Renewal Inspection Report

Care Manchester
0185

Date of Inspection: 26th February 2009
Date of Licence Committee: 10 June 2009

Index

Centre Details

Person Responsible	Mr Glenn Atkinson
Nominal Licensee	Ms Charmain Russell
Centre name	CARE Manchester
Centre number	0185
Centre address	108 -112 Daisy Bank Road Victoria Park Manchester M14 5QH
Type of inspection	Renewal
Inspector(s)	Bhavna Mehta Allison Cummings Stephanie Gadd Debra Bloor
Fee paid	Yes
Licence expiry date	30 September 2009
NHS/ Private/ Both	Private

About the Inspection:

This inspection visit was carried out on 26th February 2009 and lasted for 8 hours.

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 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.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

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 is part of the CARE fertility group and is housed within the Manchester Lifestyle Hospital. CARE Manchester has recently acquired additional rooms from Manchester Lifestyle Hospital. These have been refurbished and are to be used for consultations and examinations. The laboratory space has also been reconfigured to allow more flow hoods and incubators to be utilised. The centre has applied to vary their licence to allow pre implantation genetic diagnosis (PGD), pre implantation genetic screening (PGS) and laser hatching.

The centre provides self funding treatments to patients referred from all areas of the North West and occasionally from other regions of the UK and overseas.

As a primary centre, CARE Manchester has links with: The Beaumont Hospital, Bolton; Assisted Conception Unit, Leigh Infirmary; Calderdale Assisted Conception Unit, Calderdale Royal Hospital. The centre is a satellite centre for CARE Nottingham.

The person responsible (PR) has been in post since 1999 and is also the person with overall clinical responsibility for the centre. The PR is registered with the General Medical Council and is on the obstetrics and gynaecology specialist register.

Activities of the centre[1] for the time period from 1st September 2007 to 30th September 2008

In vitro fertilisation (IVF)	485
Intracytoplasmic sperm injection (ICSI)	733
Frozen embryo transfer (FET)	314
Donor insemination (DI)	21
Gamete intrafallopian transfer (GIFT)	0
Research	No
Storage gametes/embryos	Yes

Activities of the centre[2] for the time period from 1st January 2007 to 31 December 2008

Intra uterine insemination (IUI)	67

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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.

[2] Activity relating to IUI with partner sperm is provided to the HFEA in the form of an annual return. This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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 Licence Committee

The person responsible (PR) has been in post since 1999.

The PR has applied to:

1. renew the centre's treatment and storage licence and
2. vary the licence to allow pre implantation genetic diagnosis (PGD), pre implantation genetic screening (PGS) and laser assisted hatching.

The centre has appropriate premises, suitably qualified and experienced staff and adopts largely appropriate procedures, except for the one listed below. Patients report satisfaction with the treatment that they receive. The centre has been proactive in the continuous development and implementation of a quality management system.

Some improvement is required to the centre's premises and equipment practice and significant improvement is required relating to the centre's laboratory and clinical processes.

The inspection team is concerned that, at the time of this inspection, the centre was storing cryopreserved material without written consent. The same issue was reported in the 2007 interim report and before that, in the 2006 renewal report.

The licence committee is asked to consider what, if any, regulatory sanctions are warranted in consideration of the persistent breach documented in this report.

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, Standard Licence Conditions or Code of Practice:

The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
The centre undertakes the diagnosis and investigation of Patients, Patient Partners or Donors, or their gametes, embryos or any material removed from them, in laboratories that are not accredited. Note that the centre was also in breach of this licence condition A.7.3 and CoP standard 7.8.2 at the interim inspection on 13 December 2007.	It is recommended that the PR reviews the requirements of licence condition A.7.3 and CoP S.7.8.2 as to CPA accreditation and expedites the decision as to out-sourcing of the pathology services and update the inspectorate.	Within 6 months of date of this report- by 7th November 2009.
During the demonstration of the bring forward system, it was observed that the centre was storing cryopreserved material for six patients without written consent. This is in breach of Schedule 3 8(2) of the Human Fertilisation and Embryology Act 1990 which states that 'an embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each person whose gametes were used to bring about the creation of the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents'. This is supported by Schedule 3 1: 'a consent under this Schedule must be given in writing and, in this Schedule, "effective consent" means a consent under this Schedule which has not been withdrawn. At the interim inspection on 13 December 2007 the centre was also found to be in breach of the Human Fertilisation and Embryology Act 1990 regarding this issue.	The PR should, as a matter of urgency, ensure compliance with the requirements of the Human Fertilisation and Embryology Act in relation to the storage of gametes and embryos and 1. notify the lead inspector of the date of the monthly audit and 2. submit to the inspectorate, until the date of the next inspection: a) the results of the monthly audit of expired consents within seven days of the audit being conducted, and b) all documentary evidence of the steps taken to obtain the written consent to satisfy the requirements of the HFE Act, 1990, and c) an action plan of how the PR will assure that this breach is avoided from now on.	Immediately.

