# 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. 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:** 22 May 2013
**Purpose of inspection:** Renewal of a licence to carry out 'Treatment and Storage'
**Inspectors:** Debra Bloor (Lead); Chris Hall

## 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.

**Date of Executive Licensing Panel:** 6 September 2013

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| **Centre name** | Reproductive Medicine Unit |
| **Centre number** | 0167 |
| **Licence number** | L/0167/10/e |
| **Centre address** | Elizabeth Garrett Anderson Wing, University College London Hospitals 235, Euston Road, London, NW1 2BU, UK |
| **Person Responsible** | Ms Melanie Davies |
| **Licence Holder** | Dr Gill Gaskin |
| **Date licence issued** | 01 November 2008 |
| **Licence expiry date** | 31 October 2013 |
| **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 Medicine Unit is part of the University College London Hospitals NHS Foundation Trust and has held a licence with the HFEA since 1997.

Currently the centre provides basic partner services (intra uterine insemination with partner sperm (IUI)) to National Health Service (NHS) patients and a sperm storage service for patients who are having treatment that may impair their fertility. The centre also provides a satellite in vitro fertilisation (IVF) service to NHS patients in conjunction with The Centre for Reproductive and Genetic Health.The centre stopped providing donor insemination (DI) treatments in 2008.

The centre provided 282 IUI treatment cycles in 2012 which makes this a small centre in terms of activity.

The current licence was issued in November 2008 for a period of five years and expires in October 2013. Interim inspections were conducted in May 2010 and May 2012.

The premises have not undergone any major changes in the time since the last inspection.

There have been no variations to the centre's licence in the time since the last inspection.

**Activities of the centre:**

| Type of treatment | 2012 |
|---|---|
| Partner insemination | 282 |

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

| Outcomes* |
| --- |
| In 2012, the centre provided 282 cycles of partner insemination with 42 pregnancies. This equates to a 15% clinical pregnancy rate which is consistent with the national average. |

## Summary for licensing decision

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:

- the PR is suitable and has discharged their duty under section 17 of the HF&E Act 1990 (as amended);
- the premises are suitable;
- the practices are suitable;
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that there are areas of practice that require improvement. The inspection team recommend that the ELP requires the Person Responsible (PR) to comply with the following recommendations within the time-frames set out in this inspection report.

**Major areas of non-compliance:**

- the centre should complete the implementation of the agreed action plan to ensure that gametes are stored within the terms of effective consent by August 2013;
- the documentation and conduct of witnessing should be reviewed to ensure compliance with SLC T71 and guidance in the CoP at 18.4 (e);
- the PR should advise the HFEA of the actions planned to ensure compliance with the requirement for Clinical Pathology (UK Ltd) Accreditation (CPA);
- the PR should provide a list of all procurement and processing procedures that are considered critical including the date of review of validation and the date by which full validation is expected to be complete;
- the PR should review the procedures for submitting annual outcome information to the HFEA.

**'Other' areas of non-compliance or poor practice that require improvement:**

- the PR should ensure that the resources required to ensure compliance with HFEA requirements are available;
- nursing staff should document the assessment of their competence;
- the PR should undertake an audit of patient records to identify whether failure to document the review of welfare of the child assessments observed in the course of the inspection represent a systemic failure or a rare occurrence;
- the PR should review the existing bring-forward system and consider prioritising the establishment of a more robust procedure;

- the centre is advised to continue to store ovarian tissue under the terms of their existing HFEA licence until the tissue is to be used when advice on how to meet statutory requirements should be obtained from both the HFEA and HTA;
- the centre should review the validation of their air quality testing methodology;
- the PR should ensure that procedures for ensuring information is kept confidential are audited to ensure that they comply with the approved protocols, regulatory requirements and quality indicators in the next twelve months;
- the PR should ensure that effective mechanisms are in place to inform patients of the need to keep the centre informed of changes in circumstance; treatment outcomes; and changes in consent. It is also recommended that the PR monitors the frequency and cause of delays or cancellation of appointments;
- The PR should review the centre's website to ensure compliance with the guidance provided in Chair's Letter CH(11)02.

