Inspection Report

Date of Inspection: 24 and 25 April 2013
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 14 hours
Inspectors: Parvez Qureshi (lead), David Gibbon, Tony Knox and Cathy Hodgson

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 21 April 2011 and 5 July 2013

Date of Executive Licensing Panel: 19 July 2013

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, 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 which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Ninewells Hospital
Centre number	0004
Licence number	L/0004/15/b
Centre address	Assisted Conception Unit, Ward 35, Ninewells Hospital, Dundee, DD1 9SY
Person Responsible	Dr Vanessa Kay
Licence Holder	Mr Gerry Marr
Date licence issued	I October 2009
Licence expiry date	30 September 2013
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Assisted Conception Unit at Ninewells Hospital, Dundee, Scotland, has been licensed to provide NHS and self-funded treatments to patients from a wide geographical area since 1992.

The Centre offers a range of licensed treatments and conducted approximately 900 cycles of licensed treatment in the last year. In relation to activity levels this is a medium centre.

The Centre's licence was last renewed in October 2009 and expires in September 2013. An interim inspection of the centre was conducted in April 2011.

Since the last on-site inspection in April 2011 the centre underwent a two phase refurbishment programme. The first phase consisted of the refurbishment of the premises adjacent to the centre resulting in an extension of the licensed premises. The second phase consisted of refurbishment of the existing premises to provide additional rooms including consultation and recovery rooms. Desk based evaluations were conducted for these changes to the premises and they were approved by Executive Licensing Panel on 4 November 2011 and 20 April 2012 respectively. The new premises appeared to be of a high standard.

Activities of the Centre:

Type of treatment	Number of treatment cycles for 01 April 2012 - 31 Mar 2013
In Vitro Fertilisation (IVF)	345
Intracytoplasmic sperm injection (ICSI)	258
Frozen embryo transfer (FET)	164
Donor insemination (DI)	101
Egg share provider (sharer)	10
Egg share recipient	8
Egg donation (non egg share)	12

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

Outcomes*

For IVF/ICSI, HFEA held register data for the period January 2012 to December 2012 show the Centre's success rates are in line with national averages.

For the year 2012 the centre reported 80 cycles of partner insemination with eight pregnancies. This equates to a 10% pregnancy rate which is consistent 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 Person Responsible (PR) is suitable and has discharged her 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 Executive Licensing Panel is asked to note that at the time of the inspection there were recommendations for improvement in relation to seven major areas of non-compliance and four 'other' areas of non-compliance. Since the inspection visit the Centre has provided evidence that the following recommendations have been fully implemented:

Critical areas of concern:
None

Major areas of non compliance:

- The PR should ensure that all critical points of the clinical and laboratory processes/procedures are witnessed by two members of staff and these checks are completed and recorded at the time of the relevant procedure is carried out.
- The PR must ensure that licenced treatment data is submitted within the period required by Directions 0005.
- The PR should establish quality indicators (QIs) relevant to all licensed activities.

'Other' areas of practice that require improvement:

- The PR should ensure that either all tubes are labelled as required during egg collection or a risk assessment is conducted for the procedure.
- The PR should revise the Centre's donor information regarding payments that can be made in line with the limits prescribed in Directions 0001.

The PR has given a commitment to fully implement the following recommendations:

Major areas of non compliance:

- The PR should ensure that all critical processes are validated.
- The PR should ensure that all critical equipment is validated.
- The PR should ensure that no treatment is provided without taking into account the welfare of the child (WoC).
- The PR should conduct a detailed audit of notes to ensure they contain completed consent to disclosure forms.

'Other' areas of practice that require improvement:

- The PR should ensure that written agreements with all third parties who provide goods or services that influence the quality and safety of gametes and embryos are established. The ability of the third parties to meet the required standards is

evaluated and the content of all third party agreements is compliant with requirements.

- The PR should ensure that a clear explanation of the reasons for transferring more than one embryo where a patient meets the criteria for elective single embryo transfer (eSET) is documented in the patient's notes.

Recommendation to the Executive Licensing Panel

The inspection team recommends the renewal of the Centre's Treatment and Storage Licence for a period of four years without additional conditions subject to compliance with the recommendations made in this report within the prescribed timescales.

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.

Witnessing Guidance Note 18

The Centre has standard operating procedures (SOPs) in place for the process to be followed when carrying out witnessing checks (Standard Licence Condition (SLC) T33(b)). Discussions with laboratory staff demonstrated that processes are in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory processes (with the exception detailed below). A number of activities were observed during the course of the inspection including egg collection, sperm preparation and embryo transfer. The scientific inspector noted that the witnessing checks were carried out and documented appropriately at the time the procedures took place (with the exception detailed below) (SLC T71).