Non-Compliance

Area for improvement	Action required	Time scale
None.		

Recommendations

Area for improvement	Action required
None.	

Changes/ improvements since last inspection

Recommendations	Action Taken up to the date of this inspection
The centre has not made progress in establishing 3rd party agreements with suppliers: it was reported that suppliers have been approached by the CARE group but at the time of the inspection, no agreements had been established. This is potentially a breach of standard licence condition A. 5.1 which states that the centre shall establish a written agreement with a third party for external activities which influence the quality and safety of gametes.	The 3rd party agreements log and a sample of agreements, reviewed by the inspectorate in the course of the inspection, demonstrated compliance with HFEA guidelines.
At the time of the interim inspection, the air quality in the class 2 hood and in the laboratory housing the hood where sperm samples are processed had not been monitored. Standard licence condition A.10.19 states that gametes and embryos must be processed in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality and that it must be demonstrated and documented that the chosen environment achieves the quality and safety required.	The senior embryologist took immediate action to monitor the air quality in the andrology laboratory and settle plates were delivered to the unit before the end of the inspection. No further action was required.
Patient records are archived off site and the records of individual patients can be retrieved if required. Providing information that allows the identification and retrieval of a single set of archived notes may be a breach of section 33 (5) of the 1990 Human Fertilisation and Embryology Act. Section 33 (5) states that no person who is or has been a person to whom a licence applies, no person who is or has been a person to whom a third party agreement applies, and no person to whom directions have been given shall disclose any information falling within section 31(2) of this Act which he holds or has held as such a person.	Subsequent to the review of the draft interim report the PR reported having reviewed the storage of archived records. The PR states that currently, notes are stored offsite at one facility where all staff who come into contact with notes, have signed a confidentiality agreement. The site was visited in January 2008 and no issues were raised.

Section 31(2) of the Act states that information falls within this subsection if it relates to the provision for any identifiable individual of treatment services other than basic partner treatment services.	
Thawing and culturing of embryos has been carried out on the premises of CARE Manchester in pursuit of the licensed research of project R0176. At paragraph 4 (2) (d) of schedule 2 the 1990 Human Fertilisation and Embryology Act states that a licence cannot apply to premises of the person who holds the licence in different places. This means that the licensed research of project R0176 can only be carried out on the premises of CARE Nottingham. Carrying out research under the auspices of licence R0176 on any premises other than those named on the licence is unlawful. Under section 41 (2) (a) of the Act, a person who contravenes section 3 (1) or 3 (1A) of the Act is guilty of a criminal offence. Section 3(1A) states that no person shall keep or use an embryo, except in pursuance of a licence. It is also stated at Paragraph 4 (1) (a) of schedule 2 that a licence can only authorise activities to be carried on premises specified in the licence.	Thawing and culturing of embryos under the auspices of the licence for research project R0176 was ceased immediately after the centre were advised of the potential breach.
Analysis of patient blood samples is carried out on site at CARE Manchester. COP standard S. 7.8.2. states that if the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patient partners or donors, or their gametes, embryos or any material removed from them, these laboratories shall obtain suitable accreditation. It is noted at S. 7.8.2. that the pathology disciplines involved in diagnosis and investigation include clinical biochemistry.	The PR commented that CPA (UK) Ltd accreditation of laboratory is being investigated and initial NEQAS requirements have been undertaken. However, the PR states that he is awaiting a decision as to out-sourcing of the pathology services before proceeding with accreditation.
At the time of the interim inspection, embryos created from the gametes of a couple seeking to commission treatment with the aid of a surrogate had been stored beyond the statutory five years. Regulation 2 (1) of The Human Fertilisation and Embryology (Statutory Storage Period for	The PR stated in the pre inspection questionnaire that the HFEA was advised that the embryos have been allowed to perish.

Embryos) Regulations 1996 states that in the circumstances specified in paragraph (2) section 14(4) of the Act (statutory storage period in respect of embryos) shall have effect as if for five years there were substituted the appropriate period specified in the Schedule to these Regulations. Regulation 2(2)(b) states that those circumstances are that the woman being treated is aged under 50 on the relevant date and the treatment in question would not result in her being a surrogate mother within the meaning of section 1(2) of the Surrogacy Arrangements Act 1985.	
During the demonstration of the bring forward system it was observed that at the time of the inspection, the centre were storing cryopreserved material for 37 patients without written consent. At paragraph 1 of schedule 3 of the 1990 Human Fertilisation and Embryology Act it states that consent under this Schedule must be given in writing.	On 29 February 2008 it was reported by the PR that with the exception of the embryos of one couple, appropriate written consent to storage was in place for all embryos in stored.
Not all members of staff have completed annual mandatory training and/or induction training and/or life support training. Standard S .6.2.6. of the COP states that to enable them to carry out their designated activities, personnel shall be provided with appropriate initial/basic training which is updated as required when procedures change or scientific knowledge develops.	A document outlining the timeline for the provision of training was submitted to the HFEA as requested subsequent to the review of the draft report.