## Recommendation to the Executive Licensing Panel

Some improvement is required in order for the centre to demonstrate compliance with HFEA requirements. It is noted however, that on the basis of the centre's success rates and patient feedback, a good quality of service is provided to patients.

The inspection team is satisfied that activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The inspection team recommends the renewal of the centre's licence for a period of 4 years without additional conditions subject to compliance with the recommendations made in this report within the prescribed timescales.

## 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) 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** (Guidance note 18)

What the centre does well

The centre's procedures for double checking the identification of gametes and the patient to whom they relate are broadly compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

What the centre could do better

In the course of the review of documentation of witnessing, it was noted that while a witness signs the laboratory sheet to record that they have cross checked patient identifying information at each individual critical time point, the person carrying out the procedure confirms they have completed the whole procedure rather than each of the steps within the procedure. This was not considered to be fully compliant with the requirements of standard licence condition (SLC) T71 that checks must be recorded at the time each relevant clinical or laboratory procedure takes place.

During the transfer of gametes into cryopreservation straws it was observed that the required number of labels were generated and affixed to cryopreservation straws: straws were then loaded and the label on the first straw was cross checked by both the operator and a witness against the patient's identifying information on the laboratory sheet and the container from which the sample was loaded. The labelling on the remaining straws was not cross-checked by a witness either at the time of labelling, after loading, or before the straws were placed into storage (although a count of the straws was conducted at this time). It was explained that the label printer can only generate labels for one patient at a time and there was considered no risk that the roll of labels produced could include the details of a different patient. It was also noted that there was only one sample being processed during the procedure so there was no risk of the sperm of a different patient being loaded into the straws. This procedure was not considered to be fully compliant with CoP guidance at 18.4 (e).

## Patient and Donor selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for donors (Guidance note 13)
- Donor assisted conception(Guidance note 20)

What the centre does well

**Screening of patients and / or donors**

The centre's procedures for screening patients and patient partners 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/or storage of gametes.

**Payments for donors**

The centre does not recruit donors and this area of practice is not applicable to this inspection.

**Donor assisted conception**

The centre does not provide treatment with donor gametes and this area of practice is not applicable to this inspection.

What the centre could do better

## Good clinical practice

**What the centre does well**

**Multiple births (Guidance note 7)**

The centre does not provide treatment involving the transfer of embryos and this area of practice is not applicable to this inspection.

**Process Validation(Guidance note 15)**

The centre has undertaken a partial validation the critical processing procedures: validation ensures that these procedures are effective and do not render the gametes clinically ineffective or harmful to the recipient.

**Traceability (Guidance note 19)**

The centre's traceability procedures are compliant with HFEA requirements and ensure that the centre can:

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

**Quality management system (Guidance note 23)**
The centre has a quality management system in place that is broadly compliant with HFEA requirements. The centre is effective in using the quality management system to ensure optimum outcomes and improve the quality and safety of the treatment and services provided to patients.

**Third party agreements (Guidance note 24)**
The centre has agreements in place which cover the supply of any goods and services which may affect the quality or safety of gametes.

**Satellite and transport IVFagreements (Directions 0010)**
The centre has an agreement in place with The Centre for Reproductive and Genetic Health (centre 0044) for the provision of a satellite transport service as required by Directions 0010.

**Equipment and materials (Guidance note 26)**
The equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

**Premises (Guidance note 25)**
The centre conducts all activities on licensed premises. All diagnostic testing, with one exception listed below, is carried out by a suitably accredited laboratory.

The centre's premises were considered suitable for the activities carried out and the centre is broadly compliant with HFEA air quality requirements with the exception listed below.

**Adverse incidents (Guidance note 27)**
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all of the adverse incidents that have occurred and shares the lessons learned in order to continuously improve the services it offers.

