Inspection Report

Date of Inspection: 10 May 2012
Purpose of inspection: Renewal of Treatment Licence
Length of inspection: 8 hours
Inspectors: Mr Wil Lenton and Mrs Susan Jolliffe

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 19 May 2010 and 16 August 2012

Date of Executive Licensing Panel: 30 August 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice (CoP), to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel (ELP) which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Royal Derby Hospital
Centre number	0149
Licence number	L/0149/9/d
Centre address	Fertility Unit, Women's and Children's Services, Derby City General Hospital, Uttoxeter Road, Derby, Derbyshire, DE22 3NE.
Person Responsible	Mr Joe Darne (to 1 June 2012) Dr Kannamannadiar Jayaprakasan (from 1 June 2012)
Licence Holder	Professor Robert Shaw
Date licence issued	01 November 2008
Licence expiry date	31 October 2012
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The fertility unit at the Royal Derby Hospital was first licensed by the HFEA in 1995 for donor insemination (DI). Since the implementation of the European Tissues and Cells Directive (EUTD) in July 2007, the centre has been licensed for treatment (insemination using partner / donor sperm) and storage.

The fertility unit also acts as a satellite to CARE Nottingham (centre 0101) and patients are referred there for in vitro fertilisation (IVF).

In December 2007, the centre moved from their temporary premises of the previous 18 months to spacious new premises within the same hospital grounds. The centre re-commenced HFEA licensed treatment in March 2008 after the Licence Committee approved the variation of the licence. The Committee noted that the premises were suitable and agreed that they were content for licensed work to recommence.
The centre varied its licence in November 2009 to incorporate a change of centre title from 'Derby City General Hospital' to 'Royal Derby Hospital'.

Since the previous inspection in May 2010, no major changes have been made to the premises.

During the present inspection the person responsible (PR) informed the Executive that he was retiring on 22 May 2012 and that a prospective PR had been appointed by the NHS Trust. The prospective PR, Dr Kannamannadiar Jayaprakasan successfully completed the HFEA PR entry programme (PREP: T/1211/8), and the centre's licence was varied on 1 June 2012, to approve the new PR.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 January 2011 – 31 December 2011*
IUI (stimulated)	203
IUI (non-stimulated)	26

Other licensable activities	
Storage of eggs	N/A
Storage of sperm	✓
Storage of embryos	N/A
Research	N/A

Outcomes*

For the year 2011 the centre reported;

- 203 stimulated cycles with 7% (15) pregnancies. This is in line with the national average.
- 26 non-stimulated cycles with 8% (2) pregnancies. This is in line with the national average.

*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.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- The PR at the time of the inspection was suitable and had discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- The new PR is suitable;
- 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 at the time of inspection there were a number of areas of practice that required improvement, including four major areas of non-compliance and three 'other' areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed that all recommendations have been fully implemented:

Major areas of non compliance

- The centre has investigated the circumstances that led to the centre being temporarily without a PR to supervise activities and submitted a summary report to the HFEA documenting the findings of the investigation.
- The PR has ensured that all critical equipment, such as the centrifuge, refrigerator and pipettes are fully validated.
- The PR has ensured that audits of all critical activities are performed.
- The PR has ensured that quality indicators (QIs) have been established and documented for all critical activities.

'Other' areas of practice

- The PR has ensured that all patients are appropriately screened.
- Procedures for the operation of the flow-hood have been established which includes the action to be taken in the event of malfunctions or failure.
- The PR has ensured that a third party agreement (TPA) with centre 0101 is in place.

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Recommendation to the Executive Licensing Panel

The inspection team considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- 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
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

▶ Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

The centre has a documented SOP describing the witnessing procedure for all relevant critical points specified in CoP Guidance 18.4. Five sets of patient notes audited on inspection were found to include records of all required witnessing steps.

The centre double checks the identification of gametes and the patients to whom they relate at all critical points of the clinical and laboratory process (Standard Licence Condition (SLC) T71).

Evidence of training and competence assessment for all staff performing witnessing steps was seen on inspection (SLC T15 (a)).

Audits to ensure compliance with regulatory requirements and centre SOPs are performed. The last patient notes audit performed in November 2011 showed 100% compliance, the previous audit report documented corrective actions which have been implemented.