Additional licence conditions and actions taken by centre since last inspection

None

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
Leadership and management The person responsible (PR) has been in post since 1999. The CARE group management structure integrates activities throughout the group's assisted reproductive treatment (ART) facilities but allows each centre within the group to maintain its independence. **Organisation of the centre** The centre has a clearly defined management structure, which regulates all activities within it. This was clearly illustrated in the centre's organisational chart. **Resource management** The number of cycles has marginally increased since the last inspection. The staffing level has remained comparable to that at the time of the last inspection. The activities and resources needed are continually reviewed in terms of staff, facilities, equipment, materials and information systems. The inspectorate was shown the additional space acquired which will allow the PR to progress with plans to vary the centre's licence to offer pre implantation genetic diagnosis (PGD), pre implantation genetic screening (PGS) and laser hatching. The additional facilities will allow the centre to bid for ART contracts offered in the northwest region. **Clinical governance** The centre has in place the CARE group protocol for assessing and reporting clinical governance issues. This protocol refers to the HFEA Direction D2007/3 and is compliant with the requirements of the Code of Practice (CoP) and the HFEA Direction. The PR has stated that the CARE group promotes a 'no blame culture' and that all staff are aware of need to report incidents.

Incident management
Incidents are flagged up to unit manager and investigated by the relevant manager, unit manager or PR, as appropriate. Since the interim inspection in December 2007, the PR has been prompt in notifying the HFEA of adverse incidents. The inspection team were shown an electronic log of all incidents and the content concurred with information reported to the HFEA. The inspection team encouraged the ongoing reporting of incidents to the HFEA.

Risk management
The PIQ states that some risk assessments have been completed and a copy of the risk assessment register was sent to the inspectorate. At the inspection, staff explained that risk assessments are conducted as per the CARE group protocol. All protocols are available electronically to all staff on the centre's shared drive. The PR explained that the centre records non-conformities in environmental parameters and that corrective action is taken. For example, the bring forward system for stored material was audited in February 2009 which identified a non-conformity. Follow up action was taken and recorded (see section 4 - Areas for consideration, of this report for the detail of the audit).

Alert management
HFEA Alerts are received by the PR and disseminated to relevant departmental managers. Urgent action can be taken if required after discussion between them. HFEA Alerts are also discussed at the management team meetings as a standard agenda item and are discussed, if relevant, at monthly departmental meetings.

Complaints management
The centre has a complaints policy. On the day of inspection, this was displayed in the waiting room. The centre has a written protocol for handling complaints that refers to the HFEA CoP requirements. The induction training for all new staff covers complaints handling. The centre logs, reviews and uses the data to improve the service. A patient interviewed, told the inspectorate that the centre's complaints protocol was part of the patient information pack she received before commencing treatment.

Contingency arrangements
The centre manager, who is also the nominal licensee, is available to provide managerial cover in the PR's absence. There is provision for cross cover between other CARE centres. The CARE group has four HFEA licensed treatment and storage centres and treatment can be continued at any of the other three centres. The PR states in the PIQ that this contingency arrangement does not require a formal agreement. There is similar provision for counselling services cover across the group.

Establishment of third party agreements
Third party agreements (TPA) have been established with suppliers of goods or services that may impact on quality of gametes/embryos. The TPA log and a sample of these agreements, reviewed by the inspectorate, demonstrated compliance with HFEA guidelines.

Meetings / dissemination of information
There is an effective means for communicating with and receiving information from staff. An organised meetings structure, consisting of monthly specialist meetings, such as for nurses, 0consultants, embryologists and administration staff, are open to all staff. Operational management group meetings for managers of specialities within the centre are also held monthly. In addition, local executive meetings, medical directors meetings, registered

manager meetings, head of unit meetings, laboratory manager meetings are held regularly within the CARE group. Minutes of all meetings are available to staff electronically. Minutes of the embryology meetings reviewed at inspection, showed that 'staff suggestions' is a standard agenda item at all meetings. The laboratory staff told the inspectorate that they are invited to attend and have access to the minutes of all meetings. Other staff reported that records of meetings are kept which are available in the relevant centre unit files and are received electronically. The counsellor confirmed that she attends the monthly Ethical Advisory Committee meetings where matters including surrogacy, known donations and welfare of the child are discussed. The counsellor confirmed that these meetings are open to all staff.

Payment of licence/treatment fees
On average, in the 12 months to 8th January 2009, the centre took 28 days to pay HFEA invoices. This is compliant with standard licence condition A.16.3.

Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
All areas covered.

