# Interim Inspection Report

**Date of Inspection:** 31 March 2011
**Purpose of inspection:** Interim inspection of Treatment and Storage Licence
**Length of inspection:** 6 hours
**Inspectors:** Bhavna Mehta
Vicki Lamb

**Inspection details:**
The report covers the pre-inspection analysis, the visit and information received between 26 February 2009 and 24 June 2011.

**Date of Executive Licensing Panel:** 24 June 2011

**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 Manchester |
| **Centre Number** | 0185 |
| **Licence Number** | L0185/9/a |
| **Centre Address** | 108 -112 Daisy Bank Road, Victoria Park Manchester, M14 5QH United Kingdom |
| **Telephone Number** | 0161 249 3040 |
| **Person Responsible** | Glenn Atkinson |
| **Licence Holder** | Charmian Russell |
| **Date Licence issued** | 01/10/2009 |
| **Licence expiry date** | 30/09/2014 |
| **Additional conditions applied to this licence** | None |

# Contents

# Report to Executive Licensing Panel

## Brief description of the centre and its licensing history:

The centre is part of the CARE fertility group and is housed within the Manchester Lifestyle Clinic. The centre has been established since 1999.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. The centre is open from Monday to Friday with occasional weekend work.

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.

The centre's licence was renewed in 2009 for 5 years when pre implantation genetic diagnosis (PGD), pre implantation genetic screening (PGS) and laser hatching.
were added to licence. The Licence Committee (LC) recommended a further visit to the centre, within a year, to focus on the issue of consent for storage identified during the 2009 inspection. This further visit, as requested by LC, took place on the 25 March 2010 and focused solely on the centre's procedures for ensuring that there is written consent for storage of all cryopreserved gametes and embryos. The inspector reported that sufficient evidence was provided to conclude that the centre has well documented standard operating procedures (SOPs) for monitoring and disposal of cryopreserved material and that a robust bring forward system is in place. At the time of the inspection the centre had written consent to storage for all cryopreserved material.

## Activities of the Centre:

| Type of treatment | Number of treatment cycles for the period 1 January 2010 to 31 December 2010* |
|---|---|
| In vitro fertilisation (IVF) | 361 |
| Intracytoplasmic sperm injection (ICSI) | 819 |
| Donor insemination (DI) | 52 |
| **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 1 January 2010 to 31 December 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.

| Outcomes* |
| --- |
| For IVF/ICSI, HFEA held register data for the period 1 January 2010 to 31 December 2010 show the Centres success rates are in line with national averages. |

*The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

## Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to draw a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including four major areas of non-compliance and three other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed and provided evidence that the following recommendation has been fully implemented:

**Other areas of practice that require improvement:**

- To ensure that patients are given information regarding withdrawal of consent to parenthood. The PR has provided evidence of the written patient information that clearly states this.

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

**Major areas of non compliance:**

- To establish quality indicators (QIs) for all activities.
- To ensure that all activities are audited against compliance with approved protocols, regulatory requirements and quality indicators.
- To ensure the accuracy of data provided via the Electronic Data Interchange (EDI) system regarding consent to the disclosure of identifying information to researchers.
- To ensure the laboratory that carries out the PGS is accredited by Clinical Pathology Accreditation (CPA) UK Ltd or an equivalent body.

**Other areas of practice that require improvement:**

- To ensure that all staff can provide documented evidence of the assessment of their competence and ensure that competency is re-evaluated at appropriate intervals.

The PR has challenged the HFEA definitions of the non-compliance categories and whether it is for the inspector or the ELP to make recommendations (please see Additional comments from PR).

### Recommendation to the Executive Licensing Panel

The inspection team considers that, overall there is sufficient information available to recommend the continuation of this centre's licence without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report and further improvement is required in only a few areas of practice.