What the centre could do better.

Nothing noted at the time of inspection.

▶ Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)

What the centre does well.

The laboratories undertaking diagnosis and investigation of patients are accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd: this was confirmed by staff at the centre and review of the CPA website (SLC T21).

The centre has a documented SOP describing the critical procurement and processing procedures (SLC T33b).

On rare occasions where sperm for use in treatment was produced at home, rather than at the centre, this event is recorded on a tracking sheet and retained within the patient records.

Counselling: Guidance Note 3

The centre has a counselling SOP describing the provision of information regarding the counselling service at the initial consultation and any follow up appointments (SLC T33 (b)). The provision of a counselling service is not mandatory for patients undergoing IUI however, the centre does offer implication counselling to both its satellite IVF and IUI patients and there is a service level agreement affording all patients access to a counsellor from Care Nottingham.

The contact details of the counsellor are documented in the information leaflets and are on display in the waiting areas (CoP Guidance 3.2).

What the centre could do better.

Patients at the centre are routinely screened prior to IVF treatment for HIV, Hepatitis B and C, but are not routinely screened before IUI treatment.

It is recognised that the Commission Directive 2006/17/EC (Annex III, 2.2) states that where sperm is processed for IUI and not stored, if the centre can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes, biological testing may not be required (SLC T50).

Donor assisted conception (Guidance Note 20)

Only applicable to centres licensed to carry out treatment using donor gametes and / or embryos

What the centre does well.

The centre does not recruit donors. The centre has not provided treatment using donated gametes in the time since the last inspection and procedures for the procurement of donor gametes were not reviewed.

What the centre could do better.

Nothing noted at the time of inspection.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)

What the centre does well.

The quality management system: Guidance Note 23

The centre has a quality management system (QMS) that the inspection team considered appropriate for the services provided. Documents were seen to include a quality manual and training and reference manuals (SLC T33 (a) and (d)). Critical procedures conducted at the centre are documented in SOPs, as evidenced by the centre's master document list (SLC T33 (b)).

Patient satisfaction is monitored by the centre via a hospital-wide survey. The lead nurse stated that positive feedback has been received, although very few completed surveys are returned. The HFEA has received no patient feedback since the last inspection. A number of patients were interviewed in the course of the inspection and they made positive comments regarding the centre's services.

Process validation: Guidance Note 15

The centre's critical processes have been validated in compliance with SLC T72 and a sample of process validation documents was reviewed in the course of the inspection. The validation approach used includes reference to relevant published studies and confirmation that all consumables and reagents used are validated and traceable.

Traceability: Guidance Note 19

The centre ensures that the traceability of all consumables, reagents and equipment that come into contact with gametes is assured.

Containers used in the course of procurement and processing of gametes are labelled with the full name of the patient and partner and two further identifiers (SLC T101).

The traceability procedure is documented in a SOP (SLC T33 (b)) and was demonstrated in the course of the inspection. Traceability data, including item description, batch number, expiry date, start date and end date for all critical consumables and reagents, are recorded in the laboratory log books and on tracking sheets within the patient notes.

Third party agreements: Guidance Note 24

The centre has written agreements with third parties providing goods and services influencing the quality and safety of gametes with one exception, noted below (SLC T111).

A sample of TPAs was reviewed on inspection and found to be compliant with SLC T114.

Premises and facilities: Guidance Note 25

The centre has a SOP for the monitoring of air quality, including the actions to be taken if the required air quality is not met (SLC T33 (b)).

Evidence was provided that gametes are processed in an environment of grade C air

quality with a background of grade D in compliance with SLC T20.

Records of regular cleaning of both the premises and equipment were seen on inspection (SLC T26).

Equipment and materials: Guidance Note 26

Defined limits for the temperature of the refrigerator have been set. Records of the regular monitoring of these parameters demonstrated that these set ranges are achieved (SLC T24).

The centre has a planned preventive maintenance programme for critical equipment. Service records for the class II cabinet, centrifuge, microscopes and pipettes were reviewed on inspection and found to have been serviced within the last year (SLC T24).

Some critical equipment, such as the class II workstation, has been validated (SLC T24).