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
In the time period from the 1 January 2005 to 31 December 2007 the centre's outcomes were in line with the national average.
Areas of firm compliance
Quality management system The centre's designated quality lead works closely with the CARE group's quality manager. A Quality Management System (QMS), centrally updated each month, is in place. The quality manual includes the documented procedures required by the CoP and the index of protocols was sent to the inspectorate with the pre inspection questionnaire. The quality lead informed the inspectorate that the quality policy is made available to staff in printed form and electronically as controlled, read only, documents. The quality manual includes the centre's aims and objectives and these are reviewed at the centre's bi-annual meetings. The documents reviewed in the course of inspection were fully compliant with the requirements of document control outlined in CoP S.5.2.5. **Feedback** The centre management conducts a bi-annual review of the QMS and all the services offered. In circumstances where changes are required, opportunities for improvement are identified and implemented. The internal audits were sent with the pre inspection questionnaire and are carried out by comparing practice against policy using the HFEA CoP. For example, an audit of patient feedback was positive but highlighted the need for an additional men's production room. In response to this feedback, action was taken by adding a new room and at the same time, the original room was refurbished.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None

Evaluation
No improvement required.
Areas not covered on this inspection
All areas covered.

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance

Premises

Access to the centre is controlled by use of an entry phone into the centre and keypad entry locks, once inside. On the day of the inspection, the premises and facilities appeared well maintained and suitably equipped.

The centre provided, pre inspection, copies of risk assessments, which show that areas of the premises have been risk assessed, outcomes reviewed and corrective actions taken. For example, a fire risk assessment identified that staff training, registration of staff/patients/visitors on entry to the centre and correct signage of fire exits should be implemented. This risk assessment has a review date of June 2009. At the time of inspection, the inspectorate were asked to sign the visitor's book and observed signs on fire doors, though the inspectorate was told that new and replacement signs have been ordered. This demonstrated that some of the outcomes of the risk assessments are being implemented.

Arrangements are in place for cleaning, facilities maintenance and waste disposal. The centre has written protocols in place and records to demonstrate compliance were seen at inspection.

Clinical facilities

The PR explained that the centre has recently acquired consultation and examination rooms from Manchester Lifestyle Hospital. The centre is yet to display signage including occupancy notices, safety notices (such as fire notices) and a patient call system. These were on order and were expected within a week of this inspection. Reconfiguration of the embryo transfer room and the laboratory space will allow for a proposed increase in activity. The centre was awaiting fitting of the lighting to guide procedures. The clinical facilities provide for the privacy and comfort of those considering donation and seeking treatment; undergoing examination and treatment and producing semen specimens. The centre has systems for checking and documenting that the emergency clinical facilities and equipment are fit for purpose.

Counselling facilities

The counselling facilities provide quiet and comfortable surroundings in which sessions can

be held that are private, confidential and without interruption.

Laboratory facilities
Laboratory facilities, including equipment, premises and materials are designed and maintained for their intended purpose, minimising risks to gametes and embryos and hazards to patients and staff. The centre sends samples to a CPA accredited laboratory.

Air quality
Air quality in the laboratory is compliant with the requirements of the CoP. The centre has is in place, a protocol for air quality monitoring which was seen on inspection. Air quality is tested annually as recommended by the infection control committee who are advised by microbiologist. Settle plates are monitored annually. Test results dated February 2009 confirmed that the processing of gametes and embryos occurs in an environment of at least Grade A air quality, with a background of Grade D.

Management of equipment and materials
All equipment at the centre is covered by contracts for annual servicing and maintenance and equipment sampled during the inspection was within servicing intervals. The centre has a maintenance activity log for each piece of equipment. Evidence of real-time equipment monitoring was seen for laboratory equipment, e.g. incubators, hot blocks and fridges with computer logging of data. The inspectorate was also provided with documented evidence that monitoring of key equipment in the theatre is performed.

Equipment and materials used meet the requirements of the relevant EU, Medical Devices and In Vitro Diagnostic Medical Devices Directives. The equipment log reviewed at inspection showed that the equipment is validated by the manufacturer. Six more incubators were to be delivered following this inspection. Most large equipment is ordered centrally from the CARE main centre at Nottingham and then distributed to the other CARE centres.

Storage facilities for gametes and embryos
The storage facilities for gametes and embryos were seen to be compliant with the requirements of the CoP. The centre has acquired three new dewars, including one vapour dewar, since the last inspection, bringing the total number of dewars to nineteen. These are all kept in the one area. All those containing samples are alarmed: all dewars are fitted with low nitrogen alarms and/or low oxygen monitors, an auto-dialler and an external indicator warning system to prevent staff entering an oxygen depleted atmosphere. This was confirmed at inspection by discussions with staff, observations and reviewing documents. The centre has a documented procedure in place for responding to an alarm within and outside normal working hours.

Staff facilities
Staff facilities were seen at inspection and deemed to be compliant with the requirements of the CoP. Staff reported that they find the facilities suitable. The centre has provided staff with appropriate garments and equipment for personal protection and hygiene, toilet accommodation, a rest area with basic catering facilities and a supply of drinking water, a changing area and secure storage for personal effects and storage for protective clothing.