Five sets of patients' notes were audited during the inspection. All contained a record of required witnessing checks (Code of Practice (CoP) Guidance 18.8).

The Centre has established QIs (SLC T35) relevant to witnessing. Reports of audits performed for witnessing procedures were reviewed on inspection and it was noted that both the findings and the corrective actions had been documented and implemented (SLC T36). Documented evidence of the assessment of competence to perform witnessing was seen for a member of the laboratory staff (SLC T15 (a)).

What the centre could do better.

Retrospective witnessing takes place sometimes at weekends therefore not all relevant witnessing procedures are witnessed by two member staff of at the time the procedure is carried out (SLC T71).

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.

Procuring, processing and transporting gametes and embryos (Guidance Note 15)
All critical procurement and processing procedures have been documented in SOPs (SLC T33b). Justification for the use of gametes and embryos in treatment, based on the patient's medical history and therapeutic indications was documented in patient notes reviewed on inspection (SLC T49). An audit of ten sets of patient notes demonstrated that patients are screened for HIV, Hepatitis B and Hepatitis C as required by SLC T50. Laboratory staff confirmed that additional testing, including for HTLV-1, is carried out when required (SLC T50 c/d).

Prior to processing, the providers of gametes intended for use in treatment or storage are screened in accordance with the requirements of SLC T50 by a laboratory accredited by Clinical Pathology Accreditation (UK) Ltd (CPA) (SLC T21 and T51).

Counselling (Guidance Note 3)
Counselling is offered to all patients providing consent, as evidenced during discussion with the Centre's counsellor and the review of the Centre's patient information leaflets. Counselling is also offered to those providing consent to donation and to patients providing consent to agreed parenthood where donor gametes are used.

The Centre ensures that a woman is not provided with treatment services using embryos or donated gametes unless she and her partner, where she has one, who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with the proposed treatment (SLC T60).

There are SOPs in place for the provision of counselling (SLC T33(b)). An audit of patient records demonstrated that the offer and uptake of counselling is documented. The Centre has established QIs relevant to counselling and documented audits of counselling were seen on inspection (SLC T35 and T36).

The Centre can refer patients for specialist counselling, if required.

What the centre could do better.

Procuring, processing and transporting gametes and embryos (Guidance Note 15)
The centre has not established QIs for procurement and processing and therefore audits have not been conducted against established QIs for these procedures (SLC T35 and T36).

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)

What the centre does well.

Donor recruitment, assessment and screening (Guidance Note 11)
The Centre recruits sperm donors, provides treatment with eggs donated by altruistic egg donors and has a programme in place for egg sharing. In egg sharing arrangements, treatment services are provided to the egg share donor in the course of the donation cycle, unless there is a medical reason why they cannot be provided at that time (Directions 0001).

There are SOPs in place which document the selection and recruitment of donors (SLC T33(b)). The Centre has established QIs for recruitment of donors and a report of the most recent audit was seen on inspection (SLC T35 and T36).

Discussion with staff and a review of donors' notes showed that donors are selected on the basis of their age, health and medical information provided during consultation (SLC T52(a)). Screening undertaken (as noted during the audit of ten sets of notes) was in accordance with SLC T52(b and e). The centre has procedures in place to identify when additional screening tests may be required (SLC T52(g and h)).

Donor assisted conception (Guidance Note 20)
Patients receiving treatment with donated gametes are provided with written information on the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not their parent. Also, patients are provided with information on how to inform a child at an early age that he or she results from the gametes of a person who is not their parent (SLC T63 a and b).

The laboratory staff reported that where the provider of gametes donated prior to April 2005 has not consented to being identifiable, these gametes and any embryos created with those gametes will only be used in treatment to achieve a sibling pregnancy (SLC T54).

What the centre could do better.

Payments for Donors (Guidance Note 13)
The Centre's information for donors needs to be revised regarding payments to be in line with the requirements of Directions 0001.

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)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

The quality management system (Guidance Note 23)
There is a quality management system (QMS), which incorporates the HFEA licensed activities undertaken by the Centre (SLC T32). The Centre is ISO 9001:2008 certified.

The QMS consists of a quality manual and training and reference manuals, as required by SLC T33. On-going audits are conducted for licensed activities (with an exception documented elsewhere in the report). Evidence of audits for provision of information, consent, WoC and witnessing were seen. The Centre has a process in place for an on-going review of the performance of the QMS to ensure continuous and systematic improvement.

There is a document control procedure in place that records the history of document reviews and ensures that only current versions of documents are in use (SLC T34). Evidence of this was noted from the documents submitted for inspection and those reviewed at the time of the inspection.