What the centre could do better

**Process validation(Guidance note 15)**
The centre's process validation documentation was reviewed in the course of the inspection. The validation for the sample of processes reviewed included only a reference to professional body guidelines: the inspector was also advised that diagnostic sperm assessment is not being undertaken in line with the guidelines referenced in the validation documentation. SLC T72

**Quality management system (Guidance note 23)**
The centre has not audited how far procedures to ensure that all information is kept confidential comply with the approved protocols, regulatory requirements and quality indicators in the last two years. SLC T36

**Premises (Guidance note 25)**
Evidence that the background air in the laboratory where gametes are processed is of grade C air quality as measured by particle counting was provided in the course of the inspection. It was noted however that the assessment of air quality in the flow hoods was not carried out by particle counting: air quality in this environment is conducted annually

using settle plates. The results of the settle plate analysis did show that the air quality in the flow hoods met the required grade C air quality but it was considered surprising that the methodology used to test background air quality was potentially more robust than that used for the flow hoods where samples are processed. SLC T20

The centre undertakes diagnostic semen analysis but the laboratories have not obtained accreditation by Clinical Pathology Accreditation (UK) Ltd (CPA): a review of the centre's sperm analysis validation and NEQAS performance records did not support the conclusion that the centre has an equivalent standard of accreditation. SLC T21

## Staff engaged in licensed activity

What the centre does well

**Person Responsible (Guidance note 1)**
The PR has a key role in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision licensed activities are carried out. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

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 (PREP number T/1206/8).

**Staff (Guidance Note 2)**
The centre is broadly compliant with the requirement to have suitably qualified and competent staff to carry out all of the licensed activities and associated services: the only concern is noted below

What the centre could do better

**Staff (Guidance Note 2)**
While it is acknowledged that the centre maintains a high level of service quality for patients, sufficient time may not be available to ensure compliance with HFEA requirements. This concern is based on the observation that the centre has a large backlog of issues to resolve in relation to storage of cryopreserved material and a number of non-compliances identified in the course of the inspection that will require resource to address. It is also understood that the Trust does not allocate time within the PR's job plan to undertake the tasks associated with the responsibilities of a PR or within the job plans of members of the nursing and laboratory staff with responsibilities for quality management. SLC T12

Although there were no concerns about the competence of members of the nursing team,

not all staff were able to provide evidence of the documentation of their competence to carry out licensed activities. SLC T15

## **Welfare of the child**(Guidance note 8)

What the centre does well

The centre's procedures for taking into account the welfare of the child (WoC) are broadly compliant with HFEA requirements. The centre takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth.

What the centre could do better

In three of a sample of 11 records reviewed in the course of the inspection, there was documented evidence that a WoC assessment had been carried out but the section of the form documenting the review of the assessment by a member of the centre's staff had not been completed. SLC T56

## **Embryo testing**

- Preimplantation genetic screening (Guidance note 9)
- Embryo testing and sex selection (Guidance note 10)

What the centre does well

The centre does not undertake embryo testing and this area of practice is not applicable to this inspection.

What the centre could do better

## 2. The experience of patients

### Patient feedback

What the centre does well

During the inspection visit three patients provided feedback on their experiences. A further 13 patients also provided written feedback directly to the HFEA in the time since the last inspection. Feedback was positive with 9 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that centre staff:

- have respect for the privacy and confidentiality of patients in the clinic;
- provide patients with sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provide patients with information about the counselling service;
- provide patients with information about the drugs they will receive and the circumstances under which information about them will be shared with other people.

Patients fed back that they found the facilities for their care satisfactory.

What the centre could do better

Only one of the 13 people providing written feedback to the HFEA reported that they were informed of the need to stay in touch with the centre: if the importance of this is not communicated then patients storing material may not appreciate that they must keep the centre informed of changes of address. In turn this may impact on the effectiveness of the centre's bring forward system for cryopreserved material.

Five respondents (38%) commented negatively on the frequency with which appointments at the centre were cancelled or delayed.

### Treating patients fairly

What the centre does well

**Egg sharing arrangements (Guidance note 12)**
The centre does not undertake egg sharing and this area of practice is not applicable to this inspection.

**Surrogacy (Guidance note 14)**
The centre does not undertake surrogacy and this area of practice is not applicable to this inspection.

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

**Treating patients fairly (Guidance note 29)**
The centre appears to treat prospective and current patients fairly and ensures 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, ensuring that counselling provided by suitably qualified staff is offered to patients giving relevant consents.

**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 well-being of prospective and current patients.

What the centre could do better

## Information

What the centre does well

The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions.

