Licence Renewal Inspection Report for Treatment and Storage Centres

Centre for Reproductive Medicine and Fertility
0196

Date of Inspection: 13th February 2007
Date of Licence Committee: 20th June 2007

CENTRE DETAILS

Centre Address	Assisted Conception Unit The Jessop Wing Tree Root Walk Sheffield Teaching Hospitals NHS foundation Trust Sheffield S10 2SF
Telephone Number	0114 226 8050
Type of Inspection	Renewal
Person Responsible	Professor W L Ledger
Nominal Licensee	Sheffield Teaching Hospitals NHS Foundation Trust
Licence Number	Professor W L Ledger
Inspector(s)	Miss Sarah Hopper Ms Janet Kirkland Mr David Gibbon
Fee Paid - date	Invoice not yet sent
Licence expiry date	30/09/2007

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About the Inspection:
This inspection visit was carried out on 13th February and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between March 2006 and March 2007.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

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 Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Centre for Reproductive Medicine and Fertility has been licensed since 2001 and is a large sized clinic providing a variety of licensed treatments to self-funded and NHS patients. Unlicensed treatments are also offered and these include IUI, OI, GIFT and Surrogacy.

The unit is managed by the Sheffield Teaching Hospital NHS Trust.

The centre is open from 08:00-17:00 Monday – Friday and from 08:00-15:00 on Saturday. Clinical staff are available 24 hours a day on a rota basis.

The centre has a system in place for Quality Management and achieved ISO 9001:2000 certification in 2006.

The PR has been in post since 2001 and has appropriate qualifications and experience.

Activities of the Centre

	Number of cycles 01/11/05-01/11/06:	Treatments
Licensed treatment cycles	604	IVF IVF with donor eggs/sperm ICSI ICSI with donor eggs/sperm Chemical assisted hatching ZIFT PGD DI
Donor Insemination	49	
Unlicensed treatments	✓	IUI, OI, GIFT and Surrogacy.
Research	_	
Storage	✓	Storage of sperm (patient and donor) Storage of embryos

*Data from HFEA Centrepede system report from 01/11/05-01/11/06

Summary for Licence Committee

According to the PR there have not been any changes in demographic patient population, company status, ownership, premises or equipment since the last inspection.

The PR has put into place all the requirements from the last inspection.

Some improvements are required in the areas of quality of service, premises, information and scientific and clinical practice.

The inspectorate were impressed by the overall high level of compliance of the centre. The inspectorate therefore recommends a renewal of the centre's licence for a period of five years.

Risk Assessment

The last completed risk assessment was performed after the inspection. The risk score was 5%.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation	X		
2. Quality of the service		X	
3. Premises and Equipment		X	
4. Information		X	
5. Laboratory and clinical processes		X	

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
Witnessing the disposal of embryos is not documented in the patient records in accordance with D2004/4.	Compliance with D2004/4.	Immediately

Non-Compliance

Area for improvement	Action required	Time scale
During the patient records audit gaps in the Welfare of the Child assessment were noted. In some records there was not evidence that the forms had been checked and approved by centre staff.	Review the assessment of "Welfare of the Child" forms and ensure that the evaluation of the forms is documented.	Immediately

Recommendations	Time scale
All centre staff should be aware of the emergency contact number.	Immediately
According to the centre's policy the emergency trolley should be checked daily. At inspection it was noted that the equipment on the trolley has not been monitored this frequently. The PR should ensure that the emergency trolley is inspected and maintain ed daily. This check should be documented.	Immediately
Update patient information (see section 4)	3 months
Add criminal convictions to staff induction information.	3 months

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
The centre should perform risk assessments as necessary for procedures carried out at the centre.	A number of risk assessments have been carried out in the past year. Evidence of this was provided during the inspection. It was also noted that risk management issues are discussed at unit meetings.