Traceability (Guidance Note 19)
There is an SOP in place to ensure traceability (SLC T33(b)) and the Centre has a process in place to ensure all gametes and embryos are traceable from procurement to patient treatment or disposal. All relevant data relating to anything coming into contact with those gametes or embryos is traceable (SLC T99).

Containers are, at all stages of procurement, processing and storage, labelled with the patient's full name and a unique identifier (with the exception detailed below) (SLC T101). Staff reported that notes are archived and the centre has a procedure in place to ensure data necessary for traceability is stored for at least 30 years (SLC T103).

Reports of audits performed for traceability procedures were reviewed on inspection and it was noted that both the findings and the corrective actions had been documented and implemented (SLC T35 and T36).

Process Validation (Guidance Note 15
Laboratory staff provided evidence of validation of a number of critical procurement and processing procedures (with the exception noted for storage processes) and these were referenced to published data or retrospective analysis of the Centre's own data, including ICSI (SLC T72).

Equipment and materials (Guidance Note 26)
Laboratory staff provided documented evidence of the regular cleaning and disinfection of equipment, the maintenance and regular inspection of equipment in accordance with manufacturer's instructions.

Documented procedures for the operation of critical equipment are in place. Laboratory staff provided evidence of revalidation of equipment following repair. All equipment that affects critical processing or storage parameters is subject to monitoring, alerts and alarms. Equipment with critical measuring function is calibrated against a traceable standard (SLC T23, T24, T25, T26 and T27).

Only sterile equipment is used for the procurement of gametes and embryos. Laboratory staff reported that equipment used for the procurement of gametes and embryos was of good quality, validated or specifically certified and regularly maintained. Also, where possible the Centre uses CE marked equipment (SLC T28 and T30).

Premises suitability of the premises and air quality (Guidance Note 25)
A tour of the Centre confirmed that the premises are suitable for the licensed activities and all activities authorised by the licence are carried out in the premises specified in the licence (SLC T1). All licensed premises are located within the same building.

Review of documents and discussions with the laboratory staff demonstrated that the processing of gametes and embryos takes place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality (SLC T20).

Adverse incidents Guidance Notes 27
The Centre has a documented procedure for the reporting of adverse incidents to the HFEA (SLC T118). Staff were able to describe the process to be followed for reporting and the investigation of an incident and demonstrated a good understanding of the nature of incidents that should be reported to the HFEA within the required timeframe. The Centre has reported all the required incidents to the HFEA since the last inspection in April 2011.

Intracytoplasmic sperm injection (ICSI) (Guidance Note 21
The Centre has an SOP in place for the procedure of performing ICSI (SLC T33(b)). This procedure has been validated based on studies from established techniques (SLC T72). QIs for ICSI performance have been established and are audited on an on-going basis (SLC T35 and T36). Documented evidence of the assessment of staff competence in the performance of ICSI was seen (SLC T15(a)).

What the centre could do better.

The quality management system (Guidance Note 23)
The centre has not established QIs for some licensed activities including procurement and processing activities (SLC T35).

Traceability (Guidance Note 19)
At egg collection, not all containers used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code. (SLC T101).

Equipment and materials Guidance Note 26
Not all critical equipment has been validated (SLC T24).

Third party agreements Guidance Note 24
Written agreements have not been established with all the third parties who provide goods and services that influence the quality and safety of gametes and embryos (SLC T111 and T115). The Centre has not evaluated the ability of the third parties to meet the required standards (SLC T112). A review of five third party agreements showed that their content was not compliant with requirements (SLC T114).

Multiple Births (Guidance Note 7)

For the 2010/11 time period the Centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance likely to meet the 20% live birth rate target.

For the time period 1 April 2011 to 30 September 2012 the Centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance likely to meet the 15% live birth rate the target. On-going monitoring of the Centres clinical multiple pregnancy rate suggests that the Centre is not likely to exceed the 2012/13 multiple birth rate target of 10% (SLC T123).

What the centre does well

The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions 0003 in that:

- staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff at the Centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer.

What the centre could better
Staff maintain a log which indicates the reasons for variation from the single embryo transfer policy and outcomes but a clear explanation of the reasons for transferring more than one embryo is not documented in patient's notes in all cases (Directions 0003 (7a)).

Staff engaged in licensed activity

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

What the centre does well.

Person Responsible Guidance Note 1
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence (HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii)).

The PR has successfully completed the HFEA PR Entry Programme ((PREP) certificate number T/1002/7).

Staff Guidance Note 2
An organisational chart is in place which defines accountability and reporting relationships (SLC T11). The Centre has access to a registered medical practitioner who is able to advise on and oversee the medical activities (SLC T16). The PR confirmed that staff working under the auspices of the licence are qualified and suitable persons to participate in the activities authorised by the licence (HF&E Act 1990 (as amended) section 17 (1) (a)).