**Provision of a costed treatment plans (Guidance note 4)**
The centre provides NHS funded treatments only and this area of practice is not applicable to this inspection.

What the centre could do better

The centre's web site provides information to prospective patients on the availability of fertility treatments including IVF treatment that are carried out under the terms of a satellite agreement with The Centre for Reproductive and Genetic Health (centre 0044). At the time of the inspection, the website did not make it clear that treatments initiated at Reproductive Medicine Unit under the terms of this agreement would require patients to conclude their treatment at The Centre for Reproductive and Genetic Health. This is potentially non-compliant with guidance issued in Chair's Letter CH(11)02.

## Consent

What the centre does well

The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients have provided all relevant consents before carrying out any licensed activity.

**Disclosure of information, held on the HFEA Register, for use in research**
The centre does not provide any patient identifying information to the HFEA register and this area of practice is not applicable to this inspection.

What the centre could do better
It was noted that patients are provided with an opportunity to consent to the disclosure of information held on the HFEA register about their treatment to researchers. As no information is submitted or held on the HFEA's register relating to storage of gametes or basic partner treatment services then this consent is not a current requirement for patients undergoing this treatment or being provided with storage only services.The PR may wish to reconsider this practice.

## 3. The protection of gametes and embryos

### Respect for the special status of the embryo

What the centre does well

The centre does not create embryos and this area of practice is not applicable to this inspection.

What the centre could do better

### Storage of gametes

What the centre does well

The storage of gametes 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 centre's procedures for storing gametes are partially compliant with HFEA requirements. This ensures that the gametes are stored appropriately to maintain their quality and safety.

What the centre could do better

The centre does not have written effective consent for the storage of all cryopreserved gametes (Schedule 3, 8(1) HF&E Act). This non-compliance was identified at the time of the last interim inspection and the centre submitted an action plan to the HFEA documenting a comprehensive review of >3000 patient samples stored at the centre from 1970 onward. The PR has provided regular updates to the HFEA on progress in implementing the plan which was and is expected to be fully implemented by August 2013.

There did not appear to be an effective bring-forward system in operation to prevent samples reaching the end of the consented storage period remaining in storage. CoP Guidance 17.7

The centre is storing ovarian tissue intended without an HTA licence. CoP 17A

### Distribution and / or receipt of gametes and embryos

What the centre does well

The centre's procedures for distributing and / or receiving gametes were not reviewed in detail the course of this inspection. Transfer of gametes is done very infrequently. On the basis of the centre's self-assessment however, it is concluded that the centre is compliant with HFEA requirements.

This ensures that all gametes sent to other licensed centres within or outside the UK are appropriately labelled and relevant information is sent to the other centre to ensure the

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| continued quality and safety of the gametes and that the centre only accepts gametes from other licensed centres if the gametes are appropriately labelled and there is enough information to permit the gametes be stored or used in a way that does not comprise their quality and safety. |
| What the centre could do better |

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| **Use of embryos for training staff** (Guidance note 22) |
| What the centre does well<br><br>The centre does not create or store embryos and this area of practice is not applicable to this inspection. |
| What the centre could do better |

## 4. Information management

### Record keeping and submitting information to the HFEA

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 continuity of patient care.

What the centre could do better

**Obligations and reporting requirements (Guidance note 32)**
Centres providing basic partner treatment services only are only required to submit an annual return to the HFEA providing details of the number of treatments provided and the outcomes of those treatments (Directions 0005). This enables the HFEA to satisfy their statutory reporting responsibilities and to provide information to patients via the HFEA website about centres' success rates.

The centre has not submitted an annual return for treatments performed in 2012. The completed return is visible on the HFEA portal and is complete but has not been submitted by the PR. This means that up to date success rates or this clinic have not been published on the HFEA website.

## Section 3: Monitoring of the centre's performance

Following the interim inspection in May 2012,recommendations for improvement were made in relation to two areas of critical non-compliance and one'other' area of non-compliance.

The two critical non-compliances that were cited related to storage of cryopreserved gametes beyond the consented or statutory storage periods. The centre complied with the recommendation to establish and implement an action plan to ensure that all material is stored within the terms of an effective consent but, with the agreement of the centre's inspector and in consideration of the scale of the work to be completed, the full implementation of the plan is not anticipated to be complete before August 2013.

