Interim Inspection Report

Date of Inspection: 5 August 2010
Length of inspection: 7 hours
Inspectors: Sara Parlett (Lead, HFEA), Ellie Suthers (Clinical Inspector, HFEA), Cathy Hodgson (Observer, HFEA)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received about the centre between June 2008 and 20 October 2010.

Date of Licence Committee: 20 October 2010

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

Centre details

Centre Name	CARE Sheffield
Centre Number	0061
Licence Number	L0061/14/c
Centre Address	24-26 Glen Road, Sheffield South Yorkshire S7 1RA
Telephone Number	0114 258 9716
Person Responsible	Dr Adel Shaker
Licence Holder	Dr Simon Fishel
Date Licence issued	1 January 2009
Licence expiry date	13 December 2013
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

The inspector considers that, overall there is sufficient information available to recommend the continuation of the centre's licence years without additional conditions.

The inspector also recommends that the Executive Licensing Panel requires that the Person Responsible (PR) complies with the following recommendations within the prescribed timeframes set out in the inspection report:

Recommendations in relation to major areas of non compliance:

- To assure the accuracy of data provided via the Electronic Data Interchange (EDI) system regarding consent to the disclosure of identifying information to researchers.
- To take appropriate action regarding the set of embryos currently being stored without written consent.
- To continue with the progress made with the centre's detailed competence assessment framework and ensure all members of staff can provide documented evidence of the assessment of their competence in all designated tasks.

Recommendations in relation to other areas of practice that require improvement:

- That completion of witnessing records continues to be monitored as part of the centre's audit programme.
- That the risk of witnessing the storage location of material retrospectively is assessed and corrective action taken if the risks are found to be significant.

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Details of Inspection findings

Brief description of the centre and its licensing history:

This centre is part of the CARE fertility group and offers a comprehensive range of assisted conception treatments to both self funding and NHS commissioned patients.

The centre was last inspected by the HFEA in June 2008, following which the licence was renewed for five years without additional conditions.

An application to vary the licence to change the PR was granted by an Executive Licensing Panel in April 2010, whilst the original PR is on maternity leave.

The PR is appropriately qualified and experienced to hold this post and successfully completed the HFEA PR Entry Programme in 2007 (during the original PR's first maternity leave).

The centre is registered with the Care Quality Commission (CQC) and was last inspected in February 2009. The centre is ISO 9001:2008 certified.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01 April 2009 – 31 March 2010*
In vitro fertilisation (IVF)	156
Intracytoplasmic sperm injection (ICSI)	235
Frozen embryo transfer (FET)	137
Intra uterine insemination (IUI) (01 Jan – 31 Dec 2009)	24
Donor insemination (DI)	16

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

*These data were extracted from the HFEA register for the period April 2009 – March 2010. 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.

Relative live birth success rates from the HFEA held register data from 01 January 2007 to 31 December 2009 show:

The centre's success rates are in line with the national average for DI for all age groups and for FET and IVF/ICSI treatments for all age groups of 35 and above. The success rates for FET and IVF/ICSI treatments for the below 35 age group are significantly above the national average.

Updated actions since the centre was inspected on 5 August 2010:

Since the inspection, the PR has confirmed that action is being taken to address all issues identified in this report.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. **Costed treatment plans** The centre provides personalised costed treatment plans to its private patients prior to the start of treatment (Code of Practice 8th Ed (CoP) guidance 4.3). An intranet based costed treatment plan template was demonstrated to the clinical inspector. An individualised plan is calculated at the initial consultation appointment and a copy is given to the patient. Any amendments to the proposed treatment plan that will affect cost are first discussed with the patient. The centre's "NHS funded fertility treatment" patient information leaflet explains the point at which the cost of frozen embryo storage becomes the patient's responsibility. **Legal parenthood** The centre has a comprehensive algorithm for establishing the parental consents required when donor gametes are used. This was reviewed at inspection and was seen on display in all consultation rooms. Relevant staff have undergone training in the use of the new parental consent forms. It was confirmed at inspection that the egg donor nurse and counsellor discuss the legal implications for parenthood at the initial patient consultation and then at the counselling session. The centre has a procedure for withdrawal of consent to being the legal parent. The centre's treatment consent form describes the option to withdraw consent at any time up to the point the gametes are used in treatment (HFE Act 1990 (as amended), Schedule 3 (4)).
What they could do better. Nothing noted at the time of inspection.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. **Consent to disclosure of identifying information to researchers** The centre seeks patient consent to identifying information from the HFEA register being disclosed to researchers. During an audit of six sets of patient records, it was noted that the HFEA consent to disclosure had been completed appropriately in all cases.