The Centre has assessed the workforce requirements within the last year. The inspection team was informed by the PR that funding for IVF has been increased by a government initiative to reduce waiting times. Consequently, the Centre was in the process of recruiting additional staff to meet the increase in workload. The PR considered that the number of staff is adequate for the current volume of work being undertaken by the Centre (SLC T12).

There is a formal induction training programme in place for all staff. The PR confirmed that all staff are competent in their designated tasks and evidence supporting this was reviewed for the members of the clinical team. Staff participate in relevant professional development by attending training courses and meetings. Staff who met with the inspection team reported that they are encouraged to attend relevant external meetings including British Fertility Society and European Society of Human Reproduction and Embryology (ESHRE) (SLC T15).

Medical, nursing, scientific and counselling staff are appropriately registered with their respective professional bodies (SLC T14).

What the centre could do better.

Nothing noted at the time of inspection

Welfare of the Child (Guidance Note 8)

What the centre does well.

Welfare of the Child (Guidance Note 8)
There is an SOP in place for the process to be followed when carrying out a WoC assessment. Staff reported that prior to any patient being provided with treatment services the welfare is considered of any child who may be born as a result of the treatment and of any other child who may be affected by that birth. Also, staff reported that the completed WoC forms are reviewed and in the event that there was concern regarding any issues, the case would be discussed at the Centre's unit meeting prior to agreeing to treatment going ahead.

What the centre could do better.

Staff reported that WoC forms are reviewed. However, documented evidence of this was not seen from an audit of ten patient records. In one of the ten sets of notes audited it was noted that a WoC form was complete but not time relevant to the treatment, indicating that the Centre's SOP which clearly defines when WoC assessment should be carried out was not

being followed (SLC T56).

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)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12)
- Surrogacy (Guidance Note 14)

What the centre does well.

Treating patients fairly Guidance Note 29
There are policies in place on treating patients fairly, which ensure all licensed activities are conducted in a non-discriminatory manner.

Confidentiality and privacy Guidance Note 30
Discussions held with staff, a review of information submitted prior to the inspection and the tour of the premises indicated that the privacy and confidentiality of all patients is maintained.

Patient records are kept in a secure area and only staff on the Centre‘s licence have access to confidential information. There is an SOP in place to ensure that information is only disclosed in circumstances permitted by law (SLC T43). The Centre has a procedure in place for the control of access to health data and records which is compliant with requirements (SLC T44). As part of the Centre’s policy, all staff have been trained in the maintenance of confidentiality and documented evidence of this was seen during the inspection (SLC T15(a)).

Complaints Guidance Note 28
A complaints procedure is in place and staff were able to demonstrate their understanding of how they would resolve a complaint in a timely manner. All complaints are logged, investigated, documented and a formal response is sent to patients. Since the last inspection in April 2011 no complaints have been made to the HFEA.

Provision of costed treatment plans Guidance Note 4
Prior to any treatment being offered, self funded patients are provided with a personalised costed treatment plan. The plan provides cost details for the main elements of the proposed treatment. Patients are also informed of any possible changes to the plan, such

as medications and storage of samples, which may be incurred depending on their course of treatment. Staff reported that patients are given the opportunity to discuss the costed treatment plan with the clinical staff prior to treatment and this was also confirmed by the patients interviewed during the inspection (CoP guidance 4.3).

Egg sharing arrangements Guidance Note 12
The Centre has an egg sharing scheme in place and recruits egg sharers donating for treatment purposes only. Treatment is only provided to the egg sharer in the course of the donation cycle unless there is a documented medical reason as to why treatment cannot be provided at that time (Directions 0001). All egg sharers are screened in accordance with SLC T52 using a laboratory with CPA accreditation (SLC T53(a)).

Surrogacy Guidance Note 14
The Centre provides treatment involving surrogacy and the gamete providers in surrogacy arrangements are screened as donors. Evidence of this was seen during a review of patients' notes. The Centre registers the gamete providers in surrogacy arrangements as donors (Directions 0005).

What the centre could do better.

Nothing noted at the time of inspection.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Information Guidance Note 4
Staff reported that patients are provided with relevant written information prior to their initial consultation. Evidence of this was seen during a review of patients' notes. There is an SOP for the process to be followed when providing information to patients prior to consenting to treatment (SLC T33(b)).

Information provided at the time of inspection, including an audit of patient records; an audit of patient information submitted for the inspection, discussion with staff, patients interviewed during the inspection and the review of the responses from the HFEA patient questionnaire showed that relevant information is provided to patients before treatment is provided (with the exception of payments of donors reported within the report). The Centre's website was also reviewed and found to be compliant with Chair's letter CH (11)02 and the CoP.

