Inspection Report

Date of Inspection: 01 and 02 May 2012
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: Two days (17 hours)
Inspectors: Janet Kirkland MacHattie (Lead inspector)
Stephanie Gadd (Scientific inspector)
Gill Walsh (Clinical inspector)
Susan Jolliffe (Clinical inspector)
Chris Hall (Audit inspector)
Neil McComb (Observing)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 25 May 2010 and 25 July 2012

Date of Executive Licensing Panel: 25 July 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, 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	Centre for Reproductive Medicine and Fertility Sheffield
Centre number	0196
Licence number	L0196/7/c
Centre address	Jessop Wing, Sheffield Teaching Hospital NHS Foundation Trust Tree Root Walk Sheffield,S102SF
Person Responsible	Rachel Cutting
Licence Holder	Sheffield Teaching NHS Trust
Date licence issued	1 October 2007
Licence expiry date	30 September 2012
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Centre for Reproductive Medicine and Fertility in Sheffield has been licensed since 2001 and provides a wide range of assisted conception licensed treatments to National Health Service (NHS) and self funding patients.

The centre is self-contained, with its own dedicated entrance, and is located within the Jessop Wing of Sheffield Teaching Hospital NHS Trust.

The centre is open from 08:00 to 17:00 Monday to Friday, and from 08:00 to 15:30 on Saturday. Clinical staff are available in an emergency 24 hours a day on a rota basis.

The centre has a system in place for quality management and is ISO 9001:2008 certified.

The Person Responsible (PR) is also the Principal Embryologist for the centre and has held the post of PR since November 2010. She has appropriate qualifications and experience as defined in the HFE Act 1990 (as amended) and has successfully completed the HFEA PR entry programme.

The centre was previously licensed for Treatment (with embryo testing) and Storage. The PR has applied to renew the licence for Treatment and Storage only.

Variation to Licence

The PR has requested to change the centre name to “Jessop Fertility” as part of the renewal application.

Activities of the Centre:

Type of treatment	Number of treatment cycles	
	01 Mar 2011 - 29 Feb 2012	01 Mar 2010 - 28 Feb 2011
In Vitro Fertilisation including fresh and frozen embryo replacement cycles (IVF)	639	569
Intra cytoplasmic sperm injection including fresh and frozen embryo replacement cycles (ICSI)	259	259
GIFT	0	0
DI	36	34
Egg share provider (sharer)	23	14
Egg share recipient	21	6
Egg donation (non egg share)	15	19

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

Outcomes*

For IVF/ICSI, HFEA held register data for the period Dec 2010 - Nov 2011 show the Centres success rates are in line with national averages
For year 2011 the centre reported 365 cycles of partner IUI with 51 pregnancies. This equates to a 14% success rate.

*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 – post review of draft by PR

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 is suitable and she 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 a number of areas of practice that required improvement, including two ”other” areas of non-compliance or areas of poor practice.

Since the inspection visit on 1 and 2 May 2102 the PR has given a commitment to fully implement the following recommendations:

Other areas of practice that require improvement

- The PR should audit a sample number of patient and partner consent to disclosure consent records against that recorded with the HFEA to determine whether the consent to disclosure discrepancies noted on inspection are isolated occurrences or are more prevalent. In the event of the latter, consents recorded on patient and partner registrations forms submitted to the HFEA since 1 May 2010 should be reviewed against the consent to disclosure forms held in patient records at the centre and any discrepancies found corrected.
  The sample audit is to be completed by 2 August 2012, the results of which are to be submitted to the centre’s inspector. Pending the outcome of this a further full audit of consents recorded since 1 May 2010. In this event the centre’s inspector will monitor progress.
- The PR must ensure that data which the Authority is required to hold on its Register is provided by the dates specified in Directions.
  A reliable regular periodic check process should be introduced to ensure the authority is notified of all licensed treatment activity recorded on the centres IDEAS system in accordance with Direction 0005.
  The process for submitting licensed treatment data to the authority should be reviewed and enhanced to ensure compliance with submission times detailed in Direction 005 is achieved.
  A summary report of corrective actions implemented should be submitted to the HFEA by 2 August 2012.

The inspection team recommend the renewal of the centre’s licence for treatment and storage for a period of four years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales. The inspection team also recommend that the request to change the centre name from The Centre for Reproductive Medicine and Fertility to Jessop Fertility be approved.