Additional licence conditions and actions taken by centre since last inspection

C	N/A
A	Complied Y/N
C	N/A
A	Complied Y/N
C	N/A
A	Complied Y/N

Report of Inspection findings

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
The inspectorate agreed that there are clearly defined accountability, reporting systems and relationships within the centre. These were detailed in a management responsibilities protocol and are clearly illustrated in the centre's organisational chart. Regular meetings are held within the unit. A unit meeting takes place twice a month and all staff are expected to attend. Board meetings which involve the heads of each department are held on a monthly basis. In addition, daily multi-disciplinary meetings are held to discuss all patients undergoing treatment, at least one representative from each department attends these meetings. Documented minutes of the meetings are stored on the main server. Minutes of the unit and board meetings were provided on the day of inspection. Resources appear to be deployed effectively and efficiently; agreed activity levels are set by the management board and these take staffing levels into account. It is the Business Manager's responsibility to ensure that the number of patients booked per month does not exceed agreed levels. The Centre achieved ISO 9001:2000 certification in January 2006 and has a well established quality management system in place. An ISO team visited recently and commended the centre on its achievements. A document management system is in place which is password protected. Documents are read only and are printed as required. Revisions can only be authorised by the Quality Manager. If changes are made to documents a "change notification" email is sent out to all members of staff. This system was demonstrated to the inspectorate. Document changes are tracked within the Quality Manual. A risk management structure is in place; bi-monthly risk management meetings are held where preventative and corrective actions are discussed and recorded. In addition risk management issues are a fixed item on the agenda of unit meetings and incidents are also discussed at Board Meetings. Evidence of this was provided during the inspection.

Incident alerts are disseminated to all staff within the centre via email. Incident alerts were also seen to be posted on the staff notice board. The inspectorate suggested that a procedure could be developed to confirm that all members of staff have read the emails, for example a sign-off process. However, the Quality Manager considered that this would be an unnecessary measure.

Relevant centre protocols are examined by the Heads of Department in response to alerts and revised if necessary. Reponses to the two most recent alerts were provided to the inspection team.

The PR stated that a contingency arrangement with Hull IVF Unit (Centre 0021) is currently being drawn up by the Trust's legal team. This arrangement will allow for the transport of stored material, gametes and embryos from the Centre for Reproductive Medicine to Hull in the event of an emergency. This arrangement will be reciprocal and evidence of its establishment was submitted to the HFEA.

The Finance Department reported that there are no current concerns about payment of treatment fees but previously they have experienced some delays in receiving payment for invoices.

Areas for improvement
None

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
None

Evaluation
No improvements required.

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates

Unverified HFEA statistics on IVF, FET and DI indicate the following outcomes (these data have been extracted from the HFEA Register, have not been verified by the centre and may be subject to change):

	IVF	FET after IVF	ICSI	FET after ICSI	DI
Clinical pregnancy rate per treatment cycle: 01/11/05-01/11/06	27.27%	27.16%	24.31%	27.78%	22.03%
Live birth rate per treatment cycle: 01/11/04-01/11/05	22.12%	25.58%	21.54%	55%	12.66%

Of the total live births resulting from IVF and ICSI cycles, 25% were multiple births. In the same period no multiple births resulted from DI cycles.

This data has not been verified by the clinic and may be subject to change.

The HFEA success rate assessment indicates an IFV/ICSI success rate which is higher than the National Average in all age groups. FET success rate data show a higher than National Average success rate for age bands 38-39 and for patients below 35 years. However, FET rates were below the National Average for age bands 40-42 and 35-37 years.

The centre's success rates are included in the patient information. A consultant stated that individual chances of success are discussed during consultations.

Patient Questionnaire Analysis

The HFEA patient questionnaire data analysis (data gathered from 18/10/04-09/01/07) indicates that overall levels of satisfaction in all the six topics (clinic &staff, information, counselling, consent and treatment, drugs and sharing information) were above the National Average.

In total 71 patient questionnaires were received before the inspection and there were no serious areas of concern from these. Out of the total returned questionnaires 55% were highly complimentary about the service provided at the centre. A small number, 7%, of questionnaires contained complaints. The majority of these related to parking difficulties and requests for the centre to open at an earlier time. These were discussed with the team and the PR.

Areas of firm compliance

A system is in place for verifying the identity of people seeking treatment: sperm donors are asked to provide their passports for verification; UK patients have their details cross referenced with the NHS database system and are required to have a referral letter from their GP and patients from abroad have to provide photographic evidence.