Evidence was provided that critical measuring equipment, including the particle counter and thermometers, are calibrated against traceable standards (SLC T24).

The centre's procedures for the operation of all critical equipment were clear with one exception noted below (SLC T27).

Staff confirmed that consumables in use in the laboratory are all sterile and CE marked where applicable. This was the case for a number of items seen on inspection in the laboratory (SLC T30).

Adverse incidents: Guidance Note 27

The centre has not reported any adverse incidents to the HFEA since the last inspection. The lead clinical nurse and the PR confirmed that no adverse incidents have occurred in relation to the IUI service. However, incidents are a standing item at bi monthly quality meetings, and the trust wide system is used to report incidents.

The centre has an adverse incident SOP, documenting the procedure to follow in the event of an incident, including HFEA reporting requirements (SLC T118).

What the centre could do better.

The quality management system: Guidance Note 23

Although a wide range of audits are performed by the centre and corrective action is identified where issues are found, QIs have not been formally established and documented by the centre in all areas, such as traceability and procurement & processing (SLC T35).

Several audit reports were reviewed on inspection. Where issues were identified, the corrective action required was seen to be documented. However, the audit process is not embedded in the clinic work and needs to be more robust to be effective (SLC T36).

Third party agreements: Guidance Note 24

The satellite agreement with Care Nottingham dated December 2011 has not yet been signed by both parties (SLC T114).

Equipment and materials: Guidance Note 26

The documented procedures for the operation of critical equipment did not include a SOP for the flow hood (SLC T27).

Validation documentation is not in place for the centrifuge, refrigerator or pipettes (SLC T24).

Multiple Births (Guidance Note 7)

What the centre does well

The centre is licensed for IUI treatment only and patient information is provided to satellite IVF patients by the primary centre. The centre is therefore not required to meet the requirements of General Direction 0003.

What the centre could better

N/A

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

The centre has suitably qualified staff to carry out all of the licensed activities and associated services provided. All staff, where appropriate, are registered with the relevant professional and/or statutory bodies (SLC T14).

Person responsible: Guidance Note 1

Mr Darne held the position of PR at the centre between 1995, when the centre opened, and his retirement on 22 May 2012. Subsequent to the inspection, the PR and lead consultant role has been assumed by Mr K Jayaprakasan. Mr Jayaprakasan has successfully completed the HFEA PREP requirement, is an accredited subspecialist in reproductive medicine and surgery and has appropriate academic qualifications in the field of medical sciences with more than two years practical experience relevant to the activities authorised by the licence of the centre.

Staff: Guidance Note 2

The nominated registered medical practitioner explained that he is contactable and available to centre staff at any time. The fertility services manager confirmed this and further explained that when the consultant is on leave, centre staff can contact consultants from the adjacent unit of the Royal Derby Hospital (SLC T16).

The centre has an organisational chart defining accountability and reporting relationships of all staff (SLC T11).

Staff recruitment and selection is managed centrally by Royal Derby Hospital human resources department. Suitability of character is assessed by interview, uptake of references and Criminal Records Bureau (CRB) checks (HF&E Act 1990 (as amended), section 17(1)(a)).

The centre has an induction programme ready for the new Consultant, organised by the Medical Director. The lead nurse explained that the three clinical nurse specialists have been in post since 1997, 2000 and 2005 respectively, and the staff turnover is very low across the unit.

The training folder for the clinical nurse specialists were reviewed and appeared

comprehensive, including training in consent and confidentiality requirements (SLC T33 (b) and T15).

Evidence was provided that staff are competent in their designated tasks. Individuals are supervised and observed carrying out their duties and when appropriate are competency assessed. There is a lead Biomedical Scientist overlooking andrology. A sample of clinical staff competence assessments was reviewed and included assessments for assisting with IUIs and teaching patients to self-administer fertility drugs.

Centre staff confirmed that there is opportunity to participate in continuing professional development, including attendance at fertility conferences and training days. The lead clinical nurse also explained that staff appraisals are held at least annually (CoP Guidance 2.3).

Workforce requirements are not assessed formally, but are discussed during senior staff meetings. The centre is currently operating with a full staff complement and there is sufficient capacity with the current staffing level, with one exception relating to clerical staff hours.