The centre has established QIs relevant to the provision of information. Audits have been conducted for provision of information in the last two years (SLC T35 and T36).

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)
- Consent to legal parenthood (Guidance Note 6)

What the centre does well.

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

Written consent is obtained before gametes or embryos are used in treatment or stored. This was noted during review of the patients' notes and the laboratory worksheets (with the exception detailed below). This was also confirmed by the patients interviewed during the inspection. There is an SOP in place for the process to be followed when obtaining consent (SLC T33(b)). Staff confirmed that the identity of the person providing consent is verified and photographic evidence is included in patient records (the patients interviewed during the inspection stated that their identities had been confirmed at each stage of their treatment) (CoP 5.10). Staff reported that the identity of the person who gave consent is also cross referenced to the records before treatment is provided (CoP 5.11).

The Centre has established QIs relevant to consent procedures and audits for taking consent have been conducted in the last two years (SLC T35 and T36).

The Centre operates a bring-forward system to ensure that samples are not stored beyond their consented storage period. Evidence was seen of the Centre having written effective consent for the storage of all cryopreserved gametes and embryos (HF&E Act 1990 (as amended), Schedule 3, 8(1) and, 8(2)).

The Centre's procedure for withdrawal of storage consent includes the provision of a 12 month 'cooling off' period in cases where one gamete provider withdraws consent to embryo storage and staff were able to demonstrate their understanding of the procedure.

To determine whether the register properly reflects the consent given by patients and their partners for the use of register information for research purposes, a sample of 10 completed patient and partner disclosure consents were reviewed against disclosure consent data supplied for inclusion on the register. No discrepancies were found between the completed disclosure consents in patient files and consent information held on the register.

Consent to legal parenthood Guidance Note 6

The Centre has an SOP in place to obtain the relevant written records of consent to parenthood before treating a woman with donor sperm or embryos (SLC T33(a)).

Discussion with staff at the Centre confirmed that processes are in place to ensure that a woman is not provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been provided with information about parenthood laws (SLC T60).

There is a procedure in place to ensure that no treatment is provided where a person who has previously consented to be the second parent of a child born has withdrawn their

consent to parenthood before informing the woman being treated that they have withdrawn it. Also, where a woman being treated withdraws her consent to a nominated second parent being the legal parent, or consent to a different person being the legal parent of any child born, the Centre has a procedure in place to ensure that the nominated second parent is informed of the change in writing (SLC T64b).

What the centre could do better.

Consent to treatment, storage, donation, training and disclosure of information Guidance Note 5
During a review of ten patient notes it was noted that the documentation of consent to disclosure of information in one set of notes was incomplete, part of the consent forms had not been signed by the patient or the partner (Directions 0007).

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
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

From a tour of the licensed Centre premises, review of documentation provided by the Centre and discussions with staff, the inspection team consider that they have sufficient information to determine that all activities for which the Centre is licensed are conducted within the premises to which that licence applies. Also the inspection team considered that all staff interviewed displayed in their responses appropriate respect for the special status of the embryo when carrying out licensed activities.

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.

Storage of gametes and embryos Guidance Note 17
The Centre has a procedure documenting the process to be followed when storing gametes and embryos (SLC T33(b)). Audits have been performed and the results of a recent audit were available on inspection, where required, corrective actions were documented and implemented (SLC T36).

Prior to storage, the providers of gametes are screened for HIV 1 and 2, Hepatitis B and Hepatitis C as per the requirements of SLC T50 and T51. Laboratory staff reported that,

where required, HTLV-1 antibody testing is performed if the gamete provider originates from a high incidence area. Screening tests are carried out by a laboratory which is accredited by CPA (SLC T51).

All stored samples are within their statutory storage period and the Centre operates a bring-forward system to ensure that samples are not stored beyond their statutory/consented storage period (HF&E Act (1990) as amended, 14(1)(c)).

What the centre could do better.

Storage of gametes and embryos - (Guidance Note 17)
The procedures for storing of gametes and embryos have not been validated (SLC T72).

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)
- Export of gametes and embryos (Guidance Note 16)
- Receipt of gametes and embryos (Guidance Note 15)
- Import of gametes and embryos (Guidance Note 16)

What the centre does well.

Distribution and receipt of gametes and embryos
There is an SOP in place describing the procedure for the distribution of gametes and embryos, including the required labelling of the shipping container (SLC T33(b) and T107). The SOP also defines the responsibilities and actions that would be required if a distribution is recalled (CoP 15B). Laboratory staff ensure that the procedure is followed accurately and that all required information is provided when distributing material (SLC T110). Containers and packaging used for distribution of gametes and embryos have been validated as fit for purpose (SLC T24 and T108).