## Details of Inspection findings

### Focus of inspections for 2010-12

| **Providing information to patients in relation to costed treatment plans and parenthood** |
|---|
| What the centre does well.<br>A copy of a personalised costed treatment plan provided to patients was seen and discussed at inspection. The plan detailed the main elements of treatment proposed and the cost of that treatment. A review of five patient files demonstrated that a copy of the plan is kept in the patient's file (Code of Practice (CoP) Guidance 4.3).<br><br>Discussions with staff demonstrated that the centre uses the HFEA consent forms to provide information to patients. Staff reported that the PR provided training on the consent forms and changes in legislation in 2009, including the parenthood provisions. Staff interviewed were able to demonstrate an understanding of the legal parenthood provisions (Licence Condition T15). Staff explained that patients are given information prior to commencing treatment and that the HFEA consent forms and guidance for obtaining written consent to legal parenthood are used. |
| What they could do better.<br>At inspection, staff reported that the information on the withdrawal of consent to parenthood would only be provided to patients if necessary. Post inspection, the PR has provided evidence that centre has written patient information that clearly states the information relating to withdrawal of consent to parenthood and that this is given to patients before treatment commences. |

| Consent - particularly consent to disclosure to researchers and consent to storage |
|---|
| What the centre does well.<br>The centre seeks patient consent to identifying information from the HFEA register being disclosed to researchers. Registry information demonstrates that 25% of all patients who have been registered at the centre since October 2009 have opted in for disclosure.<br><br>Centre staff explained that information regarding consent to disclosure is given once the patient has decided to have treatment at the centre.<br><br>A review of a sample of records on the centre's database and a cross check against two patient files demonstrated that the centre has written effective consent for the storage of all cryopreserved gametes currently in store (Act, Schedule 3, 8(1)). |
| What they could do better.<br>A sample of the consents to disclosure of personal information to researchers' forms was reviewed at inspection. In four of the twelve consent forms reviewed, a discrepancy was noted between the consenting decisions in the patient records and those entered on the HFEA register (the HFEA records showed patients had consented when in fact that had not) (Direction 0005). |

| Multiple births |
|---|
| The centres multiple pregnancy rate for 2008/2009 was 26.1% with an elective single embryo transfer rate of 2.6% for the same time period [1] (http://www.hfea.gov.uk/6195.html). |
| What the centre does well<br><br>The multiple pregnancy rate is not different from the 2008/2009 multiple pregnancy rate target of 30%[2] at a statistically significant level.<br><br>The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions 0003 in that: |

[1] *This data was extracted from the HFEA's Register data as at 23/06/2010. At this time the HFEA had performed a preliminary validation process in which centres were asked to confirm the accuracy of information on treatment cycles carried out up to and including 30/06/2009 for pregnancy outcomes and 30/06/2008 for live birth outcomes. Some of the information used in this analysis may be subject to change.*

[2] *A multiple pregnancy rate of 30% has been calculated as likely to be equivalent to a 24% multiple birth rate.*

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

the centre has maintained a log which indicates the reasons for variation from the single embryo transfer policy and outcomes which are also recorded in the patients records. (Directions 0003).

**Validation of critical equipment and processes**

What the centre does well.

At inspection, a sample of the documentation of the critical processes validation was reviewed which provided evidence of compliance with requirements (T72).

All critical equipment influencing the quality and safety of gametes and embryos has been identified and validated in compliance with Licence Condition T24. Validation records for a centrifuge, microscope and incubator were reviewed and include staff training in the use of the equipment and monitoring of key performance indicators.

What they could do better.

None identified at this inspection.

| Witnessing |
| --- |
| What the centre does well.<br><br>The laboratory staff confirmed that the identification of samples and the patients or donors to whom they relate is witnessed by two members of staff at all critical points of the clinical and laboratory processes. The Centre's witnessing SOPs were reviewed and covered all critical points. The centre utilises both an electronic and a manual witnessing system (T71).<br><br>The centre's witnessing audit report was reviewed during the inspection. The report recorded a small number of discrepancies. The Principal Embryologist explained that these were omissions that had occurred when manual witnessing had been performed alongside electronic witnessing. Therefore electronic witnessing had taken place but evidence of manual witnessing (as per guidance in Code) was not present. Evidence of corrective action being taken was provided to the inspector (T36).<br><br>Four sets of patient notes were audited at inspection and found to include complete records of the name, status and signature of the practitioner and witness for all required witnessing steps (Licence Condition T71). The date and time of the procedure were also recorded (CoP Guidance 18.7 (b)). |
| What they could do better.<br>None identified at this inspection. |