What the centre could do better.

Person responsible: Guidance Note 1

During the renewal inspection on 10 May 2012 the centre's inspector was advised that the PR would be resigning from his post and would be leaving the centre on 22 May 2012. The proposed new PR is not available to assume the role of PR until 18 June 2012 and an application to appoint a new PR was not received by the HFEA until 24 May 2012.

It is unlawful (under Section 12(1)a of the HF&E Act 1990 as amended) for an HFEA licensed centre to undertake licensed activity without a PR.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Five sets of patient notes reviewed on inspection demonstrated that WoC assessments had been completed by both patient and partner prior to the treatment date (SLC T56).

What the centre could do better.

Nothing noted at the time of inspection.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)

What the centre does well.

Evidence was provided on inspection that patients have treatment only on the licensed premises.

From discussion with staff and observations made on inspection, the inspection team was assured that all licensed activities are conducted in a non-discriminatory manner with respect for the privacy, confidentiality, dignity, comfort and well being of all prospective and current patients and partners. The effective use of translation services and translators was noted (CoP Guidance 29.3).

Complaints: Guidance Note 28

The centre has a procedure for dealing with complaints regarding the fertility service, using the same approach as Royal Derby Hospital, with access to the patients' advocacy service (PALS) as required (SLC T33 (b)).

The lead nurse described the centre's complaints procedure. Patients will generally be invited to a meeting to discuss the outcome of the complaint investigation, otherwise a written report is sent. There is a clear section on the noticeboard in the waiting area explaining how complaints and compliments are processed, and these are discussed at the bi monthly quality meeting.

The HFEA has received no complaints about the centre since the last inspection.

What the centre could do better.

Nothing noted at the time of inspection.

Information

- Information to be provided prior to consent (Guidance Note 4)

What the centre does well.

The centre had a suite of patient information in the waiting area, covering the requirements of the CoP. This included information about the nature of the treatment being offered, the possible side effects and the importance of patients informing the centre about the eventual outcome of treatment (SLC T58 and CoP Guidance 4.2 (g) and (j)).

The centre's website was reviewed prior to inspection. The inspection team considers that appropriate and accurate information is given regarding the centre's success rates.

The centre has a SOP for the provision of information prior to obtaining consent for IUI treatment (SLC T33 (b)). The consultant or nurse specialist is responsible for providing both verbal and written information to patients at the initial consultation. Patients are given the opportunity at this consultation to ask any questions. Patients interviewed in the course of the inspection confirmed that the information provided was clear, understandable, and staff explained the procedures/risks.

Costed treatment plans

Patients are provided with information regarding the cost of their treatment before it commences. Costed treatment plans were seen in patient records, detailing the main elements of the treatment proposed and the cost of that treatment (CoP Guidance 4.3).

What the centre could do better.

Nothing noted at the time of inspection.

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)

What the centre does well.

Centre staff provided evidence that written consent is obtained from patients prior to treatment and the centre has a documented SOP for obtaining consent (SLC T33 (b)).

Centre staff explained that photographic evidence of patient/partner identity is not used to verify patient identity, the use of NHS number, date of birth and address is used. The centre is comparatively small and at inspection it was clear that staff know their patients and this system works well (CoP Guidance 5.10).

Patient information is given and the consent required is explained to the patients at the initial consultation. The patients then have the opportunity to take the consent forms away for further consideration prior to making a decision before commencing treatment.

Five sets of patient records were reviewed on inspection. All had appropriately completed consent forms; the centre uses the HFEA consent forms.

What the centre could do better.

Nothing noted at the time of inspection.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)] • Licensed activities only take place on licensed premises
What the centre does well. **Premises and facilities: Guidance Note 25** A tour of the centre demonstrated that the activities authorised by the centre's licence are carried out at the premises specified in the licence (SLC T1).
What the centre could do better. Nothing noted at the time of inspection.