Import and export of gametes and embryos (Guidance Note 16)
The Centre has not imported or exported gametes or embryos under general directions in the last year.

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.

The Centre does not currently use embryos for the training of staff. However, laboratory staff confirmed that embryos would only be used for training activities that have been expressly authorised by the Authority (SLC T93).

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.

Record keeping and document control Guidance Note 31
Ten patient records reviewed at the time of inspection were legible and complete. Each record reviewed included the patient's first name, surname, date of birth, age and sex. Details of how the patient had been identified by staff were also evidenced. Patient's notes also included details of the service provided to them, a medical history, relevant documented consents, laboratory data and the results of tests carried out (SLC T46). The Centre has procedures in place to ensure that records are protected from unauthorised amendment and are retained and readily retrieved in this condition throughout their specified retention period (SLC T47).

To determine whether all licenced treatment activity is reported to the HFEA and within required timescales, a sample of treatments undertaken over a 12 month period and recorded within the Centre's laboratory records was compared to data submitted by the Centre for inclusion on the register. All 108 DI treatments and 149 of 150 IVF treatments within the audit sample had been reported to the HFEA as required by Direction 0005.

To confirm that data submitted by the Centre for inclusion on the statutory register accurately reflects that found in source records an on-site sample of 49 assorted form type data submissions were reviewed against source documentation held on patient and donor files. No critical errors or omissions were found in the data (i.e. errors that would prevent the authority fulfilling its statutory obligations). Additionally no systematic error was identified within the sample (SLC T9(e) / T41. Direction 0005).

Record keeping and document control Guidance Note 31
The reporting of one of 150 IVF treatments in the audit sample was outstanding at the time of inspection. This finding may indicate that other treatments outside the sample have also not have been reported to the Authority in accordance with Direction 0005.

A significant proportion (23%) of the licensed treatment data in the audit sample has been submitted to the HFEA outside the period required by Direction 0005.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well.

Obligations and reporting requirements of centres Guidance Note 32
The PR provided all information required by the application process prior to inspection. Centre staff cooperated fully with the inspection team and all further information requested for the inspection was provided in a timely manner.

What the centre could do better.

Nothing noted at the time of inspection.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

What the centre does well.

Confidentiality and privacy Guidance Note 30
Discussions held with staff, a review of information submitted prior to the inspection and the tour of the premises indicated that the privacy and confidentiality of all patients is maintained.

Patient records are kept in a secure area and only staff on the Centre‘s licence have access to confidential information. There is an SOP in place to ensure that information is only disclosed in circumstances permitted by law (SLC T43). An SOP for the control of access to health data and records was also seen and was compliant with requirements (SLC T44). The PR reported that as part of the Centre’s policy, all staff have been trained in the maintenance of confidentiality and documented evidence of this was seen during the inspection (SLC T15(a)).

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

The centre seeks consent from relevant parties to the disclosure of information held on the HFEA register to medical or other researchers. During an audit of ten patient records consent to disclosure forms were seen to be completed.

What the centre could do better.

Nothing noted at the time of inspection.

5. Changes / improvements since the previous inspection on 21 April 2011

Area for improvement	Action required	Action taken as evidenced during this inspection
The validation of critical equipment has not been completed. Licence Condition T24. This was an issue at the last inspection	The PR should ensure that the validation of critical equipment is completed. The PR should submit an action plan, including a summary of all equipment requiring validation and timeframes for completion, by the time the PR responds to this report.	Validation of critical equipment has not been completed. Further action required.
The validation of critical processing procedures has not been completed. Validation performed to date is not based on data from published studies or well established processing procedures, by retrospective evaluation of clinical results. Licence Condition T72. This was an issue at the last inspection.	The PR should ensure that the validation of critical processing procedures is completed. The PR should submit an action plan, including a summary of the validation approach, a summary of all procedures that require validation and timeframes for completion. For submission by 21 July 2011. The PR should submit quarterly reports to the Executive regarding the progress of the implementation of this plan until it is completed. For full completion by April 2012.	Validation of critical processes and procedures has not been completed. Further action required.
Withdrawal of consent The centre does not have a SOP documenting the process to follow for the withdrawal of consent to legal parenthood. The centre's "withdrawal of consent to storage" SOP does not include the provision of information regarding counselling or mediation services available	The PR should ensure that an approved SOP is in place for the process to follow for the withdrawal of consent to legal parenthood. The PR should ensure that the centre's "withdrawal of consent to storage" SOP is revised to include this provision of information. 21 July 2011.	The centre has an SOP in place for the withdrawal of consent to parenthood. No further action required.