Storage of records
The PIQ states that patient notes are stored offsite at one facility. The process for retrieving stored information has been risk assessed and controls have been implemented to ensure

patient confidentiality is not breached. All staff at the offsite facility that come in contact with notes have signed a confidentiality agreement and are aware of HFEA confidentiality requirements. The centre staff visited this site in January 2008. The PR stated that no issues were identified. The centre has plans for electronic scanning and storage of notes. The centre has carried out a risk assessment on implementing this and has entered into a third party agreement with the company providing the service.

Areas for improvement

Laboratory facilities

The centre has a laboratory that performs diagnostic analysis of blood samples that is not accredited by CPA (UK) Ltd or any other body as required by S.7.8.2. The PR has stated that the opportunity to out-source services has arisen again and the PR is pursuing this option.
It is recommended that the PR reviews the requirements of licence condition A.7.3 and CoP S.7.8.2 as to CPA accreditation and expedites the decision as to out-sourcing of the pathology services and update the inspectorate.

Areas for consideration

None.

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the PR making a decision as to out-sourcing of the pathology services.

Evaluation

Some improvement required.

Areas not covered on this inspection

None

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
Information for service users General information regarding the centre, opening times, facilities and location are available on the centre's website and in written pre appointment information sent to all patients. Comprehensive written patient information is readily available. Information relating to patient support groups, local meetings and the complaints procedure was displayed in the patient waiting areas. The HFEA licence was displayed in the reception area. Written information for those considering treatment, donation or egg sharing provided by the centre appears to be clear, comprehensive and easily understood. A review of patient information was compliant with the requirements of the CoP. A patient interviewed during the inspection stated that she felt the information she had received by post and at meetings with staff, was easy to read and understand; that she and her partner then met with the consultant to discuss the treatment options; that consent forms and welfare of the child issues were explained and that the staff at the centre gave the patients time to consider and reflect on the information. Following the medical consultation, the patient met with a nurse to discuss the proposed treatment plan and was given the opportunity to ask further questions or seek clarity on any matters presented. The nurse explained the medication to the patient. The patient also reported that she received help in completing the consent forms. **Welfare of the child** Discussions with staff identified that welfare of the child matters are discussed at the monthly held Ethical Advisory Committee meetings. The centre provides written patient information on welfare of the child assessments. The centre has a written protocol, including flow diagrams, for these assessments, the results of which are noted in patient records. Patient records reviewed at inspection provided evidence of this. **Consents** There are documented procedures ensuring no activity involving gametes of embryos is carried out without the appropriate consents. The laboratory staff double check the consents check list and sign off before conducting treatment. A sample of patient records were reviewed at inspection and consents were found to be present and consistent with the treatments provided. **Access to health records** The centre has a documented procedure in place for responding to a request by a patient for a copy of their medical notes.

Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None.
Evaluation
None.
Areas not covered on this inspection
Provision of information to the HFEA register

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	4.1
NMC registered nurses	9.9
Non NMC registered clinical staff	5.2
HPC registered scientists	5.15
Scientists working towards registration	2.0
Support staff (receptionists, record managers, quality and risk managers etc)	16.54
Counsellors	0.53

Summary of laboratory audit
Not provided.
Summary of spot check of stored material
A spot audit check of stored material was carried out samples were tracked from the file to tank and vice versa and no discrepancies encountered. Separate dewars are used for quarantined and non-quarantined samples.
Areas of firm compliance
Staff training and competency The centre has access to a nominated registered practitioner to advise and oversee the centre's medical activities. Staff working within the centre are appropriately qualified and registered to perform their duties. The PIQ states that there are processes in place to monitor and record staff competencies and for staff annual appraisal. On inspection, an audit of personnel files showed that staff are given a job description and initial basic (induction) and update training is provided, as appropriate. Comprehensive records of training and competencies were seen for both the laboratory and clinical staff. The records showed that competencies for all staff, including trainees, is continually monitored and reviewed. The

nurses reported having attended courses and conferences relating to their specific responsibilities including the scanning and fertility courses and the BFS conference. The PR organised a training workshop on 'consent' at the end of 2008 for the nurses. The documentation of this training was reviewed at inspection - a log of consent forms, completed with patients and signed off by a competent member of staff was seen. The quality lead reported that all staff are given training in auditing and monitoring.

The counsellor reported having attended BICA training days, both national and locally held. The counsellor's training records, including CPD, were not available on the day of inspection but the counsellor discussed her plans for obtaining BICA accreditation through the 'grandparent' scheme and CPD training.

Clinical practice

- ***Screening***

The centre operates an egg sharing scheme and the egg providers are treated, assessed and screened in the same way as potential gamete donors. CARE Manchester has sperm donor, sperm and egg sharing programmes and altruistic egg and embryo donation programmes.

The centre recruits sperm donors and all donor screening is conducted in compliance with professional body guidelines prior to material being stored. The centre records the following information for all donors registered at the centre: donor identification, purpose of the donation and if not used, any specific instructions for disposal, donor medical history, all clinical and laboratory assessment data and donor consent. A review of patient files at inspection verified this. The documented laboratory procedures ensure that donated gametes are not used or distributed after the donor has reached the ten family limit. The PIQ states that accurate records are kept as to use and outcome and there is a strict control of allocation of donor sperm between the four CARE centres with use denied until results of treatments are known. This is centrally co-ordinated at CARE Nottingham. The centre's donor payment protocol and a sample of donor files were reviewed at inspection and found to be compliant with the HFEA direction on donor payments.