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 uses an electronic witnessing system to ensure the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process and to ensure that patients receive treatment using the correct gametes or embryos. Standard Licence Condition (SLC T71) A comprehensive Standard Operating Procedure (SOP) pertaining to witnessing was seen on inspection in addition to quality indicators (QI). The results of a witnessing audit performed in October 2012 was provided for the inspection team. In one instance the electronic witnessing of disposal of a sperm sample had not been recorded but manual witnessing by two individuals was seen to be in place. Staff competencies for witnessing are documented (SLC T15 (a)) An audit of patient files on inspection confirmed a printed copy of the “witness” record is in the patient record (SLC T71). An SOP is in place should manual witnessing be required. (SLC T33(b))
What the centre could do better. Nothing noted at the time of the 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

Procuring, processing criteria and laboratory tests (Guidance Note 15)

Critical procurement and processing procedures have been validated and documented in SOP's which are reviewed annually (SLC T72 T33(b)).

Validation for 14 critical processes including assessment of fertilisation, embryo transfer, oocyte collection and observation and sperm preparation were seen on inspection.

Quality indicators and objectives have been established and audits of procedures performed (SLC T35 ,T36).

Screening tests are conducted in a Clinical Pathology Accreditation (CPA) (UK) Ltd laboratory and are documented in patient records (SLC T21).

Diagnostic andrology testing is carried out in the centre's laboratory which is not accredited by CPA. The centre has validated procedures and processes for semen analysis, an ISO certified quality management system and staff suitably qualified to interpret semen analysis. As required for accreditation by CPA, the laboratory also participates in the National External Quality Assessment Scheme (NEQAS) for semen assessment. It is considered that in relation to semen analysis, this has an equivalent status to that of CPA accreditation.

Distributing gametes or embryos

An SOP is in place detailing the circumstances, responsibilities and procedures for the release of stored material before distribution (SLC (T33b)).

Validation documentation was seen for containers and packages used for distribution (SLC(T108)).

SOP's include a recall procedure for the handling of returned gametes and embryos (Code of Practice CoP 15 (c)). The inspection team were informed that any recall would be reported as an incident.

A checklist was seen detailing information provided when distributing gametes and embryos (SLC T110).

Patient selection criteria

Patient selection criteria were clearly explained by the counsellor and senior nurse in line with the SOP. An audit of 10 patient records found the medical history was easy to find and legible, the records detailed the screening tests which matched the checklist at the front of each record. The PR informed the inspection team that screening tests are performed in a CPA accredited laboratory.

Counselling: Guidance Note 3

The senior counsellor has been in post since 2001, she has an MA in Psychology and is a senior accredited member of BICA. There are two counsellors based at the centre and both are British Infertility Counselling Association (BICA) members.

A comprehensive audit performed in July 2011 was seen on inspection and included timely provision of counselling and accordance with SOPs and regulations. A total of 152 service user questionnaires were given out and 52 were returned. The findings were shared with the centre team and recommendations implemented (SLC T36).

The SOP for the provision of counselling was last reviewed in August 2011.

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

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
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 runs a small egg share programme. The Senior Nurse confirmed that they are not currently advertising for the recruitment of sperm donors, but do accept donors introduced by recipients or altruistic donors.

The centre's donor recruitment procedures are supported by SOPs and checklists. Five sets of medical records pertaining to egg donors were audited during the course of the inspection. This sample of records provided evidence that:

- donors are being selected on the basis of their age, health and medical history provided in a questionnaire and through a personal interview by a qualified and trained medical professional
- donors are being screened in accordance with the requirements of SLC T52 and relevant professional bodies.

Blood samples of donors are additionally tested by nucleic acid testing (NAT) and are therefore exempted from the requirement to quarantine (SLC T53).

The centre maintains records that enable donors to be provided with information on the number, sex and year of birth of persons born as a result of their donation (HF&E Act 1990 (as amended), Schedule 31ZD (3)).

The centre keeps a record of all reimbursements made to donors and is aware of the changes introduced from 1 April 2012 in Directions 0001. No donors have been recruited since 1 April 2012.

What the centre could do better.
Nothing noted at the time of the 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)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

The quality management system: Guidance Note 23

The centre is ISO 9001:2008 certified and QIs have been established for centre activities and are embedded in the centre's internal audit schedule (SLC T35). The centre's audit schedule is agreed annually and a selection of audit reports were reviewed on inspection. Audits reviewed included those for welfare of the child assessment and the selection and recruitment of donors (SLC T36).