The "other" non-compliance related to documentation of staff competence. Although this report also recommends a minor improvement in this respect, it is recognised that ensuring that all staff have documented evidence of their competence is an on-going requirement and the recurrence of this recommendation is not considered indicative of significantly poor practice.

## 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 |
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| No critical non-compliances noted on this 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 |
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| 1. The centre does not have written effective consent for the storage of all cryopreserved gametes (Schedule 3, 8(1) HF&E Act). This non-compliance was identified at the time of the last inspection and the centre submitted an action plan to the HFEA documenting a comprehensive review of >3000 patient samples stored at the centre from 1970 onward. The PR has provided regular updates to the HFEA on progress in implementing the plan which was and is expected to be fully implemented by August 2013. | No further action is required beyond completion of the agreed action plan. The PR should continue to keep the HFEA informed of progress in completing the review by 31 August 2013. | The project has progressed well and we have reviewed all storage up to and including 2003.<br><br>We have updated consents or discarded samples as appropriate. Unresolved samples are being assessed individually.<br><br>We can provide a detailed report to 31 August as required. | We acknowledge progress made by the PR especially given the scale of the review. We await the report and will work with the PR if further action is required. |

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| 2. The documentation of witnessing was not considered to be fully compliant with the requirement of SLC T71 that checks must be recorded at the time the relevant clinical or laboratory procedure takes place.<br><br>Witnessing procedures at the time of loading of cryopreservation straws were not considered to be fully compliant with CoP guidance at 18.4 (e). | The documentation of witnessing should be revised to ensure compliance with SLC T71. The HFEA should be advised of the actions taken to achieve this by the time this report is considered by a Licensing Committee.<br><br>While it is acknowledged that the risks of the non compliance related to the witnessing of the labelling of cryopreservation straws may be low, the PR should consider whether practices could be further improved. The HFEA should be advised of the outcome of this consideration and actions taken to mitigate any risks by the time this report is considered by a Licensing Committee. | The SOP for witnessing of procedures has been updated to include the additional signature and time stamp at each stage by the operator in addition to the second witness. This has removed any potential ambiguity from the observed practice where a single signature was required to imply that the person performing the procedure was necessarily present and witnessing.<br><br>A copy of the updated SOP can be provided.<br><br>The SOP details the strict cross-checking of all three unique patient identifiers at each critical step of a procedure, while processing one sample at a time to minimise any risk of mismatch. The observed procedure of witnessing appears to be an isolated incidence of deviation from the documented procedure. Staff have been retrained in line with the revised SOP, | We request that a copy of the revised witnessing SOP is forwarded to the centre's inspector. |

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| | | and competency assessments of each member of staff to perform each witnessing step correctly are carried out with increased frequency. | |
| 3. The centre undertakes diagnostic semen analysis but the laboratories have not obtained accreditation by Clinical Pathology Accreditation (UK) Ltd (CPA): a review of the centre's sperm analysis validation and NEQAS performance records did not support the conclusion that the centre has an equivalent standard of accreditation SLC T21. | The PR should advise the HFEA of the actions that will be taken and the anticipated timescale for their implementation to ensure future compliance with the requirements of SLC T21 by the time this report is considered by a Licensing Committee. | As discussed during the inspection, our resources have been prioritised for the resolution of previous critical non-compliance (storage project). Discussion with the Inspectors suggested that 18 months is a reasonable timeframe for enrolment | We request that the PR provides regular up-dates on progress made towards compliance with this licence condition. |
| 4. The centre has not fully validated the all critical procurement and processing procedures. SLC T72 | The PR should provide a list of all procurement and processing procedures that are considered critical including the date of review of validation and the date by which full validation is expected to be complete. The list should be provided to the HFEA by the time the report is considered by a | Validation of equipment and processes was identified as an area of non-compliance during the interim inspection in 2010. Following this, validation documents were submitted to the HFEA within the agreed timeframes. The 2012 inspection deemed this | We will continue to work with the PR to enhance the quality of the centres validation documentation, and the PR should seek further advice from their inspector if needed. Following 22 November 2013, an inspector will arrange to review a sample of revised validation |