to the gamete providers. Licence Condition T33 (b) and CoP Guidance 5.35. Import from previous report		
Competence assessments. Licence Condition T15 (a) This was an issue at the last inspection.	The PR should ensure that all staff can provide documented evidence of the assessment of their competence in the performance of their designated tasks. The PR should submit a detailed plan, including a summary of all staff and the competence assessments they need to complete, including anticipated timeframes for completion, by 21 July 2011. The PR should submit quarterly reports to the Executive regarding the progress of the implementation of this plan until it is completed.	The PR reported that all staff were competent in the performance of their designated tasks. 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 identified at the time of 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
1. Not all critical processes have been validated. SLC T72 (This was an area for improvement in the last report).	The PR should ensure that all critical processes are validated. Validation may be based on data from published studies or retrospective analysis of the Centre's own data. The PR should submit a list of all critical processes to be validated to the lead inspector by the time the PR responds to this report. This action should be complete by 25 July 2013.	Following our paper-based inspection in November 2011, all critical processes had been validated. We note that no mention was made about this issue at the informal feedback session after the inspection and the only outstanding process validation that we are aware of is oocyte cryopreservation. We will perform the process observations next time this procedure is performed and advise you accordingly. Please advise us if any specific areas that require addressing.	The PR's response is noted This somewhat reflects the inspection findings that no evidence was made available during the inspection whether all the storage processes had been validated. A copy of the documentation should be provided to the Centre's inspector on completion of the outstanding validation. Further action required.
2. Not all critical equipment has been validated. SLC T24 (This was an area for improvement in the last report).	The PR should ensure that all critical equipment is validated. The PR should submit a list of all critical equipment to be validated to the lead inspector by the time the PR responds to this report. This action should be complete by	Initial critical equipment validation was completed by November 2011 and continued when our new laboratory was equipped. There are some areas that are in progress following receipt of further equipment and this will be ongoing	The lead inspector considers this to be an acceptable response and will continue to monitor Centre's progress in the completion of validation of all critical equipment. Further action required.

	25 July 2013.	exercise. Please advise us if there are any specific areas that require addressing.	
3. Retrospective witnessing takes place sometimes at weekends therefore not all relevant witnessing procedures are witnessed by two member staff of at the time the procedure is carried out. SLC T71.	The PR should ensure that all critical points of the clinical and laboratory processes/procedures are witnessed by two members of staff and these checks are completed and recorded at the time of the relevant procedure is carried out. The lead inspector to be updated by the PR by the time the PR responds to this report.	We immediately implemented double witness of all weekend procedure. This was following informing medical and nursing staff that there may be need to assist with this at weekends and when required a second embryologist is placed on the weekend rota.	The lead inspector considers this to be an acceptable response. No further action required.
4. Staff reported that WoC forms are reviewed. However, documented evidence of this was not seen from an audit of ten patient records. In one of the ten sets of notes audited it was noted that a WoC form was complete but not time relevant to the treatment, indicating that the Centre's SOP which clearly defines when WoC assessment should be carried out was not being followed (SLC T56).	The PR to ensure that no treatment is provided without taking into account the WoC who may be born as a result of the treatment or any other child who may be affected by the birth. The PR should conduct a detailed audit of notes to ensure they contain completed WoC forms and these are time relevant to the treatment. The lead inspector to be updated	We have introduced HFEA WoC forms from 15th June 2013.	The PR to forward to lead inspector by 30 September 2013 a copy of the of the audit report. Further action required. .

	by the PR by the time the PR responds to this report.		
5. During a review of ten patient notes it was noted that the documentation of consent to disclosure of information in one set of notes was incomplete. Directions 0007.	The PR should conduct a detailed audit of notes to ensure they contain completed consent to disclosure forms. The PR should submit an action plan outlining the proposed timescale for addressing this issue including any staff training by the time the PR responds to this report.	A detailed audit of notes to ensure that they contain completed consent to disclosure will be completed by 30th August 2013.	The PR to forward to lead inspector by 30 September 2013 a copy of the of the audit report. Further action required.
6. The reporting of one of 150 IVF treatments in the audit sample was outstanding at the time of inspection. This finding may indicate that other treatments outside the sample have also not have been reported to the Authority in accordance with Direction 0005. All licenced treatment activity is not reported to the HFEA within required timescales.	The PR must ensure that licenced treatment data is submitted within the period required by Directions 0005. The outstanding licensed treatment identified at the time of inspection must be reported immediately. The lead inspector to be updated by the PR by the time the PR responds to this report.	This form had been actually been submitted but patient number at variance with other forms on register. A detailed audit of all entries on HFEA register for entire year has been cross-matched with the Centre's records and this was the only one outstanding, therefore the assumption that other treatments may not have been reported is incorrect.	The lead inspector considers this to be an acceptable response. No further action required.