Storage

The centre has a bring-forward system in place to ensure that patients are provided with sufficient notice prior to the end of the consented storage period (CoP guidance 17.17), which was described by the laboratory manager. Administrative staff are responsible for sending letters to patients with material in storage four, two and then one month prior to the end of the consented storage period. If contact has not been made after the final letter is sent, the embryology team is informed. They then follow up with telephone calls to the patient and their GP to ascertain if they have the current address. All communication attempts are logged on the centre's database.

A rolling audit of stored material is conducted by the centre (CoP guidance 17.16). An annual dewar audit schedule was reviewed at inspection, and audits were up to date. The laboratory manager explained that the information in the laboratory freeze book is checked against the computer database and that they would only perform a physical audit check if the records did not tally. Physical audits are performed prior to thawing of samples, at the time a patient's treatment cycle is set up.

The centre's consent SOP was reviewed at inspection and includes a description of the cooling off period (HFE Act 1990 (as amended) Schedule 3, paragraph 4A (4)) and the procedure to follow if one gamete provider withdraws their consent to embryo storage (CoP guidance 5.35).

What they could do better.

Consent to disclosure of identifying information to researchers

An audit was performed at inspection of patient/partner consents to identifying information from the HFEA register being disclosed to researchers against that recorded on the HFEA register. The consents of four patients/partners were audited. In three cases, discrepancies were noted between the consenting decisions in the patient records and those entered on the HFEA register. This non compliance has been raised as an issue across the sector. The centre recognised that errors had been made and that they would be rectified.

Storage

The centre produces a monthly laboratory manager report, which includes a review of all material in storage without valid consent. The July 2010 audit of frozen material reported embryos of two patients currently in storage without valid consent:

- The consent for storage of one set of embryos expired on 13 July 2010. It was recorded that the patient had paid for further storage and that new consent forms had been posted, but that the completed consents had not yet been received despite reminders. Later on the day of inspection, the laboratory manager informed the inspectorate that the completed consent forms had just been returned.

- The consent for storage of one set of embryos expired on 16 March 2010. This is a breach of paragraph 8(2) of Schedule 3 of the HFE Act 1990 (as amended). Consent to extend the storage period cannot be obtained because the male gamete provider has died. The centre has made considerable effort to ensure that the patient is well informed of the options available to her and they are currently seeking legal advice. The centre has kept the HFEA fully informed regarding this situation.

Multiple births

What the centre does well.

The PR reported an overall multiple clinical pregnancy rate at the time of inspection of 18.4% (data from period January – May 2010).

In compliance with General Directions 0003, the centre has a documented record of their multiple birth minimisation strategy (MBMS) including:

- How the centre identifies suitable cases for single embryo transfer (SET), including criteria in relation to embryo assessment and patient selection criteria (Directions 0003 (5(a)).
- How the centre aims to reduce the multiple birth rate and how to ensure that the rate does not exceed the maximum specified rate of 20% (Directions 0003 5 (b)).

One Primary Care Trust has stipulated SET for all NHS patients since 2009. The centre estimates this to represent 5% of all cycles.

The centre maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer as set out in the strategy (Directions 3(c)).

From January to May 2010, 54% of patients meeting the criteria for SET, proceeded to have a SET.

Where more than one embryo has been transferred, the centre has recorded in the patients' records an explanation of the reasons for transferring more than one embryo in that particular case and a note confirming that the risks associated with multiple pregnancy have been fully discussed with the patient (Directions 7(a) (b)).

Where three embryos are transferred, the centre has provided a detailed record in the patients' notes explaining the reason(s) for transfer. A computerised log recording the details requested in Directions 1(a) and (b), was seen at inspection. The Nurse manager confirmed that a paper summary log is also kept.

The centre has carried out regular audits and evaluations of the progress and effectiveness of its strategy. The centre's most recent audit of clinical pregnancy rates from January to May 2010 was reviewed at inspection. The centre's MBMS states quarterly reviews of the strategy are held and a full review is planned for April 2011 to reassess the strategy.

The centre's "risks and complications of assisted conception" patient information leaflet was reviewed and includes a section on the risks of

multiple pregnancy and reference to the 'one at a time' website (CoP guidance 7.5). 'One at a time' leaflets were observed on display in the main patient waiting area.

What they could do better.

Nothing noted at the time of inspection.

Validation of critical equipment and processes

What the centre does well.

All critical equipment has been identified and validated in compliance with Licence Condition T24. The laboratory manager confirmed that validation and maintenance files are in place for each piece of critical equipment. The file for one incubator was reviewed and includes records of validation, staff training in the use of the equipment and temperature mapping measurements from September 2009. The laboratory manager stated that temperature mapping is repeated six monthly. The centre's dry shipper validation report from October 2009 was reviewed, and includes ongoing routine temperature monitoring over a three day period.