Use of embryos for training staff (Guidance Note 22)
What the centre does well. Not applicable. The centre is not licensed for the use of embryos for the purpose of training staff.
What the centre could do better. Nothing noted at the time of inspection.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping • Record keeping and document control (Guidance Note 31)
What the centre does well. All patient records reviewed during the inspection were seen to be clear, legible and well organised and satisfied all of the requirements of SLC T46. The centre's 'retention of records' SOP documents the requirement to maintain patient records for thirty years (SLC T48). Centre documents are version controlled and reviewed at the quality meetings. All documents reviewed on inspection were seen to be controlled and reviewed within the last twelve months (CoP Guidance 31.6).
What the centre could do better. Nothing noted at the time of inspection.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)] • Obligations and reporting requirements of centres (Guidance Note 32)
What the centre does well. All members of staff cooperated fully with the inspection team and information requested throughout the inspection process was provided in a timely manner. The centre submitted its 2011 annual IUI return within the timeframe required by General Direction 0005.
What the centre could do better. Nothing noted at the time of inspection.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.
There is a SOP for the procedure for the storage of sperm (SLC T33b). This SOP includes the validation of this process (SLC T72 and T75).

Evidence was provided to demonstrate that all material currently in store is within the consented storage period (SLC T79 and T80).

Prior to storage, patients and donors are screened for HIV and Hepatitis B and C (SLC T50 and T52). Only samples from patients who have screened negative for HIV and Hepatitis B and C are stored at this centre.

All screening is performed in a CPA accredited laboratory (SLC T51 and T53).

What the centre could do better.Nothing noted at the time of inspection.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)

What the centre does well.

Confidentiality and privacy: Guidance Note 30
The centre ensures that information about people having treatment, donors and children born as a result of assisted conception is not disclosed unless authorised to do so.

During an audit of five sets of patient medical records it was noted that the appropriate HFEA consent to disclosure had been completed in all sets of records and has been recorded accurately on the HFEA Register of Information.

The centre's 'procedure for correct storage of confidential notes' SOP includes procedures for the control of access to health data and records and the appropriate disposal of records (SLC T44).

What the centre could do better.

Nothing noted at the time of inspection.

5. Changes / improvements since the previous inspection on 19 May 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
The TPA presently in place with primary centre 0101 detailing the specific arrangements concerning satellite services is not being reviewed / updated on a regular basis. T114(c) and CoP8 guidance 23.12(d); 23.13.	Regular review of TPA with primary centre 0101.	A satellite agreement with Care Nottingham dated December 2011 was provided for review on inspection: the date provides evidence that the agreement has been reviewed in the last 12 months. No further action required
Amendment and re-submission of self assessment questionnaire (SAQ) in order to give more accurate information about centre activities and processes.	Amendment and re-submission of SAQ in order to accurately record centre activities.	The centre submitted a revised SAQ on 27 April 2012 prior to the current inspection. No further action required
SOPs to be developed for: i. the provision of patient information ii. the performance of a traceability audit.	A specific SOP for the provision of patient information should be formulated and form part of the QMS. A specific traceability audit SOP should be formulated and form part of the QMS.	The centre has a SOP for the provision of information prior to obtaining consent and the traceability audit procedure is documented in a SOP (SLC T33 (b)) and was provided for review in the course of the inspection. No further action required
Specific QIs need to be developed for the following areas: i. Provision of information ii. Consent iii. Welfare of the Child assessment iv. Traceability v. Procurement and processing vi. Submission of data to the HFEA	Specific QIs should be developed for the areas of practice identified.	QIs relating to all areas of practice have still not been established and documented (SLC T35). **Further action required**

Development of the centres present audit system to include audits of; i. Information provision ii. Consent iii. Welfare of the child assessment iv. The quality management system v. Submission of data to the HFEA	Audits should be established for the specified areas of practice and be embedded within the QMS.	Several audit reports were reviewed on inspection. Where issues were identified, the corrective action required was seen to be documented. However, the audit process is not embedded in the clinic work and further work is considered necessary to embed the process. (SLC T36). **Further action required.**
Staff competence assessment for: i. Storage of gametes ii. Witnessing iii. Submission of data to the HFEA	Staff competence to perform the specific duties cited should be assessed and recorded.	Evidence was provided in the course of the inspection that staff are competent in their designated tasks. No further action required
Quality management review.	The PR should establish a periodic review of the QMS in order to ensure continuous and systematic improvement.	The QMS is established and subject to periodic review. No further action required
Validation of all critical equipment and processes	Completion of validation of all critical equipment and processes required	Some critical equipment has not been validated (SLC T24) **Further action required**
Accurate information concerning MBMS policy at primary centre 0101 for self-funding IVF/ICSI patients and/or other licensed centres where patients may be referred on to for treatment.	Accurate MBMS policy information from primary centre 0101 to be available to self-funding patients seeking satellite IVF/ICSI treatment. Similar information to be available to other patients if they are referred on to other licensed centres for treatment.	Accurate information seen. No further action required