The inspection team considered that the scope and methodology for the audits had been planned carefully and demonstrated that audits are considered an important tool for continuous improvement by centre staff. Findings and the corrective actions identified and implemented were also documented.

Process validation: Guidance Note 15
Critical procurement and processing procedures and all equipment used in these processes have been validated. Documents were available to view on inspection (SLC T24 and T72).

Traceability: Guidance Note 19
Centre staff were able to demonstrate that all gametes and materials coming into contact with gametes used in treatment which may affect their quality and safety are traceable throughout from procurement to treatment or disposal and that there is an SOP to direct this process (SLC T22, T33 (b) and T99).

All tubes/dishes are labelled with patient / donor name and a unique identifier. This was confirmed during the inspection by the observation of two separate witnessing procedures in the laboratory which demonstrated the identification and labelling of tubes and dishes containing patient gametes and embryos.

Quality indicators relevant to traceability have been established and procedures audited Staff competence to perform traceability procedures has been documented (SLC T35, T36, T15(a)).

Third party agreements: Guidance Note 24
The centre has established written agreements with all third parties who provide goods or services that influence the quality and safety of gametes (SLC T99). Evidence was seen that confirmed that the centre has evaluated the ability of third parties to meet the required standards (SLC T100) and that the content of the agreements is compliant with SLC T102 and T114(f) where applicable. A list of all third party agreements in place is maintained by the centre (SLC T103). Third party agreements in place were audited on inspection and were considered to be compliant with standard licence conditions.

Premises and facilities: Guidance Note 25
A tour of the centre confirmed that the centre's premises are suitable for the licensed activities and that all activities to which the centre's licence applies are conducted in the licensed premises (SLC T1)). Evidence was provided that the processing of gametes takes place in an environment of the appropriate air quality (SLC T20), and that air quality is regularly monitored.

Equipment and materials: Guidance Note 26

Maintenance and validation records were seen for equipment including a suction pump, dewar, centrifuge and incubator (SLC T23 T24). The inspection team were informed that no equipment had been repaired in the last year and that all equipment is revalidated annually.

SOP's are in place for the operation of all critical equipment and they outline actions to be taken if the equipment malfunctions or fails (SLC T27)).

Calibration certificates are obtained for each item of equipment at the time of routine maintenance. Records were seen for the cleaning and disinfection of equipment (SLC T26)).

Disposable instruments are used for the procurement of gametes and embryos. The PR informed the inspection team that the instruments/materials are CE marked where possible (SLC T30).

Adverse incidents: Guidance Note 27

The centre has reported adverse incidents to the HFEA since the last inspection. Reporting was completed within required timescales (SLC T120 T121 and General Direction 0011).

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

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 10%.

The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to be better than the target/performance at a statistically significant level, unlikely to be due to random variation.

On-going monitoring of the centre's multiple clinical pregnancy rate shows that the centre is likely to meet the 2011/12 multiple birth rate target of 15% (SLC T123); currently the centre's clinical multiple pregnancy rate is 11%.

What the centre does well

The centre has a detailed multiple birth minimisation strategy (MBMS) incorporating a clear action plan for 2012. The MBMS documents how the centre identifies suitable cases for

elective single embryo transfer (eSET), including criteria in relation to patient selection and embryo assessment (General Direction 0003, 5 (a)).

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;
- staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and outcomes which are also recorded in the patients records.

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

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 biological sciences as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has several years of practical experience which is directly relevant to the activity to be authorised by the licence.
The PR has successfully completed the HFEA Person Responsible Entry Programme. She is a Principal Embryologist and a member of the HFEA's licensed centres panel and chair of ACE executive committee and has also been involved in developing national guidelines for the implementation of eSET (elective single embryo transfer).

Staff: Guidance Note 2

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).

The centre has a stable workforce with a low turnover of staff. Whilst the PR confirmed that at this time they were working with a full complement of staff they have completed a business case for a new counsellor and clinician and have a planned induction programme in place (SLC T15).

Evidence was provided that staff are competent in their designated tasks. A sample of staff competence assessments was reviewed and included donor recruitment and assessment, provision of information and obtaining consent (SLC T12,T15(a)).

Laboratory staff competence assessments seen on inspection included taking consent, procurement and processing procedures, storing cryopreserved material, witnessing, traceability procedures and ICSI.