There is a written protocol on confidentiality which is explained during the staff induction programme.

Arrangements are in place for patients to have privacy during their treatment. Following egg collection patients are placed in their own recovery rooms rather than in a large ward. A second separate waiting area has been designed for patients who are attending the centre with young children. As it is often a quieter area it is also used by male partners who are waiting to produce samples for the laboratory. This was considered to be a sensitive arrangement in which the privacy and dignity of patients has been considered.

The complaints procedure was clearly on display in the waiting room and detailed logs are kept of complaints received by the centre. A protocol for dealing with complaints has been developed as part of the quality manual.

Patients' views are collected via a suggestion box which is located in reception and also by targeted patient questionnaires. In the past year a satisfaction survey was handed out to patients attending for IVF cycles, this focused on the service provided by the laboratory team. Analysis of this questionnaire was provided to the inspection team. At the time of inspection a questionnaire about counselling services had just been launched and the counsellor plans to review the results in three months time. The Quality Manager is currently developing a general patient questionnaire to be distributed later this year.

Two patients were interviewed on the day of inspection and they gave positive feedback about the quality of service they had experienced at the centre. They reported that they could contact the centre at any time and were treated with dignity and respect. The patient information and consent forms were well explained and they were made aware of the side effects of the drugs and the risk of OHSS. The patients stated that they would recommend the clinic to anyone.

A separate counselling room is situated at the quieter end of a corridor in the unit. The room was considered to be fit for purpose by the inspectorate. The counsellors are well integrated into the team and attend the regular unit meetings and the bi-monthly Ethics Committee meetings. This was indicated in the minutes of the most recent unit meetings.

The Ethics Committee has been used 23 times in the past year. The PR stated that patients are notified if their case is going before the committee and are given an opportunity to write a deposition about their case which can be presented to the Committee. The outcome of the Committee is relayed to patients by letter and appointments with a consultant and counsellor are organised should the patients wish to discuss the implications of the decision.

A poster providing contact details for the Trust representative for child protection procedures for children under 18 years old was seen to be on display in the nurses office.

Areas for improvement
During the patient records audit gaps in the "Welfare of the Child" (WOC) assessment were noted. In some records there was not evidence that the "WOC" forms had been checked and approved. In one case the patients did not give permission to the centre to contact their GP regarding welfare of the child. Evidence of a discussion about the welfare of the child was not seen anywhere in the patient notes although the patients were seen for treatment. The PR should ensure that the protocol for assessment of welfare of the child is followed by all members of staff and that decisions regarding welfare of the child are clearly documented in the patient notes.

Executive recommendations for Licence Committee
Note discrepancies in the welfare of the child assessment procedure.

Areas not covered on this inspection
Donor selection Egg sharing

Evaluation
Some improvements needed

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
The premises were considered to be fit for purpose. The inspectorate also agreed that the centre is a patient friendly environment. Emergency call buttons were seen to be present in theatres, clinical rooms, recovery rooms, the male production room and toilets. The laboratory facilities were upgraded in 2005 to meet good manufacturing practice (GMP) standard. The laboratory suite now comprises of a series of laboratories which have grade B air throughout. The laboratory area is restricted to laboratory personnel and senior heads of department via a proximity card reader. This system also logs the entrance and exit of each member of authorised staff. The cryopreservation laboratory is located within the laboratory suite and has further security measures in place: another proximity reader is located on the cryopreservation laboratory door. All dewars were seen to be locked and fitted with low nitrogen level alarms. A low oxygen monitor was seen to be in place and the laboratory staff were able to explain what their response would be in the event of an alarm. The appropriate procedures to be followed when the alarms sound has been documented within a protocol. The laboratory has an established facility monitoring system: this computer based system monitors the room pressure; particles; incubator temperature and carbon dioxide levels; fridge and freezer temperature, liquid nitrogen low levels in dewars, oxygen depletion in the laboratories and gas pressure in pipes. A protocol for monitoring air quality and for maintenance of laboratory equipment is in place. This document and the service schedule were provided on the day of inspection.
Areas for improvement
According to the centre's policy the emergency trolley should be checked daily. Guidance outlining this policy was seen to be posted on the notice board in the nurses' office. However, during the tour of the premises it was noted that the emergency trolley had not been checked this frequently. The PR was advised to ensure that daily checks are carried out. During staff interviews it was noted that not all centre staff are aware of the contact number to be used in cases of emergency.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
Some improvements required