All critical processes have been identified and validated in compliance with Licence Condition T72. Validation documentation of the centre's procedures for sperm preparation, insemination and ICSI were reviewed at inspection.

Prior to implementing any significant change to a process, the modified process is validated and documented (Licence Condition T73). Documented validation was seen for several process changes implemented recently, including a report from February 2010 prior to changing the length of time for which culture oil is incubated at 37^{o}C prior to use. The laboratory manager explained that the results of studies are shared between all CARE units and that one other CARE facility is currently researching the use of low oxygen culture systems.

What they could do better.

Nothing noted at the time of inspection.

Witnessing

What the centre does well.

The centre's witnessing SOP submitted prior to inspection includes double checks of the identification of samples and patients at all critical points (Licence Condition T71).

The laboratory manager explained that other CARE fertility units are using an electronic witnessing system and that this may be implemented at the

centre later this year.

An embryo transfer was observed at inspection and witnessing procedures were compliant with Licence Condition T71. Three sets of patient notes chosen at random were audited at inspection and were found to include records of all required witnessing steps.

The centre's detailed witnessing competence assessment programme was reviewed and includes a "witnessing and patient identification" presentation explaining the requirements, importance and implications of witnessing, a multiple choice test and a reflective diary. A witnessing log sheet is used to record the practical assessments of the member of staff's ability to witness. Assessment of competence includes the consideration of the member of staff's 'confidence to refuse to witness' (Licence Condition T15 (a)).

Audits of witnessing records are carried out on a monthly basis for the treatment cycles of all patients from the previous month. A witnessing audit from May 2010 was reviewed and showed no omissions in the records. The laboratory manager confirmed that if omissions were noted, they would be investigated and corrective action taken (Licence Condition T36).

What they could do better.

The laboratory manager stated that witnessing is carried out at the time of the procedure, with the exception of cross checking the storage location of gametes and embryos in the dewar during cryopreservation, which is sometimes carried out retrospectively. Whilst this step could not result in the misidentification or mislabelling of samples, Licence Condition T71 states witnessing must be performed at the time of the procedure and CoP guidance 18.4 (g) lists cross-checking the position in the dewar in which the gametes or embryos are placed as a witnessing step.

During the observation of the embryo transfer procedure at inspection, the practitioner signature for one sperm preparation witnessing step was seen to be missing in the patient records (non compliant with Licence Condition T71).

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

The centre's donor assessment and screening procedures are supported by SOPs that were reviewed at inspection. Five sets of medical records pertaining to gamete donors (egg and sperm donors) were audited during the course of the inspection. This sample of records provided evidence that:

- Donors are being selected on the basis of their age, health and medical history, provided in a questionnaire and through a personal interview and physical examination performed by a qualified and trained medical professional (Licence Condition T52 (a)).

- Donors are being selected in accordance with the screening requirements of Licence Condition T52 and relevant professional bodies. [1]
- The laboratory tests required by Licence Condition T52 have been carried out by a qualified laboratory which has been accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd (Licence Condition T53 (a)).
- Donor sperm is being quarantined for a minimum of 180 days, after which repeat testing is performed (Licence Condition T53 (c)).

The centre's donor patient information was reviewed at inspection and found to include all requirements of CoP guidance 11.24.

The centre recently audited a random selection of egg donor and sperm donor records to assess compliance with centre SOPs for the recruitment and assessment of donors. Corrective action has been taken where appropriate and the centre plans to re-audit in January 2011 (Licence Condition T36).

The centre's "expenses for semen donors" SOP was reviewed at inspection. No loss of earnings reimbursements over £250 for each course of donation are given and no flat fee is offered (Directions 0001).

A record of all reimbursements paid to donors are kept in the donor's medical records. Centre staff confirmed that they reimburse costs for child care, travel and loss of earnings (where supported by a letter from the employer) and evidence of this was seen at inspection. Staff use online maps to confirm distances travelled prior to reimbursing travel costs.
The centre imports donor sperm from a European sperm bank. The centre provided written evidence that these donors are reimbursed in compliance with Directions 0001.

What they could do better.

Nothing noted at the time of inspection.

Welfare of the Child (in relation to basic partner treatment services only)

What the centre does well.

Not reviewed as this centre does not solely provide basic partner treatment services.

What they could do better.

Not reviewed as this centre does not solely provide basic partner treatment services.

[1] The 2008 UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors produced by BFS, BAS, ACE and RCOG.