Evidence was reviewed demonstrating that centre staff are given the opportunity to participate in continuing professional development, including attendance at workshops and

unit training held at the centre (SLC T15).
What the centre could do better. Nothing noted at the time of the inspection

Welfare of the Child (Guidance Note 8)
What the centre does well. The centre has a documented welfare of the child (WoC) SOP which was reviewed in October 2011. 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). The centre has audited their WoC procedures (SLC T36) and a copy of the audit was seen on inspection. Assessment of staff competencies in WoC assessment were documented and staff interviewed were able to demonstrate a full understanding of WoC requirements (SLC T15(a)).
What the centre could do better. Noting noted at the time of the inspection.

Embryo Testing – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening)* • Preimplantation genetic screening (Guidance Note 9) • Embryo testing and sex selection (Guidance Note 10)
Patients requiring treatment involving embryo testing are referred to another HFEA licensed centre.

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) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the centre does well.

Treating patients fairly :Guidance Note 29

Evidence was provided on inspection that the premises are suitable for the treatments to be licensed.

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

The Senior Nurse and the Counsellor stated that all patients attending the centre are considered equally for treatment. The centre has an ethics committee to help with any issues.

Patient satisfaction is monitored by the centre. The HFEA has received five patient questionnaires since the last inspection and only one had negative comments, none of the issues raised were considered to be problematic at the inspection.

Confidentiality and privacy: Guidance Note 30

A tour of the centre confirmed that access to all confidential information is restricted to authorised personnel (SLC T43). Access to the centre is restricted and key pad locks provide additional restriction to sensitive areas. A tour of the centre confirmed that patient records are stored securely. The building is alarmed at night.

SOP's are in place to ensure that all information is kept confidential and only disclosed in circumstances permitted by law (SLC T33 (b)). Evidence of training in confidentiality for the administration team was seen on inspection.

Complaints: Guidance Note 28

The centre actively seeks patient feedback and investigates and learns from patient

complaints. The centres complaints log for the period covering 01 January 2012 to 31 March 2012 was reviewed on inspection. Evidence of investigation, response, progress with or actions in resolution was seen in each instance.

Costed treatment plans: Guidance Note 4

Patients are provided with information regarding the cost of their treatment before it commences (CoP Guidance 4.3).

Egg sharing arrangements: Guidance note 12
The centre has an egg sharing scheme. All egg sharers are screened in accordance with legal requirements and are registered with the HFEA as donors
The centre has appropriate agreements with both the egg sharers and the patients receiving treatment with the donated eggs.

Patient records reviewed on inspection included patients who had been in the egg sharing programme. The records documented the screening tests conducted, that counselling was offered and contained relevant consents.

Surrogacy: Guidance note 14

The centre has a surrogacy programme and the patient records of a commissioning couple and host were reviewed on inspection.

All parties were seen to have been offered counselling and all consents were in place.

The commissioning couple had been screened and registered as donors (SCL(T53c and Directions 0003)).

What the centre could do better.
Nothing noted at the time of the 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 preimplantation genetic testing (Guidance Notes 9 & 10) – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening*
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

The centre submitted a suite of patient information prior to the inspection, covering the majority of the requirements of the CoP. Centre staff confirmed that the specific information not provided in leaflets is provided verbally during appointments, prior to obtaining consent.

Three patients interviewed on inspection were complimentary about the centre staff and care received. They expressed satisfaction with the level of information received and communication and contact with the centre. They were all aware of the contact number to use in the case of an emergency.

The centre provides treatment with donor gametes to women and couples who may or may not be married or in a civil partnership. Those affected by legal parenthood legislation

are informed of how the nomination of a second legal parent affects them and of the consent process prior to treatment being offered. (SLC T60)
What the centre could do better. Patient information is reviewed as part of the quality management programme. This is documented on the centre's server including the dates of review. The actual printed leaflets have an issue number and authorisation date but no review date. Whilst the inspection team accept and saw evidence that the information had been reviewed patients or other parties reading it could be misled into assuming that the information was out of date.

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.

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 is used to verify patient/partner identity. Copies of photographic identification were seen in the patient notes reviewed on inspection (CoP Guidance 5.10).

Ten sets of patient records were reviewed on inspection. All had appropriately completed consent forms.