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None noted at the time of 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
Licensing During the renewal inspection on 10 May 2012 the centre's inspector was advised that the PR would be resigning from his post and would be leaving the centre on 22 May 2012. The proposed new PR is not available to assume the role of PR until 18 June 2012 and an application to appoint a new PR was not received by the HFEA until 24 May 2012. It is unlawful (under Section 12(1)a of the HF&E Act 1990 as amended) for an HFEA licensed centre to undertake licensed activity without a PR. However, the HFEA have been	The centre has been required to review procedures to ensure that in future, sufficient notification is provided to the HFEA to prevent the centre acting in breach of the Act. The centre has been required to investigate the circumstances that led to this situation arising and submit a summary report to the HFEA documenting the findings of the investigation, any proposed corrective action and the timescale for implementation of any corrective actions. This summary report should be provided to the HFEA within 3 months (1 September 2012).	This happened probably because I was from a different hospital when appointed. However, the process was initiated and completed with a slight delay. The unit complied with the HFEA advice and did not perform any licensed treatment activities during the gap. There will be a plan in place with an SOP to ensure that this will not happen in the future. The SOP is already prepared. Abovementioned SOP supplied by PR 16 August 2012.	**No further action required**

assured that in the time since the outgoing PR left the centre, no licensed treatment has been undertaken.			
Equipment and materials Some critical equipment, such as the centrifuge, refrigerator and pipettes have not been fully validated (SLC T24).	The PR should ensure that all critical equipment is appropriately validated.	Validation reports for all outstanding critical equipment supplied by PR 16 August 2012.	**No further action required**
Audit The centre has not audited how far procurement and processing procedures comply with the approved protocols and QIs (SLC T36).	The PR should review the centre's procedures and processes for audit to ensure that the activities and processes authorised by the licence and other activities carried out in the course of providing treatment services are audited against compliance with the regulatory requirements and approved protocols and QIs. These audits must be performed at least every two years, by trained and competent staff. Findings and corrective actions must be documented and implemented.	We thought we have complied with performing all the necessary audits by appropriately qualified persons. We will be more explicit about stating the real compliance score against the QI. We have also made the audit plans for the next two years, which we will forward before the stipulated deadline. We were not sure about any failing in doing the audits. We are also not clear about what you mean by audit of procurement and processing procedures? Did you mean this for the samples or	Annual audit schedule documenting completed activities supplied by PR 16 August 2012. **No further action required**

	An audit of procurement and processing procedures should be completed and a summary report of the findings of the audit; any corrective actions, and; a timescale for the implementation of corrective actions should be provided to the HFEA by 10 August 2012. A schedule of planned audits for the next two years and the timescale for their completion should be provided to the HFEA within the same timescale.	consumables? Could you please clarify? Thanks. Audit plan and summary report incorporating the outcomes of the audit/ corrective actions if needed were already in practice. This is now modified as advised by the HFEA.	
QIs QIs have not been formally established and documented for all activities. QIs not seen at inspection; 1. Traceability. 2. Procurement. 3. Provision of information (SLC T35).	The PR should ensure that QIs are established and documented for all activities. The HFEA should be provided with documentary evidence that this recommendation has been implemented by 10 August 2012.	Again we thought we have complied with establishing and documenting most necessary activities. However, we shall expand the notes audit and document explicitly. We shall also do it every three months. Traceability of samples/ consumables will form part of the notes audit. Procurement of consumables: we will be covering this by SOP and reviewing this often.	Annual audit schedule documenting completed activities with relevant QIs supplied by PR 16 August 2012. **No further action required**