Embryo testing (if applicable)
What the centre does well. Not applicable for this centre.
What they could do better. Not applicable for this centre.

2. Changes / improvements since the last inspection on 19 June 2008

Breach

Area for improvement	Action required	Action taken as evidence during this inspection
Routine diagnostic and investigative procedures such as semen analysis and standard blood tests are being performed either in the centre's laboratory or using the automated blood analysis equipment in the centre.	The PR should seek advice on the requirement for Clinical Pathology Accreditation (CPA) of the blood diagnosis facilities.	The quality manager confirmed that standard blood tests are performed at the centre's endocrine laboratory for monitoring purposes only. Diagnostic tests are performed by an external CPA accredited laboratory. Semen analysis is carried out at the centre to decide between IVF and ICSI only rather than for initial diagnosis. **No further action is required.**

Recommendations

The centre should ensure that the HFEA patient information publications on display at the centre and on their website is the most current version available as per the HFEA website to download.	/	All HFEA patient information seen on display at the centre were current versions. No HFEA patient information was seen on the centre's website. **No further action is required.**
The centre should implement their competency assessment programme	/	See section "other areas of concern". **Further action is required.**
The centre should ensure that the information contained within their policies and other documentation is current and in accordance with current guidance and legislation.	/	All documents seen at inspection were within their review date and were seen to be reviewed annually (CoP guidance 31.6). A selection of SOPs reviewed at inspection were in accordance with current guidance and legislation. **No further action is required.**

3. Areas of concern

The analysis of the centre's self assessment questionnaire (SAQ) and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
The SAQ states that the centre is partially compliant with respect to staff providing documented evidence of the assessment of their competence in the performance of their designated tasks (Licence Condition T15 (a)).	The inspectorate commends the centre on the establishment of a comprehensive, well researched and robust competence assessment framework. Assessments of competence are currently in progress. Competence assessments for consent taking were sampled for one nurse and included: o Attendance at a consenting presentation; o A self declaration after reading the relevant consent sections of the HFEA CoP; o Practical competence assessment with patient feedback of the process and o Final sign off by the PR, after confirmation that the correct consents were completed appropriately. Two nurses are currently undertaking the British Fertility Society ultrasonography course. Embryologists' competence assessments were reviewed for one embryologist and included	**Further action is required.**

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
	assessments of giving information to patients, witnessing, semenology, freezing and thawing of gametes and embryos and laboratory equipment quality control. Senior staff confirmed that they aim to reassess staff competence on an annual basis or after an extended period of time off work (Licence Condition T12). Documented evidence of staff competence in the assessment of the welfare of the child and traceability procedures is not kept by the centre.	
The SAQ states that the centre has not audited all licensed activities or activities carried out in the course of providing services that do not require a licence (Licence Condition T36).	The centre has established a comprehensive audit programme and the centre's audit schedule for 2010 was seen at inspection. Recent welfare of the child and traceability audits were reviewed at inspection. Patient record audits are performed monthly and include checking the presence of correct consents (including the HFEA CD form) and Welfare of the child assessments. Ten sets of notes for patients who had treatment in the previous month are chosen at random. Audits from May and April 2010 were seen at inspection. Where issues are identified, corrective action was seen to be taken (Licence Condition T36).	**No further action required.**
The SAQ states that the	A comprehensive list of the centre's third party	**No further action required.**

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
centre is almost compliant with respect to the evaluation of the ability of all third parties to meet the required standards.	agreements (TPAs) was seen (Licence Condition T115). Three TPAs were reviewed at inspection and were compliant with the requirements of Licence Condition T114. The quality manager explained that some TPAs currently refer to the 7th edition of the CoP and reference obsolete HFEA standards. The quality manager explained that they were aware of this as the issue was raised at a recent inspection of another CARE centre (centre 0016) and that they are about to send out new agreements to their third parties which reference the current edition of the CoP.	
The SAQ states that not all eligible staff working in the clinical embryology laboratory are registered with the Health Professions Council (HPC).	The laboratory manager confirmed that all eligible staff are HPC registered with one exception. This embryologist is currently working towards registration and is expected to attain registration by the end of the year.	**No further action is required.**

Areas of practice that require the attention of the Person Responsible

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

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None noted at the time of inspection.					