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| | licensing committee.<br><br>The PR should provide monthly updates to the HFEA on progress in completing validation. It is expected that validation will be prioritised on the basis of risk associated with the procedure and that validation will be complete by 22 November 2013. On completion the validation programme the HFEA will ask for a sample of validation documents to be submitted for review. | Centre compliant with the regulatory requirements as described in the Code of Practice, and no further action was required.<br>This inspection has highlighted some improvements that could be made to the documentation of validation and a more comprehensive collection of validation documents will be prepared. | documents. |
| 5. The centre has not submitted an annual return for treatments performed in the 2012. The completed return is visible on the HFEA portal and is complete but has not been submitted by the PR. This means that up to date success rates or this clinic have not been published on the HFEA website. Directions 0005. | The PR should review the procedures for submitting annual return information to the HFEA. The PR should submit the form and provide information on the actions taken to ensure that this information will be submitted within the prescribed timeframes in the future by the time this report is considered by a licensing committee. | We had prepared the annual return within the prescribed timeframe and submitted it but the PR had been unable to navigate the HFEA website successfully. | We can confirm that the centre's IUIP form has now been submitted.<br><br>The PR should ensure that future IUIP forms are submitted on time, and should contact their inspector should they encounter similar difficulties. |

## 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 |
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| 6. While it is acknowledged that the centre maintains a high level of service quality for patients, sufficient time may not be available to ensure compliance with HFEA requirements. This concern is based on the observation that the centre has a large backlog of issues to resolve in relation to storage of cryopreserved material and a number of non-compliances identified in the course of the inspection that will require resource to address. It is also understood that the Trust does not allocate time within the PR's job plan to undertake the tasks associated with the responsibilities of a PR or within the job plans of | The PR should ensure that the resources required to ensure compliance with HFEA requirements are available. The HFEA should be advised of the actions taken in relation to this recommendation by the time this report is considered by a Licensing Committee. | Thank you for your support for our service.<br>The job plan review has led to 2 hours per week being allocated to the role of Clinical Lead/Person Responsible.<br>The nursing staffing is still below complement but we are actively trying to recruit. | We are pleased to hear that time has been allocated to the PR. We will continue to monitor the situation, for example using implementation of recommendations in this report as an indicator of resources available. |

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| members of the nursing and laboratory staff teams with responsibilities for quality management. SLC T12 | | | |
| 7. Although there were no concerns about the competence of members of the nursing team, not all were able to provide evidence of the documentation of their competence to carry out licensed activities. SLC T15 | The member of staff interviewed in the course of the inspection undertook to document the assessment of her competence. No further action is required beyond this. | N/A | No further action required. |
| 8. In a sample of three records reviewed in the course of the inspection, there was documented evidence that a WoC assessment had been carried out but the section of the form documenting the review of the assessment had not been completed. SLC T56. | The PR should undertake an audit of patient records to identify whether the inspection observations represent a systemic failure or a rare occurrence. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 22 August 2013. Within three months of the implementation of any required corrective actions, the centre should conduct an audit of WoC | An audit of patient notes is carried out monthly which includes completion of WoC assessment. This has not exposed any systemic failure. It is the Centre's practice to give out the Welfare of the Child questionnaires at the first consultation and complete the assessment when treatment is offered. We are uncertain whether the notes reviewed were for patients undergoing treatment. | We will forward to the PR information to help identify the records viewed on inspection in which reviews of the WoC assessment had not been completed. The PR should review appropriate documents the files and provide an up-date to their inspector. |