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
In total 15 patient records were examined by the inspectorate. All HFEA consent forms were seen to be completed correctly and copies of the consent forms were present in all sets of notes. Welfare of the Child forms were present in all records but were completed inconsistently in some cases. In three records the patients had completed the forms but there was no evidence that the forms has been considered and responded to by centre staff. In one set of records the patients indicated that they did not want their doctor to be contacted with regard to welfare of the child. The clinician's response to this was not evident in the notes nor was any discussion of the welfare of the child.
Areas of firm compliance
Patient records are stored in paper copy and on the IDEAS database system. Paper records are stored in a records room behind the reception. This room is lockable and the key held by senior members of staff. Electronic records are password protected and the database is backed up on a secure server. Patient information was considered to be detailed and lay friendly. The IVF information was thought to be extremely detailed and included the risks associated with multiple pregnancies and clear pre-conceptual guidance. Written information on IVF cycles is supported by detailed flow charts. Patients requiring advice out of clinic hours are advised to call the hospital switchboard. The switchboard team are provided with a rota of staff on call for the centre, initially a nurse would be contacted and she in turn could contact a doctor if she felt it was necessary. Patients requiring admission would be admitted to the main hospital and their treatment overseen by the clinic team. The patient information regarding out of hours calls is very clear and it was noted that patients are encouraged to contact the centre rather than their GP or local hospital. A small library of books and videos are made available to patients should they require any further information. The Register Department have reported problems in receiving treatment forms from the centre but this was due to difficulties with the integrated EDI system. This has now been resolved.

Areas for improvement

Although the patient information was considered to be of a high standard, some amendments are required:

- The HFEA address needs to be updated on various information sheets.
- Patient and donor information should be revised in line with the SEED review. Currently the information states that "the maximum number of live births is 10". The information should be clarified to explain HFEA policy that gametes (or embryos created using gametes) from an individual donor should not be used to produce children for more than 10 families as a result of licensed assisted conception services.
- Donor information states that "donors can be paid up to £15 plus expenses per donation". This must be updated in line with D2006/1 to show that donors may be compensated for loss of earnings (but not for other costs or inconveniences) up to a daily maximum of £55.19 but with an overall limit of £250 (or the equivalent in local currency) for each course of sperm donation or each cycle of egg donation.
- Sperm donor information must be updated so that it informs donors of the possibility that a child born disabled as a result of a donor's failure to disclose defects, about which the donor knew or ought reasonably to have known, may be able to sue the donor for damages (Code of Practice 5.7 vii)
- It was noted that the information provided for egg donors was more detailed than that for sperm donors although many issues discussed are applicable to both groups. For example, information for egg donors includes guidance about the process of registering as a donor (information that the donor will need to be provide etc) and explains what the processes will be in the future if a child resulting from their donation wishes to find out identifying information but this information is not contained in the sperm donor leaflet. It was suggested that the forms should be reviewed together so that any further discrepancies can be noted and responded to.
- Ensure that patient and egg donor information refers to the putative risk of cancer associated with treatment (Code of Practice 5.5v)
- Information for patients considering PESA and TESA procedures states that "under British Law in the event of your death, although it is technically possible for you to become a biological parent you cannot become a legal father". This information needs to be updated in line with the Deceased Fathers Act 2003 and should make reference to posthumous consent forms.
- The information sheet on blastocyst transfers should be amended to include that fact that the long-term effects of blastocyst culture are still unknown.
- Although the assisted hatching information states that the procedure is only suitable for a very limited number of patients it does not include success rates achieved with the technique and the inspectorate had concerns that the information appeared biased towards assisted hatching. It was suggested that the patient information should include a statement saying that there is no universal evidence that indicates it is of benefit. The PR stated that few patients have assisted hatching and that they may cease offering this procedure in the future.
- Patient information about embryo transfers (included in the general IVF information) should be updated. Currently, guidance about the number of embryos that can be legally transferred varies between information sheets. The IVF information states that "By law a maximum of three embryos may be transferred, but the HFEA has recently made directions that a maximum of two embryos should be replaced in most treatment cycles, unless there are exceptional circumstances. This and all information sheets

should be revised to reflect the current guidance on the number of embryos to transfer (Code of Practice 8.20-8.22).