Consent to legal parenthood: Guidance Note 6

SOP's were seen to be in place to obtain the relevant written records of consent to parenthood (SLC T33(b)). Staff interviewed on inspection confirmed that information regarding legal parenthood is given. Staff demonstrated an understanding of the process for consenting and the need to ensure that should a nominated second parent withdraw their consent the named woman would not be treated until she was informed (SLCT64(b))

Eight sets of records of patients who had undergone treatment using donor sperm were reviewed. Consent to legal parenthood was obtained appropriately in all cases.

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

Premises and facilities: Guidance Note 25

Discussions with the PR and 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 or that of a third party (SLC T1).

All staff at the centre has respect for the special status of the embryo when carrying out assisted conception treatment services.

Donor compensation: Guidance Note 13
The centre keeps a record of all reimbursements made to donors, and has adapted their SOPs in consideration of the changes introduced from 1 April 2012 in Directions 0001: no donors have been recruited in the time since new Directions were introduced.

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

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well

All gametes and embryos in storage at the centre are stored in accordance with patient consents.

Information on the database confirmed that material currently in storage is within the

statutory storage limit .(Act14(1)(c))

Sperm tank audits performed in February 2102 showed no discrepancies.

An SOP is in place for the procedure for storing gametes and or embryos (SLC T33b)). SOP's are reviewed annually and have been validated and quality indicators established (SLC T72, T75).

Competency assessments audit practice against protocols and documentation of these assessments were seen on inspection (SLC T36)).

Staff are aware of the recent changes to the statutory storage periods for gametes and embryos and understood the provision for a 12 month cooling off period if gamete providers are in dispute about what to do with stored embryos.

The Person Responsible confirmed that prior to storing their material patients are screened in accordance with (SLC T50)). This was evidenced on SOP's and checklists seen on inspection. Unscreened samples are stored in a temporary dewar.

The protocol for a bring forward system to ensure that notice is given in advance of the consented storage period was seen on inspection.

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

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*
- Export of gametes and embryos (Guidance Note 16) – *only applicable for centres that has exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*
- Import of gametes and embryos (Guidance Note 16) – *only applicable for centres that has imported gametes and / or embryos*

What the centre does well

An SOP was seen to be in place detailing the circumstances, responsibilities and procedures for the release of stored material before distribution (SLC T33b). SOP's include a recall procedure and procedures for the handling of returned gametes and embryos. The inspection team were informed that any recall would be reported as a Trust incident.

Validation documentation was seen for the containers and packages used for distribution (SLC T108).

A checklist was seen detailing information provided when distributing material (SLC T110).

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

Use of embryos for training staff (Guidance Note 22)
What the centre does well The centre uses embryos, with the written consent of the patients whose gametes were used to create the embryos, in order to train laboratory staff in embryological techniques. All the procedures for which the embryos are used have been approved by the Authority (SLC T93).HFEA consent forms are double checked by a senior embryologist prior to the use of embryos in training. SOP's include that no embryos which are used for the purpose of training are kept or used for providing treatments.(SLC T92)
What the centre could do better Nothing noted at the time of the 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 and legible and satisfied all of the requirements of SLC T46. Each record reviewed included: patient/donor first name, surname, date of birth, age and sex. Details of how the patient/donor had been identified (passport/driving licence): the treatment provided; a medical history; welfare of the child assessment; relevant documented consents and clinical and laboratory data and the results of tests carried out.

Centre documents are controlled and reviewed on an annual basis (CoP Guidance 31.6). The inspection team were informed that in order to ensure that only current versions of documents are used they are read only and a maximum of 20 documents are in print at any time (SLC T34)).

What the centre could do better.

Whilst the centre staff could describe and demonstrate their document control system it was considered by the inspection team that by omitting to put the review date on a document which is in print people (i.e. patients who are unaware of the system) may assume that the information in the document is out of date.

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

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

What the centre does well.

The PR provided all information as required by the application process prior to inspection. All members of staff cooperated fully with the inspection team and all further information requested at the time of and post inspection was provided in a timely manner.

The PR has fully implemented the recommendations from previous inspections with no outstanding issues.

SOP's are in place for the process for submitting data to the HFEA in compliance with Directions 0005 (SLC T33 (b). Quality indicators had been established and an audit performed in March 2012 was seen on inspection (SLC T35,T36)). Corrective actions had been documented and implemented and the audit was to be repeated six months later.