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| | assessment procedures and a summary report of the findings of the audit should be provided to the HFEA. | | |
| 9. There did not appear to be an effective bring-forward system in operation to prevent samples reaching the end of the consented storage period remaining in storage. CoP Guidance 17.7 | The PR should review the existing bring-forward system and give consideration to prioritising the establishment of a more robust system as this will limit the likelihood that further material will be stored beyond the consented or statutory storage periods.<br><br>A summary report of the review findings including any required corrective actions and the timescale for their implementation should be submitted to the HFEA by 22 August 2013. The PR should provide monthly updates to the HFEA on progress in implementing corrective actions. | The gamete storage database enables patients with near-expiring consent to be identified. The review of samples is now up-to-date (patients storing in 2003 with 10-year consents have been contacted) and we are organising earlier reviews for 2004 onwards. This will undoubtedly improve the compliance of our storage laboratory.<br>A new SOP detailing better-defined bring-forward system has been developed. A copy can be provided. However provision of monthly updates is unrealistic. | We request that the SOP is forwarded to the centre's inspector. |
| 10. The centre is storing ovarian tissue intended without an HTA licence. CoP 17A | HFEA and HTA have issued a joint policy statement that acknowledges that ovarian tissue can be stored under the auspices of an HFEA licence but without an HTA | No action required. | No further action required until the centre intends to use ovarian tissue in storage. |

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| | licence where the intention is to extract eggs from the tissue for in vitro maturation prior to IVF. If the intention is to use the tissue for transplantation then this currently also requires an HTA licence. In recognition that tissue may be being stored without a clear intention of its future use the centre is advised to continue to store this material under the terms of their existing HFEA licence until the tissue is to be used. At this time, advice on how to meet statutory requirements should be obtained from both HFEA and HTA. | | |
| 11. Evidence was provided that the air quality in the flow hoods (where samples are processed) meets HFEA requirements but the testing methodology used to test background air quality was potentially more robust than that used for the flow hoods where samples are processed. | The centre should review the validation of their air quality testing methodology. The HFEA should be advised of any changes in practice implemented as a result of this review by 22 August 2013. | Both the measured air quality of flow hoods and background area, and the methods to assess the air quality, are compliant with the recommendations documented in section 15.16 of the CoP. The validation document will be reviewed alongside others (item 4, above).<br>The differing methodology has | We request that the PR forwards a copy of their validation for testing air quality in their flow hoods by 22 September 2013. |

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| SLC T20 | | arisen from the contractual arrangements of the NHS Hospital Trust for maintenance of equipment and the PFI for maintenance of the building including environmental air quality. | |
| 12. The centre has not audited how far procedures to ensure that all information is kept confidential comply with the approved protocols, regulatory requirements and quality indicators in the last two years. SLC T36<br><br>Although failure to audit practice is usually considered a major non-compliance, in consideration that no risks to maintenance of confidentiality were observed in the course of the inspection and no incidents relating to breaches of confidentiality have been reported to the HFEA this has been classified as an "other" non-compliance. | The PR should ensure that procedures to ensure that all information is kept confidential comply with the approved protocols, regulatory requirements and quality indicators are audited in the next twelve months. The HFEA should be provided with a summary report of the audit findings by 22 May 2014. | This audit will be initiated and the report submitted. | We await the PRs report, to be received by 22 May 2014. |

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| 13. Only one of the 13 people providing written feedback to the HFEA reported that they were informed of the need to stay in touch with the centre: if the importance of this is not communicated then patients storing material may not appreciate the importance of keeping the centre informed of changes of address. In turn this may impact on the effectiveness of the centre's bring forward system.<br><br>Five respondents (38%) commented negatively on the frequency with which appointments at the centre were cancelled or delayed: there is concern that this could be indicative of insufficient staffing levels. | The PR should ensure that there are effective mechanisms for informing patients of the need to keep the centre informed of changes in circumstance; treatment outcomes; and, changes in consent. The HFEA should be informed of the actions taken to achieve this by the time this report is considered by a Licensing Committee.<br><br>It is also recommended that the PR monitor the frequency and cause of delays or cancellation of appointments. A summary report of the findings of this monitoring should be provided to the HFEA by 22 November 2013. | During the inspection, evidence was presented that male patients storing sperm are requested to keep the laboratory updated with any changes of contact details or circumstance: patient information leaflet, in-house consent for sperm storage, and check-list for sperm storage consent session.<br><br>Couples undergoing treatment are requested to inform the Centre of the outcome and this is documented in their patient information.<br><br>Re cancellations, we have highlighted this to our hospital management and will work together to produce a summary report. | We acknowledge that relevant patient information was submitted with the initial application that clearly outlines the importance of staying in touch with the centre.<br><br>We await the summary report regarding appointment cancellations. |