When these issues were raised with the centre staff, it was explained that the team had already realised that certain patient information sheets required updating. Indeed a complete review of all patient information had been set as a quality management objective for this year. Monthly meetings have already begun with the aim of reviewing all patient information. Evidence of this document review process was provided to the inspection team.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
None

Evaluation
Some improvements needed

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	3.6
NMC registered nurses	5.72
HPC registered scientists	3
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	5.5

Summary of laboratory audit
The andrology team completed their annual storage audit in February 2007. Minor discrepancies with location information were noted. The Senior Embryologist reported that an audit of stored embryos was completed in January 2007. No major discrepancies were noted.
Summary of spot check of stored material
A spot check of stored material performed on the day of the inspection found no discrepancies. Sperm samples belonging to two patients were checked from tank to records and then two more were assessed from records to tank. The same process was undertaken for stored embryos.
Areas of firm compliance
Audits into all areas of practice have been conducted in the past year and the quality audit schedule for the next year was made available to the inspectorate. The Quality Manager was able to provide evidence of an audit of witnessing practice and an audit of compliance with laboratory SOPs. The laboratory participates in a programme of quality assurance. Evidence of participation in the NEQAS scheme was provided. Key performance indicators are closely monitored and graphically analysed by the Senior Embryologist. Recent analysis of the laboratory performance measures was made available to the inspectorate.

Sufficient staff are in post within the laboratory, clinical and administration teams to conduct the current number of treatment cycles. The PR stated that he feels that there is a need for another member of staff in the nursing team. Consequently an application for funding a new nursing post has been placed with the Trust and this is currently being processed. The Clinical Nurse Specialist reported that in the event of an acute shortage of nursing staff the hospital could provide a bank nurse.

The Trust has detailed polices for recruitment of staff. The PR confirmed that he is involved in the recruitment process as he sees all CVs for prospective staff and sits on the panel for senior post interviews. Members of senior staff are involved with the interview process for other positions within the unit.

A detailed counselling, nursing and laboratory induction programme was seen to be in place for trainee members of staff.

All staff interviewed stated that they were satisfied with the provision for CPD. The Clinical Nurse Specialist stated that nursing staff attend mandatory Trust training, local ACU training, national and international conferences. Evidence of this was provided to the inspection team. The Clinical Nurse Specialist also stated that she is planning to introduce in-house training for ultrasound: a Trust consultant will perform this training and nurses also have the opportunity to attend the early pregnancy unit and gynaecology department to gain further experience in their scanning techniques. The inspectorate recommended that it would be good practice to ensure that a log of this training is kept and that competencies are signed off by qualified personnel.

Laboratory staff also expressed satisfaction with their CPD. The HPC registered staff are enrolled on the ACE CPD scheme and trainee members of staff are completing the ACE Certificate.

Training needs appear to have been well considered by the laboratory management. For example, as PGD cases have not taken place since 2005, the Senior Embryologist plans to send members of the team to the Assisted Conception Unit at Guys and St Thomas' Hospital Trust (Centre 0102) for retraining and to ensure that the embryologists maintain their competence to perform biopsies.

Areas for improvement

Although laboratory staff stated that they witness the discard of embryos, this is not documented as required by D2004/4: A contemporaneous record must be made in each patient's medical records confirming: (a) the procedure undertaken; (b) the date and time of the procedure; (c) the name and status of the person undertaking that procedure and the signature of that person; (d) the name and status of the witness to the procedure and the signature of that person.

Interviews with staff suggested that the training provided for the nursing and clinical teams was thorough and the inspectorate did not have any concerns about the level of training provided. However, logs have not been maintained of the training that staff have undertaken. This is a particularly important issue for the nursing staff who have an extended role within the unit, including conducting embryo transfers and administrating IV sedation for egg collection.