Training in submitting data to the HFEA was underway at the time of the inspection.

Completeness and timeliness of licensed treatment reporting
To determine whether all licenced treatment activity is reported to the HFEA within required timescales, a sample of treatments recorded within the centres laboratory books was compared to data submitted by the centre for inclusion on the register.

All 122 IVF treatments within the sample had been reported to the Authority.

Failure to report treatments involving the use of donor gametes and to report them on time potentially affects the authority's ability to fulfil statutory obligations to offspring. Late treatment and outcome reporting has an impact upon the effectiveness of tools the authority has designed to monitor clinical pregnancies.

A sample of 45 assorted form type submissions were reviewed against source documentation held within patient and donor files and the laboratory data base. No critical error or omission was found in the data (i.e. errors or omission that would prevent the authority fulfilling its statutory obligations).

What the centre could do better.

Three (7%) of the 46 DI treatments sampled in the course of the inspection had not been reported. In each instance the data was found to have been recorded on the centre's system but the form data had not been uploaded to the Authority.

87% of IVF and 93% of DI treatments within the sample had not been reported to the Authority within 5 working days as required by Direction 0005.

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.

A tour of the centre confirmed that access to all confidential information is restricted to authorised personnel (SLC T43). Access to the centre is restricted and key pad locks provide additional restriction to sensitive areas. A tour of the centre confirmed that patient records are stored securely. The building is alarmed at night.

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.
The centre is seeking consent to the disclosure of information, held on the HFEA register of information to medical or other researchers.

Consent to disclosure of register information for research purposes

To determine whether the register properly reflects the consent given by patients and their partners for the use of register information for research purpose, completed patient and partner disclosure consents in patient files were reviewed against disclosure consent data supplied by the centre for inclusion on the HFEA register.

Ten completed patient and partner forms were reviewed against the register and all were completed appropriately and reported accurately to the HFEA with the exceptions listed below. .

What the centre could do better.

In one record a patient had given consent to disclosure but this was not reflected in the data submitted by the centre for inclusion on the HFEA Register. In another instance the relevant section of the form had not been completed, though the register reflects that consent has not been given. Where the relevant section of the form has not been completed the intention of the patient and their partner is unclear.

Discrepancies could mean that the consent expressly given by patient and/or partner and provided to the authority is at variance with the consent actually given and/or that the pool of data available to researchers is reduced.

5. Changes / improvements since the previous inspection on 25th May 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
The centre's manual witnessing records include the signatures of both the person performing and witnessing the activity , but not their name and status	The PR should ensure that the record of witnessing checks kept in the patients records include the name, status and signature of the person performing the activity and the person witnessing the procedure.	A witness identification sheet was seen in three patient records. **No further action required**
One WOC assessment seen during the patient notes audit at inspection had not been signed by a clinician.	The PR is reminded that WOC assessments should be signed by the member of staff undertaking the assessment. It is recommended that completion of WoC assessments continues to be monitored as part of the centre's audit programme.	An audit of WoC assessment was seen at inspection. **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 the inspection.		No response required	

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
None noted at the time of the inspection.		No response 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
In one record a patient had given consent to disclosure but this was not reflected in the data submitted by the centre for inclusion on the HFEA Register. In another instance the relevant section of the form had not been completed, though the register reflects that consent has not been given. **Reference** Chair's Letter CH(10)05 Guidance supplementary to Chair's Letter CH(10)05 and amended Directions 0005 and 0007	The PR should audit a sample number of patient and partner consent to disclosure records against that recorded with the HFEA to determine whether the consent to disclosure discrepancies noted on inspection are isolated occurrences or are more prevalent. In the event of the latter, consents recorded on patient and partner registrations forms submitted to the HFEA since 1 May 2010 should be reviewed against the consent to disclosure forms held in patient records at the centre and any discrepancies found corrected. The sample audit is to be completed by 2 August 2012, the results of which are to be submitted to the centre's inspector. Pending the	Further audit completed and submitted. Error rate low. Staff have been reminded of the importance of the accuracy of data input.	A completed audit has been provided by the PR that includes corrective actions. No further action required.