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
An audit of consents to identifying information from the HFEA register being disclosed to researchers against that recorded on the HFEA register found discrepancies between the consenting decisions in the patient records and those entered on the	Directions 0005, paragraph 8 and Directions 0005, paragraph 9.	The PR should audit the consent to disclosure of identifying information from the HFEA register in the patient records against the decisions which have been submitted to the HFEA register via the EDI system. Discrepancies will need to be corrected. This audit will need to encompass all patients for whom consent to disclosure has been submitted over the EDI system. The PR should ensure	This action should be completed by 5 November 2010 and a report provided to the Executive by 15 November 2010.	Extension given of one month to 3 December 2010 - due to current staff shortages Audit of research consents has been instigated Report will be provied by 13 December 2010 Steps to address when this information is captured have been revised and responsiblility made	The extension request was approved by the Executive. It is recommended that the Executive continues to monitor progress. Evidence of compliance should be submitted within the revised timeframe.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
HFEA register.		that in the future, all data submitted through the EDI system regarding consent to disclosure of identifying information from the HFEA register is entered accurately and is supported by the patient record.		clear to appropriate personnel.	
At the time of inspection one set of embryos were being stored without written consent. Consent to extend the storage period cannot be obtained because the male gamete provider has died. The centre has made considerable effort to ensure that the patient is	HFE Act 1990 (as amended) Schedule 3, section 8 (2).	The PR must take appropriate action regarding the continued storage of these embryos.	5 October 2010.	A letter has gone out to the patient concerned offering a review appointment to re-discuss her options of use.	It is recommended that the Executive continues to monitor progress.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
well informed of the options available to her and they are currently seeking legal advice. The centre has kept the HFEA fully informed regarding this situation.					
Staff cannot provide documented evidence of the assessment of their competence in all designated tasks.	Licence Conditions T12 and T15 (a).	The PR should ensure that the framework includes assessment of the welfare of the child and traceability procedures. The PR should ensure that all staff can provide documented evidence of the assessment of their competence in all designated tasks.	By the time of the next inspection. The PR should submit a detailed plan, including a summary of all staff and the competence assessments they need to complete, including timeframes, before the	The process of developing competencies for WOC and traceability have begun - see plan to complete attached	The centre has provided a detailed plan for the development of a competency framework for the assessment of the welfare of the child and traceability procedures. The Executive has requested a further plan to include a summary of all centre staff and other competence

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
			report is to be considered by the Executive Licensing Panel. The PR should submit quarterly reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.		assessments that remain outstanding. It is recommended that the Executive continues to monitor progress.

Other areas of practice that requires improvement

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

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
The witnessing record of the person performing one procedure was omitted in one set of patient notes seen at inspection.	Licence Condition T71.	The PR should ensure that witnessing checks are completed and recorded at the time the relevant procedure takes place. It is recommended that records of witnessing checks continue to be monitored as part of the centre's audit programme.	To review at the time of the next inspection.	Witnessing audits are on going and this procedure will be monitored as part of that process.	It is recommended that the Executive assess compliance at the next inspection.
Cross checking of the storage location of gametes and embryos in the dewar during cryopreservation is sometimes carried out retrospectively.	CoP guidance 18.4 (h).	The PR should consider the risk and the action that would need to be taken if the samples could not be found in the recorded location at the time of the retrospective witnessing step. Corrective action should be taken if the risks are found to be significant.	5 November 2010.	A risk assessment of this process is being undertaken and a report will be submitted in given time frame.	It is recommended that the Executive continues to monitor progress. Evidence of compliance should be submitted within the prescribed timeframe.

Additional Information from the Person Responsible
All actions are underway from inspection report and time frames noted.

HFEA Executive Licence Panel Meeting

20 October 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 7

Centre 0061 (CARE Sheffield) - Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Juliet Tizzard, Head of Policy	Joanne McAlpine Observing: Claudia Lally, Compliance Business Support

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The centre is part of the CARE fertility group and offers a comprehensive range of assisted conception treatments to both self funding and NHS patients.

2. The Panel noted that, in April 2010, it granted an application to appoint the current Person Responsible (PR), taking over temporarily whilst the previous PR is on maternity leave.

3. The Panel noted that the Executive is satisfied that the PR is of suitable character and has the appropriate experience to discharge their duties under section 17 of the HFEA Act (as amended).

4. The Panel noted that the PR has appropriately completed his PR Entry Programme (2007), to the satisfaction of the Executive.

5. The Panel considered the Interim Inspection Report and was satisfied that the Centre was broadly compliant. The Panel noted that there were some recommendations made within the report by the Executive, and endorsed these recommendations.

6. The Panel noted the Executive's recommendation to continue the centre's licence with no additional conditions.

Decision

7. The Panel agreed to the continuation of the Centre's licence without any conditions placed upon it. The Panel endorsed the Inspectorate's recommendations and associated timeframes for the PR to meet these recommendations.

Signed: Peter Thompson Date 2/11/2010.

Peter Thompson (Chair)