Evidence of the IV sedation training and achieved competencies of nursing staff was requested during the inspection but not provided. This was a matter of concern for the inspectorate who would have liked to have seen evidence that the nurses have been trained to perform their extended role and that they are working within guidelines from the Trust re competence in giving IV sedation. To prove competencies, all staff should develop and maintain training logs.

There is no current mechanism for staff to report criminal convictions to the PR. It was suggested that this requirement should be added to the staff induction information.

Executive recommendations for Licence Committee
Require compliance with D2004/4.

Areas not covered on this inspection
Assessment of patients and donors Safe handling systems Procedures in practice

Evaluation
Some improvements required.

Report compiled by:

Name……Sarah Hopper…….

Designation……Inspector……..

Date……16th February 2007……

Appendix A: Centre Staff interviewed

Professor Ledger (PR) and 8 members of centre staff.

Conflicts of interest – the PR is also a member of the HFEA Authority.

Appendix B: Licence history for previous 3 years

Licensing History

Centre: Centre for Reproductive Medicine and Fertility, Sheffield

Number: 0196

PR: William Ledger

2006

Licence Committee 8th June 2006
The Committee agreed that the centre's licence should continue with no additional conditions.

2005

Licence Committee 22nd September 2005
The Licence Committee agreed to the change of Nominal Licensee. The representative of the Trust will be Mr C C Linacre.

Licence Committee 9 May 2005
Licence continued with no conditions.

Licence Committee 28 April 2005
Temporary change of premises approved.

Licence Committee 9 February 2005
Licence varied to add PGD for Diamond Blackfan Anaemia with HLA typing

2004

Licence Committee 22 April 2004
Report of an incident

Licence Committee 5 April 2004
Licence renewed for 3 years

2003

Licence Committee 11 June 2003
Licence renewed for 1 year.

2002

Licence Committee 12 September 2002
Licence renewed for 1 year.

Licence Committee 27 June 2002
Temporary licence granted for 2 months

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR……..

Date of Inspection……..

Date of Response……

Please state any actions you have taken or are planning to take following the inspection with time scales

WOTC issues have been discussed and implemented as per SOP

We have already put in place witnessing of embryo disposal and have checked staff awareness of emergency procedures etc. The regular inspection of the arrest trolley has been highlighted and will be signed off by the inspecting person on each occasion.
Patient information updating has been completed
The recommendations regarding criminal convictions notification for new staff members will be put in place when we next conduct interviews, and on each subsequent occasion.

I have read the inspection report and agree to meet the requirements of the report.

Signed……

Name……

Date……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

20 June 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Centre for Reproductive Medicine Sheffield (0196)
Licence Renewal

Members of the Committee:
Sharmila Nebhrajani, Lay Member – Chair
Anna Carragher, Lay Member
Emily Jackson, Lay Member
Maybeth Jamieson, Embryologist

In Attendance:
Frances Clift, Legal Adviser
Marion Witton, Head of Inspection
Shamima Rouf, Committee Secretary

Observers:
Andrew Leonard, Inspector
Rong Li and Joy Zhang from Peking University Third Hospital

Conflicts of Interest: Members of the Committee agreed that they had no conflicts of interest with this item. However it was noted that Professor William Ledger is a member of the Authority.

The following papers were considered by the Committee:

- papers for Licence Committee (37 pages)
- no papers were tabled.

1. The papers for this item were presented by Sarah Hopper, HFEA Inspector. Ms Hopper drew the Committee's attention to the centre's risk rating with regard to compliance with the EUTCD, which was 1%, in the low range. She added that the submitted EUTD application was a good application.

2. Ms Hopper drew the Committee's attention to the recommendations made on the inspection visit which took place on the 13 February 2007. The response from the Person Responsible confirmed that a majority of these issues have now been rectified.

3. The Committee noted with concern the breach of Directions D 2004/4 and welcomed the Person Responsible's response that the centre has put in place proper witnessing of embryo disposal since the inspection.

4. The Committee noted the need for improvement in patient and donor information. The Committee agreed that the centre should submit the revised

information for approval by the Executive within one month from receipt of these minutes.

5. The Committee agreed to renew the licence for five years.

Signed…….. Date…….
Sharmila Nebhrajani (Chair)