- ***Multiple births***

The centre has a multiple births minimisation strategy and the clinical director PR is aware of the requirements of the HFEA Direction 2008/5 to keep a log for the documentation of cases in which multiple embryos have been transferred back. The clinical director said that centre's multiple birth rate remained static in the last year.

Laboratory practice

Each change of location or procedure is adequately witnessed and documented in the relevant notes and additionally in the electronic record system. There is a proposal that the 'Matcher' system will be employed at CARE Manchester which will add further to the electronically verified steps.

The records of a patient whose gametes had been exported were reviewed in the course of the inspection: the senior embryologist was able to provide evidence that the export had been carried out in compliance with the requirements of directions D2006/1.

Procurement, distribution and receipt of gametes and embryos

There are documented procedures for procurement, packaging, distribution, recall and receipt

of gametes and embryos that ensure: quality and safety of the gametes; risk of contamination is minimised; evaluation, assessment and safety of the provider and that procurement conforms with appropriate age limits for gamete providers. Discussion with laboratory staff verified that these procedures are followed.

Traceability and coding
Procedures are in place to ensure all gametes and embryos and data relating to anything contacting them, are traceable from procurement to patient treatment or disposal. The centre has a written protocol in place and the staff demonstrated that the procedure is followed. The centre uses a colour coding system for lot numbers, which is managed by two members of staff. Only one batch is in use at any one time. The centre uses the group (CARE) system of identification for traceability of all gametes and embryos which ensures that all samples of gametes and embryos are labelled with at least the patient's/donor's full name and a unique identifier.

The centre permits the production of samples at home and records are kept for those samples. A protocol in place and a review of patient files provided evidence that photographic identification is checked and verified and that this information is recorded on patient files.

Comprehensive laboratory, clinical and embryology notes are kept and labelling of dishes, tubes and straws is also comprehensive.

Information contained with the procured gametes includes a unique code and split number of the donation, the type of gamete, the date and time, of the donation, the identity of the donor and in the case of known donations, includes the identity of the intended recipient. Staff explained that the dishes are labelled with the recipient's name and details once the collection is completed.

The laboratory staff demonstrated a working understanding of the protocols for transport conditions, receipt of gametes and embryos from other centres and traceability from procurement to treatment or disposal and vice versa.

Selection and validation of laboratory procedures
At inspection, the inspectorate was shown a comprehensive file of validated laboratory procedures, based on previously published studies or retrospective evaluation of the centres own data. The centre has started to validate the air quality monitoring process and based on these findings, a decision will be made to set the frequency of testing in the future.

Witnessing
The inspectorate observed at inspection that each time gametes or embryos are the process is witnessed and documented on the embryology work sheets. The centre has a written protocol in place for witnessing.

The centre's witnessing protocol was reviewed and practice discussed and observed at inspection. This was found to be fully compliant with HFEA guidance in the CoP. In addition, a risk assessment of the witnessing system has been performed and documented. A review of patient files conducted at inspection provided evidence of compliance.

Counselling practice
The counsellor interviewed at inspection, said that she works part time and has been in post

for nine years. The counsellor sits on the centre's Ethical Advisory Committee providing advice and support. Patients are able to make appointments with the counsellor direct or via reception. The other part time counsellor, who worked one day a week, has recently left the centre, but the counsellor interviewed said that she does not anticipate any issues and feels able to absorb the extra work for now. The PIQ states that the CARE group has four units with counsellors who can work between units, providing contingency cover.

- **Counselling audit**

The counselling audit for the period November 2007 to December 2008 was submitted prior to the inspection. The audit report documents that counselling sessions were provided to 445 sessions and 35 sessions cancelled their appointments.

Storage of gametes and embryos

The centre has a full time administrator who deals with embryo and sperm storage audits. Material with an imminent expiry date is identified and referred to the PR who agrees/signs off disposal of the material. The expired material is usually disposed of monthly.

Areas for improvement

During the demonstration of the bring forward system it was observed that at the time of the inspection, the centre were storing cryopreserved material for six patients without written consent. The PR explained that this breach of the Human Fertilisation and Embryology Act (HFE Act) arises because of the CARE group policy to ask patients to consent to a three year storage period initially and to extend storage after this time, if required. The ongoing storage of the gametes without written effective consent was discussed with the PR who acknowledged awareness of the HFE Act, but explained that the decision to continue storage of material without written consent had been made in consideration of the clinical needs of the patients.

The PR and staff at the centre explained that:

- all six patients had been contacted by letter,
- all six patients had been given information on the need for the consent to be in writing and were sent the appropriate forms to be completed and returned to the centre,
- all six patients had telephoned the centre and given verbal consent to extend the period of storage.