	outcome of this a further full audit of consents recorded since 1 May 2010. In this event the centre's inspector will monitor progress.		
Three (7%) of the 46 Donor insemination (DI) treatments audited in the course of the inspection had not been reported to the HFEA. In each instance the data was found to have been recorded on the centre's system but the form data had not been uploaded to the Authority via the electronic data interface (EDI) system. 87% of IVF and 93% of DI treatments within the sample had not been reported to the Authority within 5 working days as required by Direction 0005 **Reference** SLC T9(e) & T41 Direction 0005	The PR must ensure that data which the Authority is required to hold on its Register is provided by the dates specified in Directions. A reliable regular periodic check process should be introduced to ensure the authority is notified of all licensed treatment activity recorded on the centres IDEAS system in accordance with Direction 0005. The process for submitting licensed treatment data to the authority should be reviewed and enhanced to ensure compliance with submission times detailed in Direction 005 is achieved. A summary report of corrective	I would like to highlight that we are currently in the process of training administration staff to input cycle information on the database which should lead to improvements in form submission times	The PR's comments are noted. The timely submission of register information to the HFEA will be the subject of on-going monitoring by the HFEA's business information team.

	actions implemented should be submitted to the HFEA by 2 August 2012.		

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

25 July 2012

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

Minutes – Item 1

Centre 0196 – (Centre for Reproductive Medicine and Fertility, Sheffield) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Charlotte Augst, Head of Business Intelligence Paula Robinson, Head of Business Planning	Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item. The Panel noted that the Person Responsible (PR) has carried out work for the HFEA in the past, but the Panel agreed that this did not present any conflict of interest.

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 has been licensed by the HFEA since 2001 and provides a wide range of licensed assisted conception treatments to National Health Service (NHS) and self-funding patients.

2. The Panel noted that the centre was previously licensed for Treatment (with embryo testing) and Storage and that the Person Responsible (PR) has now applied for a Treatment and Storage only licence.

3. The Panel noted that the PR has been in post since November 2010.

4. The Panel noted that the centre has requested to change its name to Jessop Fertility as part of this renewal application.

5. The Panel noted that the outcome data for IVF/ICSI during December 2010–November 2011 showed that the centre's success rates are in line with national averages. The Panel noted that for 2011 the centre reported 365 cycles of partner IUI with 51 pregnancies, equating to a 14% success rate.

6. The Panel noted that the centre's multiple clinical pregnancy rate for 2010/11 for all IVF, ICSI and FET cycles for all age groups was 10%.The Panel noted that on-going monitoring of the centre's multiple clinical pregnancy rate shows that the centre is likely to meet the 2011/12 multiple birth rate target of 15%.

7. The Panel noted that the centre's current multiple clinical pregnancy rate is 11% and commended the PR for the exemplary progress that has been made concerning the reduction of multiple births.

8. The Panel noted that at the time of the renewal inspection there were a number of areas of practice that required improvement, including two 'other' areas of poor practice which required attention.

9. The Panel noted that, since the inspection, the PR had given a commitment to implement the recommendations identified at the inspection within the appropriate timescales.

10. The Panel noted that the PR has taken steps to address the areas identified in the inspection report relating to patient and partner 'consent to disclosure' consent records and the submission of data to the HFEA register. The Panel encouraged the PR to implement these areas within the prescribed timeframe since it is important to patients to ensure accurate reporting of data to the HFEA register.

11. The Panel noted the Inspectorate's recommendation that the centre's licence be renewed for four years with no additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales.

12. The Panel noted that the Inspectorate also recommended that the request to change the centre name from The Centre for Reproductive Medicine and Fertility to Jessop Fertility be approved.

Decision

13. 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.

14. The Panel was satisfied that the PR's character and qualifications are such that she is able to carry out her duties under section 17 of the HFE Act 1990 (as amended).

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

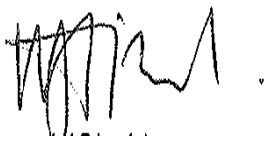
16. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence provided within the report.

17. The Panel noted that the application does involve the use of embryos for training purposes.

18. The Panel had regard to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states that the Executive Licensing Panel will normally grant a renewal licence for treatment/storage/non-medical fertility services for a period of up to four years where the evidence before it reveals no concerns regarding the matters specified in paragraph 4.3.

19. The Panel agreed that it had no major concerns about the centre based on the evidence before it.

20. The Panel endorsed the Inspectorate's recommendations and agreed to renew the centre's licence for a period of four years with no additional conditions, and to approve the centre's name change to Jessop Fertility.

Signed:  Date: 3/08/2012

Juliet Tizzard (Chair)