection.
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)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32 ; General Directions 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Obligations and reporting requirements
Discrepancies and omissions were noted in the data submitted to the HFEA register relating to one donor, and 28% of treatments sampled during the inspection were not reported within the time period specified in General Directions 0005. (SLC T9e). See recommendation 10.

The PR did not submit a SAQ despite several reminders to do so (SLC T4). The PR did not provide written notification of the number of cycles of partner insemination performed in 2013 (General Directions 0005). See recommendation 1.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to two areas of critical non-compliance and four areas of major non-compliance.

In the time since the last inspection the PR did not provide any information or evidence that any of the recommendations had been implemented.

During the inspection, evidence was provided that the two critical non-compliances and one of the major non-compliances have now been implemented but were not completed within the required timescales.

The following recommendations have not been implemented:

- The PR should ensure that an annual return is completed reporting the number of cycles of partner insemination.
- The PR should ensure that consent to disclosure to researchers is accurately reported to the HFEA.
- The PR should ensure that a self assessment questionnaire (SAQ) is submitted within the required timescale in support of an inspection.

On-going monitoring of centre success rates

In October 2014, the centre was asked to review procedures for the provision of ICSI treatment in patients aged 38 and over. The PR did not respond to the request but success rates for this patient group do remain in line with the national average.

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, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, 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 for action	PR Response	Executive Review
1. Obligations and reporting requirements The PR did not submit a reviewed SAQ in support of this inspection despite several reminders to do so. As noted at the last inspection, the PR has not ensured that an annual return is completed reporting the number of cycles of partner insemination (SLC T4 and General Directions 0005). This issue has been escalated to 'critical' as failure to submit an SAQ and an annual return	An appropriately completed SAQ and annual return should be submitted via the Clinic Portal by 26 February 2015.		No SAQ or annual return has yet been submitted by the PR. No response was received from the PR concerning any of the recommendations or the content of the report.

were issues at the last inspection.			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Equipment and materials Some consumables and reagents, such as pipettes, hyaluronidase and the freezing kit, currently in use are not CE marked (SLC T30).	The PR should ensure that wherever possible CE marked equipment and reagents are used. The PR should provide evidence of the approval for non CE marked hyaluronidase to remain on the market and evidence of the CE mark status of the vitrification kit by 26 February 2015. If this is not available then the PR should advise a plan of action to source suitable CE marked alternatives.		The executive has been informed by the manufacturer of the vitrification kit that this has now been withdrawn from the market pending CE approval.
3. Process validation The frequency and methodology for air quality	The PR should ensure that the frequency and methodology for air quality testing is validated		

testing has changed, and the new testing procedure has not been validated. The embryo biopsy procedure and the use of the vitrification kit have not been validated (SLC T72).	and the processes for embryo biopsy and use of vitrification kit are validated. The validation documents should be submitted to the centre's inspector by 26 February 2015.		
4. Safeguarding Not all members of staff were fully aware of the requirements of safeguarding and their role in ensuring that patients, partners and staff are safeguarded (SLC T15).	The PR should implement suitable arrangements to ensure that those attending the centre are safeguarded against the risk of abuse, by ensuring that all staff have undertaken safeguarding training and know how to identify, report and respond appropriately to suspected or actual abuse. The PR identify those staff that require safeguarding training, and at what level. The PR should provide evidence to the centre's inspector by 26 May 2015, to demonstrate that all relevant staff have completed their safeguarding training to an appropriate level.		
5. Disclosure of information, held on the HFEA Register, for use in	The PR should correct the submissions that have been identified as being incorrect		The executive are continuing to work with the PR to resolve these issues.

research Seven sets of patient notes were audited on inspection and two inconsistencies were noted between the patient files and the consent data held on the register where the completed patient and partner consent indicated that consent had been given to disclosure while the information submitted to the HFEA register indicated that consent had been withheld (General Directions 0005 and SLC T9e). This issue has been escalated to 'major' as inconsistencies regarding disclosure of information were an issue at the last inspection.	and review systems and processes to ensure that, going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms. By 26 February 2015. Six months after implementing any changes to this process the PR should audit the submission of consent to disclosure data to confirm that any changes made to systems and processes are having the desired effect. A summary of this audit should be provided to the centre's inspector by 26 November 2015. *(NB. The Centre's PR has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected).*		

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
6. Safety and suitability of premises and facilities Although centre staff undergo regular training in how to evacuate in the event of a fire, this is only done at centre 0157 and a fire evacuation drill has never been performed at centre 0206 (SLC T2).	The PR should ensure that a fire evacuation drill is performed at centre 0206. The PR should provide a summary report to the centre's inspector detailing when the drill was performed, any corrective actions identified and the action taken to resolve these issues by 26 February 2015.		
7. Infection control Although there is a hand washing basin in the theatre, the inspection team were informed that this is not used by the laboratory or clinical staff. The staff use the basin in the kitchen area to wash their hands (SLC T2).	The PR should investigate any barriers to the use of the hand washing basin in the theatre. The PR should inform the centre's inspector of the findings of this investigation and provide an action plan to ensure that appropriate infection control measures are in place by 26 February 2015.		
8. Multiple births Centre staff were not able to provide summary logs for treatment cycles involving the	The PR should establish, and ensure the accurate use of, summary logs for treatment cycles involving, the placing in		

placing in a woman of three embryos, or for cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer (General Directions 0003).	a woman of three embryos, and for cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. By 26 February 2015. Six months after the establishment of the logs the PR should conduct an audit of the documentation of cases where three embryos have been transferred, or multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. A summary report of the audit findings including corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 26 September 2015.		
9. Quality management system (QMS) SOPs are not in place for patients wishing to withdraw their consent to treatment, storage or legal parenthood and for dealing with	The PR should ensure the development of documented SOPs for these procedures. Copies of the SOPs should be provided to the centre's inspector by 26 May 2015.		

unexpected medical, or other, emergencies. The SOP for testing laboratory air quality does not reflect current practice (SLC T33b).			
10. Obligations and reporting requirements Discrepancies and omissions were noted in the data submitted relating to one donor, and 28% of treatments sampled during the inspection were not reported within the time period specified in General Directions 0005. (SLC T9e).	The PR should ensure that the systems and processes employed by the centre ensure that accurate donor information is submitted to the HFEA. Discrepancies identified should be corrected by 26 February 2015. The PR must ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Direction 0005. *(NB. The Centre's PR has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected).*		The executive are continuing to work with the PR to resolve these issues.

Reponses from the Person Responsible to this inspection report