The centre's log of expired consents (until January 2009) notes the communications with patients and shows that all six patients have verbally indicated their wishes to extend storage.

This is an ongoing issue of concern at CARE Manchester. At the time of both the 2006 renewal and the 2008 interim inspections, a number of cryopreserved samples were in storage for which there was no effective consent. This is breach of the HFE Act.

Areas for consideration

None.

Executive recommendations for Licence Committee

The PR should, as a matter of urgency, ensure compliance with the requirements of the HFE Act in relation to the storage of gametes and embryos.
It is recommended that a condition be applied to the centre's licence requiring the monthly

submission of a report of the consents that expired in the previous month; the report should include the date of disposal or the date of expiry of any newly provided consent.
Evaluation
Some improvement required.
Areas not covered on this inspection
All areas covered.

Report compiled by:

Name: Bhavna Mehta

Designation: Inspector

Date: 20th March 2009

Appendix A: Centre staff interviewed

PR
Centre staff

Appendix B: Licence history for previous 3 years

First licensed 1999

Licence	Type Active	From	Expires
L0185/7/a	Treatment with Storage	01/10/06	30/09/2009

The Committee agreed that the centre's licence should continue with no additional conditions.

L0185/8/a	Treatment with Storage	05/07/07	30/09/2009

The Committee noted that the recommendations by the inspection team had been satisfactorily addressed by the Person Responsible and agreed that the centre's licence should continue with no additional conditions.

Appendix C: Response of Person Responsible to the inspection report

Centre Number…0185……

Name of PR……Glenn Atkinson…….

Date of Inspection……26th February…2009……..

Date of Response……6th May 2009……

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

Signed……  ……

Name……Glenn Atkinson…….

Date……6th May 2009……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

The report is generally factually accurate. CARE Manchester does treat NHS patients as we have NHS patients satellited from Leigh Infirmary and Calderdale Royal hospital. Although these are satellites should the final box on page 3 and the second paragraph on page 5 be altered to reflect this?

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

The report details 2 basic areas of concern to the inspection team which are detailed on page 7 under the heading 'Breaches of the Act'. I feel that the HFEA should note that ultimately the inspection report will become a public document but it is provided prior to any decisions made by the licence committee. Labelling this section as such implies that the decision as to whether a breach has occurred has already been made by the inspection team whereas surely it is the licence committee's remit to decide what is or is not a 'breach of the act'? I believe that this section should be labelled 'potential breaches of the Act'. The first 'potential breach' relates to CPA accreditation. It was recommended that I as PR review the requirements of the licence condition A.7.3. This condition relates to 'laboratory tests required from donors of reproductive cells'. CARE Manchester sends such samples from all our donors to 'The Doctors laboratory (TDL)' which is a CPA accredited laboratory. CARE Manchester is not therefore in breach of this licence condition. Standard S.7.8.2 relates to investigations performed on all patients and the need for CPA accreditation. CARE Manchester was progressing along the CPA accreditation route however TDL have now

opened a laboratory in Manchester and therefore the opportunity to out-source services has arisen. The TDL laboratory only became operational in February of 2009. The reports read as if nothing has been done as regards accreditation or that decisions have been deliberately delayed which is not the case. I would accept that a decision has to be made within the timescale suggested by the inspection team.
The second potential breach relates to the storage of cryo preserved material without written consent. This relates to 6 patients. Two of whom were commissioning couples for surrogacy that are, at the moment, unable to extend their storage period for their embryos beyond the 5-year limit unlike all other patients. I am aware that it is proposed by the HFEA that this anomaly is rectified as part of review of the HFEAct which should come into force later in the year. I am also aware that the premature disposal of embryos in surrogacy cases is the subject of a potential legal challenge from surrogacy support groups. In these circumstances it seems reasonable to maintain the embryos in storage and await the outcome of the above events.
The remaining 4 patients had all been contacted and expressed a wish to maintain storage of the embryos, had all been sent the relevant consent forms (some on more than one occasion) but had failed to return these forms by the date of expiry of original consents. The absolute requirement for written consent in the presence of verbal consent seems to be peculiar to the storage of embryos and gametes. I expressed extreme reluctance to destroy embryos under these circumstances. I would be grateful for confirmation that verbal consent can never be legally acceptable in order to justify disposal under these specific circumstances. Further attempts have been made to obtain the relevant forms with two received from the four patients and one electing for disposal.
I believe that the suggested action of monthly reports required is extreme and would question what action the HFEA would be able to undertake as a result of the reports on a monthly basis. Little will be gained by monthly reporting except placing an extra administrative burden on the clinic which may impact on the effective operation of the centre without affording benefit to patients or the clinic.
CARE Manchester has demonstrated a robust system for identification, communication and action required related to storage consents. I hope that there is no suggestion that CARE Manchester is not proactive in trying to deal with this problem but, is at all times, working in the patients best interest. In these circumstances such timing issues related to storage and consent will always occur. CARE Manchester is continually seeking to minimise these issues. The evidence for this being that the number of embryos stored without consent has reduced from the number identified in the last inspection and our continued efforts to reduce the incidence of storage without consent. Whilst agreeing that all clinics must work towards the goal of all consents being appropriate at all times some consideration has to be given for the practicalities involved.