SLC T9(e), SLC T12, T41 and Directions 0005.			
7. The centre has not established QIs relevant to procurement and processing activities. SLC T35.	The PR should establish QIs relevant to all licensed activities. An action plan to be submitted to the lead inspector by the time the PR responds to this report.	From your informal feedback after the inspection, we noted that QIs were in place and audited. From our recent external quality review we are planning to expand our QIs. Please can you specify which QIs you felt were lacking?	It was noted at the time of the inspection that procurement and processing activities had been audited but not against established QIs. However, review of information submitted by the PR shows that QIs relevant to procurement and processing activities will be audited in the future. 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
8. At egg collection, not all containers used during the procurement of eggs are labelled with the patient's/donor's full name	The PR should ensure that a risk assessment, documenting the Centre's rationale for not complying with SLC T101 and the risk mitigation steps that have been introduced is	Since beginning of June all oocyte recovery tubes are labelled with a unique patient identifying number. The SOP has been updated.	Following review of the information submitted by the PR, the lead inspector considers this to be an acceptable response.

and a further identifier or a uniquely identifying donor code. SLC T101.	documented and submitted to the inspector by 25 July 2013.	We plan to review the implementation of this practice and if appropriate arrange a risk assessment.	No further action required.
9. Written agreements have not been established with all the third parties who provide goods and services that influence the quality and safety of gametes and embryos. The Centre has not evaluated the ability of the third parties to meet the required standards and the content of all third party agreements was not compliant with requirements. SLC T111, T112, T114 and T115.	The PR should ensure that written agreements with all third parties who provide goods or services that influence the quality and safety of gametes and embryos are established. The PR should also ensure that the ability of the third parties to meet the required standards is evaluated and the content of all third party agreements is compliant with requirements. This action to be completed by 25 July 2013.	Forms have been redesigned and sent to all suppliers. These are now being return. An updated list will be sent once all have been received.	The lead inspector considers this to be an acceptable response. The PR to inform the Centre inspector on completion of this action. Further action required.
10. A clear explanation of the reasons for transferring more than one embryo, where the patient meets the criteria for eSET, are not documented in patients notes in all cases	The PR should ensure that a clear explanation of the reasons for transferring more than one embryo where a patient meets the criteria for eSET is documented in the patient's notes.	All medical and embryology staff were reminded that details of counselling in this situation should be clearly documented in the patient notes. A tick list will be introduced to ensure that all	The lead inspector considers this to be an acceptable response. The PR to inform the centre inspector on completion of this action.

(Directions 0003(7(a)).	This action should be completed by the time the PR responds to this report.	important issues are covered. A doctor and embryologist are designing this tick list and will implement by 30th July 2013.	Further action required.
11. The centre's information for donors needs to be revised regarding payments to be in line with the requirements of Directions 0001.	The PR should revise the Centre's donor information regarding payments that can be made in line with the limits prescribed in Directions 0001. This action should be completed by the time the PR responds to this report.	Information – amended 26th April 2013.	Following review of the information submitted by the PR, the lead inspector considers this to be an acceptable response. No further action required.

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

19 July 2013

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

Minutes – Item 2

Centre 0004 – (Ninewells Hospital) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair) Matthew Watts – Regulatory Policy Manager Joanne Anton – Policy Manager	Rebecca Loveys

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 medium-sized centre which has held a licence with the HFEA since 1992.

2. The Panel noted that the centre provides a full range of fertility treatments (excluding IUI).

3. The Panel noted that the centre is on a four-year licence due to expire September 2013, and that the inspection took place on 24-25 April 2013.

4. The Panel noted that the centre provided approximately 900 cycles of treatment in the last year.

5. The Panel noted that outcomes for IVF/ICSI are in line with the national averages.

6. The Panel noted that for the time Period 1 April 2011 to 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%, and that this represents performance that is not likely to exceed the 2012/13 multiple birth rate target of 10%.

7. The Panel noted that, at the time of inspection, seven major and four other areas of non-compliance were identified by the Inspectorate.

8. The Panel noted that, since the time of inspection, three major and two other areas of non-compliance have been addressed by the PR, and a commitment has been made to fully implement the remaining four major and one other areas of non-compliance.

9. The Panel noted in particular the non-compliances relating to the validation of all critical processes and critical equipment (both of which were identified as areas for improvement in the last inspection report), although these have now been addressed by the PR.

10. The Panel noted that the application form does not state the use of embryos for training but that procedures for it are in place at the centre.

Decision

11. 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.

12. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities.

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

14. 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.

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

Signed: Date: 26 July 2013

Juliet Tizzard (Chair)