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Patient screening IVF Patients are screened for HIV and Hepatitis B and C. IUI patients are not screened for HIV and Hepatitis B and C (SLC T50). It is recognised that the Commission Directive 2006/17/EC (Annex III, 2.2) states that where sperm is processed for IUI and not stored, if the centre can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes, biological testing may not be required.	The PR should ensure that patients are screened for HIV and Hepatitis B and C. If the PR decides not to screen patients prior to processing for IUI treatment, the reason for this should be communicated to the Executive. Evidence demonstrating that the risk of cross contamination and staff exposure has been addressed must be submitted by 10 August 2012.	We agree that this would be the best clinical practice. We discussed this formally at the internal meeting and the divisional management board and decided to start doing the screening tests for HIV, Hepatitis B and C tests with out delay.	The PR's confirmation that this recommendation has been implemented is noted and evidence of this will be reviewed at the next inspection. **No further action required**
TPA The TPA with Care Nottingham dated December 2011 has not yet been signed	The PR should ensure that the TPA is signed by both parties and submitted to their inspector for review.	We have signed TLA in place for self funded patients, but not for the NHS funded patients. This may have been an oversight and sorry for this.	**No further action required**

by both parties (SLC T114).	For completion by 30 August 2012	We will ensure that the TPA is signed appropriately by both the parties within the next few weeks. The PR informed the Executive on 16 August 2012 that a TPA with CARE is now in place for both NHS funded and self funded satellite IVF cycles.	
Equipment and materials: The documented procedures for the operation of critical equipment did not include a SOP for operation of the flow hood (SLC T27).	Procedures for the operation of the flow-hood must be established and documented: procedures must document the action to be taken in the event of malfunctions or failure A copy of the SOP should be provided to the HFEA by 10 August 2012.	A SOP for the operation of the class 2 flow hood was supplied by the PR 16 August 2012.	**No further action required**

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

30 August 2012

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

Minutes – Item 1

Centre 0149 – (Royal Derby Hospital) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Hannah Darby, Senior Policy Manager	Joanne McAlpine

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 centre had first been licensed by the HFEA in 1995 for Donor Insemination (DI). Since the implementation of the European Tissues and Cells Directive (EUTCD) in July 2007, the centre has been licensed for treatment (insemination using partner/donor sperm) and storage.

2. The Panel noted that the centre acts as a satellite centre to Care Nottingham (centre 0101) and patients are referred there for in vitro fertilisation (IVF).

3. The Panel noted that the centre had carried out 203 stimulated IUI cycles resulting in 15 pregnancies and 26 non-stimulated cycles resulting in 2 pregnancies during the year of 2011.

4. The Panel noted that, in November 2009, the centre's licence had been varied to incorporate a change of centre name to 'Royal Derby Hospital'.

5. The Panel noted that, during the recent renewal inspection, the Person Responsible (PR) informed the Inspectorate that he was retiring on 22 May 2012 and that a prospective PR had been appointed by the NHS Trust. The Panel noted that the prospective PR had completed his PR Entry Programme and the centre's licence was varied on 1 June 2012.

6. The Panel noted that, at the time of the inspection, the Inspectorate identified a number of areas of non-compliance or areas of poor practice that required improvement, including four major and three other areas.

7. The Panel noted that, since the inspection, all areas of non-compliance have now been fully addressed and that the PR had responded positively to all recommendations within the report.

8. The Panel noted that the Inspectorate recommended the renewal of the centre's licence for a period of four years with no additional conditions.

Decision

9. 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 Direction 0008.

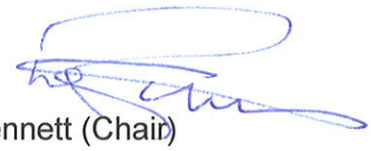
10. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act.

11. The Panel was satisfied that the licence renewal application doesn't concern treatment or non-medical fertility services which relate to gametes intended for human application.

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

13. The Panel noted that the application doesn't involve embryos for training or the testing of embryos.

14. The Panel agreed to the Inspectorate's recommendation and renewed the centre's licence for a period of four years with no additional conditions.

Signed:  Date: 6 Sept 2012

Mark Bennett (Chair)