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| 14. The centre's web site provides information to prospective patients on the availability of fertility treatments including IVF treatment that are carried out under the terms of a satellite agreement with The Centre for Reproductive and Genetic Health. At the time of the inspection, the website did not make it clear that treatments initiated at The Reproductive Medicine Unit under the terms of this agreement would require patients to conclude their treatment at The Centre for Reproductive and Genetic Health. This is potentially non-compliant with guidance issued in Chair's Letter CH(11)02. | The PR should review the centre's website to ensure compliance with the guidance provided in Chair's Letter CH(11)02. | We have asked our general manager to update the hospital website in accordance with this. | We acknowledge the statement on the centre's website that:<br><br>'This part of the treatment [egg collection] takes place on another site at the Centre for Reproductive and Genetic Health which is a private service, however patients remain under the care of UCLH throughout their treatment.' |

| Reponse from the Person Responsible to this inspection report |
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# HFEA Executive Licensing Panel Meeting

**6 September 2013**

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

## Minutes – Item 1

**Centre 0167 – (Reproductive Medicine Unit) – Renewal Inspection Report**

| Members of the Panel: | Committee Secretary: |
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| Mark Bennett – Director of Finance and Facilities (Chair) | Rebecca Loveys |
| Paula Robinson – Head of Business Planning | Observing: |
| Rachel Hopkins – Head of HR | Sam Hartley – Head of Governance and Licensing |

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

**The Panel also had before it:**

- HFEA Protocol for the Conduct of Meetings of 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 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 Publication of Authority and Committee Papers

**Consideration of Application**

1. The Panel noted that this is a small centre that has been licensed by the HFEA since 1997.

2. The Panel noted that the centre provides basic partner services (intrauterine insemination with partner sperm (IUI)) to NHS patients and a sperm storage service for patients having treatment that may impair their fertility.

3. The Panel noted that the centre provides a satellite IVF service to NHS patients in conjunction with centre 0044 (The Centre for Reproductive and Genetic Health).

4. The Panel noted that the centre has a five year licence due to expire in October 2013 and that the inspection took place on 22 May 2013.

5. The Panel noted that the centre provided 282 IUI treatments in 2012 with 42 pregnancies. The 15% clinical pregnancy rate is consistent with the national average.

6. The Panel noted that, at the time of inspection, five major and nine other areas of non-compliance were identified, some of which have since been reported as addressed. The Panel discussed these in terms of scope and number and the effects they might have, individually and in aggregate, on the effective operation of a small clinic.

7. The Panel was reassured to note that, since the inspection, the other non-compliance related to failure to document welfare of the child assessments had been investigated further and was not systemic.

**Decision**

8. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

9. The Panel was satisfied that the qualifications and character of the Person Responsible (PR) are such as is required for the supervision of the licensed activities.

10. The Panel was satisfied that the licence renewal application concerns treatment or non-medical fertility services which relate to gametes intended for human application.

11. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence within the report.

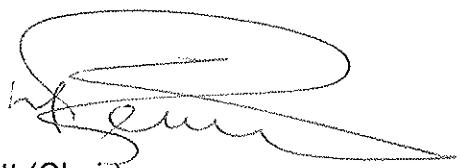
12. The Panel noted the Inspectorate had recommended renewal of the licence for four years, without additional conditions.

13. The Panel was reassured by the progress reported on several actions to address non-compliances. For remaining non-compliances, the Panel urged the PR to address the non-compliances identified in the report in accordance with the timescales recorded. In particular, the Panel noted the major non-compliance related to storage without effective written consent was due to be completed during August 2013; on which a status report had been promised by the PR.

14. The Panel requested the Inspectorate to continue to monitor the centre's progress on actions related to non-compliances and to take appropriate and effective action should progress not be maintained or not prove sufficient.

15. In the light of the number and extent of the non-compliances, the Panel considered granting a two year licence. Taking into account the absence of critical non-compliances, the evidence of success rates and quality of service overall and the progress and commitment made by the PR to resolve non-compliances, the Panel agreed to offer a four year licence.

16. The Panel endorsed the Inspectorate's recommendations and associated timescales in the report. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed:  Date: 9 Sept 2013

Mark Bennett (Chair)