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

I would agree that a decision as to the CPA accredited laboratory CARE uses for routine blood tests should be made within 6 months.
CARE Manchester has a robust system to contact patients whose embryos are coming to the end of their agreed storage period as noted in the report. Great attempts are made to obtain

new consent forms with patients informed of potential consequences should they not return the consent forms even in the presence of verbal consent. I would be grateful for the HFEAs advice, as above, as to legal obligations under these specific circumstances.

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

HFEA Licence Committee Meeting
10 June 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

CARE Manchester (0185) – Renewal

Members of the Committee:	Committee Secretary:
	Kristen Veblen
Anna Carragher (lay)	
Rebekah Dundas (lay)	Legal Adviser:
Emily Jackson (lay)	Sarah Ellson, Field Fisher, Waterhouse
	Observers:
	Brandon Welsh, HFEA
	Charlotte Augst, HFEA

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

The following papers were considered by the Committee:

- papers for licence committee (53 pages)
- tabled papers (1 page).

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee noted that this Centre is part of the CARE fertility group and considered the papers, which included an application for renewal, application for variation, inspection report including the response from the Person Responsible (PR) and minutes of the previous meeting of the Committee.

2. The Committee noted that the licence renewal inspection took place on 26 February 2009 and in particular considered the potential breaches described in the report.

3. The Committee agreed that, in light of the PR's response to the inspection, the Centre was in fact not in breach of licence condition A.7.3 and Code of Practice standard S7.8.2 in relation to donors.

4. The concern expressed by the inspection team regarding the persistence of the breach of schedule 3 8(2) of the HFE Act 1990 (as amended), storage of cryopreserved material contrary to regulations and/or in the absence of written consent, was shared by the Committee. The Committee noted that this breach had been recorded in the previous two inspections in 2006 and 2007 as well as at this inspection and discussed possible causes for the persistence of this breach.

5. The Committee sympathised with the view of the centre that when only verbal consent has been received, there is a conflict between the staff's understanding of the patients' wishes and the legal requirements.

6. Further to this breach, the Committee noted the response of the PR in relation to the storage beyond the term of consent for commissioning couples for surrogacy. The Committee understood some of the difficulties but wished to remind the Centre that the legislation is clear on the time limits for lawful storage of embryos to be used in surrogacy. The 2008 Act will not have retrospective effect. If the centre continues to be concerned, they should seek their own legal advice in relation to this matter.

7. Some concern was expressed by the Committee about the Centre only having a part time counsellor, given the number of cycles carried out. The Committee also noted point 19 of the previous minutes and asked that the Executive ensure that the audit referred to had been submitted by the Centre.

8. The Committee considered the application to add preimplantation genetic screening, preimplantation genetic diagnosis and laser assisted hatching.

9. This application accompanied a renewal of the Centre's licence. The Legal Adviser informed the Committee that they were empowered to make the decision to "vary" at the time of renewal in that they could grant a new licence with additional treatments if they wished. It was a matter for the Committee to determine whether they had sufficient information to be satisfied as to the procedures, premises, staff etc to grant a licence to cover these treatments.

10. The Committee noted the information provided in the application that the Centre would follow the same operating and patient information as was used by CARE Fertility, Nottingham, who already conducted PGD and PGS. The Committee noted that the Centre would have a full time embryo biopsy practitioner, who would be supported by experienced colleagues from CARE Nottingham.

The Committee's Decision

11. The Committee noted the tabled paper confirming that the Person Responsible had completed the PR Entry Programme and that there were no issues regarding the character, qualifications or experience of the Person Responsible or his ability to perform his duties under section 17 of the HFE Act 1990 (as amended). On the basis of the information provided the Committee agreed that it was satisfied that the PR was suitable.

12. On the basis of the information provided the Committee agreed that it was satisfied as to the suitability of the Centre's premises and practices.

13. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision on both the renewal of the licence and the addition of treatment types to the licence.

14. It was noted that the Committee was in receipt of a signed application form and the relevant fee had been paid.

15. The Committee decided to grant a licence for five years and to add PGS, PGD and laser assisted hatching to this licence.

16. In light of the persistence of the breach of schedule 3 8(2) of the HFE Act 1990 (as amended), the Committee decided to impose a condition on the new licence that:
    - By 31 December 2009Centre 0185 should provide to the HFEA Executive:

- evidence to demonstrate that it has conducted a risk assessment and review of the policy of only seeking consent to storage for three years to determine if this policy contributes to the persistent breach of the HFE Act 1990 (as amended)
- evidence as to how it has responded to any issues raised in this review.

17. The Committee further directed that there should be an inspection of the Centre within one year specifically to focus on the issue of consent for storage.

Signed..Anna Carragher... Date..25.6.2009

Anna Carragher (Chair)