| Gamete and embryo donation – reimbursement, information provision and screening |
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| What the centre does well.<br><br>Audit of donor files on the day of the inspection found that the centre has only used donor gametes or embryos created using donor gametes from identifiable donors. The reimbursements are in line with HFEA Directions 0001, 0006 and 0007. Provision of information and screening tests are carried out in accordance with HFEA requirements (T52 9b)). Other evidence in support of compliance with Direction 0001, 0006 and 0007 has been reviewed and meets the current requirements. |
| What they could do better.<br>None identified at this inspection. |

| Welfare of the Child (in relation to basic partner treatment services only) |
| --- |
| What the centre does well.<br>Not reviewed as this centre does not solely provide basic partner treatment services. |
| What they could do better.<br>N/A |

| Embryo testing (if applicable) |
| --- |
| What the centre does well.<br>The centre uses the same methodology for PGS as CARE Nottingham (HFEA Licensed centre 0101) where the processes are established. The centre has set quality indicators and has audited their practice against their standard operating procedure. No corrective actions were required. |
| What they could do better.<br>The laboratory that carries out the PGS is not accredited by Clinical Pathology Accreditation (CPA) UK Ltd or an alternative body accrediting to an equivalent standard (T21). The laboratory staff have stated that the laboratory is in the process of applying for accreditation. |

## 2. Changes / improvements since the last inspection on 26 February 2009

| Area for improvement | Action required | Action taken as evidence during this inspection |
|---|---|---|
| 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.<br><br>Within 6 months of date of this report- by 7th November 2009. | All diagnostic assessments carried out at the CPA accredited laboratory.<br><br>No further action required. |
| 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 | 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<br><br>1. notify the lead inspector of the date of the monthly audit and<br>2. submit to the inspectorate, until the date of the next inspection:<br>a) the results of the monthly audit of expired consents within seven days of the audit being conducted, and<br>b) all documentary evidence of the steps taken to obtain the written consent to satisfy the requirements of the HFE Act, 1990, and<br>c) an action plan of how the PR will assure that | The Licence Committee had recommended that there should be an inspection to focus on the consent for storage.<br><br>The visit took place on the 25 March 2010 and focused solely on the centre's procedures for ensuring that there is written consent for storage of all cryopreserved gametes and embryos. The inspector reported that sufficient evidence was provided to conclude that the centre has well documented standard operating procedures for monitoring and disposal of cryopreserved material and that a robust bring forward system is in place. At the time of the inspection the centre had written consent to storage for all cryopreserved material. |

| Area for improvement | Action required | Action taken as evidence during this inspection |
|---|---|---|
| Schedule must be given in writing and, in this Schedule, "effective consent" means a consent under this Schedule which has not been withdrawn.<br>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. | this breach is avoided from now on.<br><br>Immediately. | No further action required following the above visit. |

## 3. Areas of concern

The analysis of the centre's self assessment questionnaire 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 |
|---|---|---|
| **GN14 - Surrogacy**: Does the centre quarantine sperm for 180 days before use (T53c) | The PR explained pre-inspection that the samples are not quarantined as the samples are tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV (T53c). | No further action required. |
| **GN22 – Research &Training** Have procedures designed to ensure compliance with training licence requirements been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years? [Schedule 3A (10) 2006/86/EC, Appendix 1 F and T36]. No | The centre has carried out an audit of their practice against their SOP. This audit report was reviewed at inspection. No corrective actions were required. | No further action required. |

| Area of concern | Inspection findings | Assessment of whether the action taken meets requirement or whether any further action is required |
|---|---|---|
| **23 – QMS:**<br>Quality indicators (T35).<br>Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established.<br><br>Audits (T36)<br>Trained and competent persons must audit the activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in | Quality indicators have not been established for all activities carried out, including for the provision of patient information and consenting procedures, including the withdrawal of consent to legal parenthood.<br><br>Not all activities authorised by the licence have been audited as required, including providing patient information, consenting and donor recruitment procedures. | **Further action required.** |

| Area of concern | Inspection findings | Assessment of whether the action taken meets requirement or whether any further action is required |
|---|---|---|
| an independent way, at least every two years. Findings and corrective actions must be documented. | | |
| Can all staff provide documented evidence of the assessment of their competence in the performance of their designated tasks (T15 (a)).<br><br>The competency of the personnel must be evaluated at appropriate intervals (T12). | Nursing staff explained that competence assessments are performed at induction and upon introduction of any new process or piece of equipment. Except for the laboratory staff, documented evidence of the assessment of competency was not available at inspection.<br><br>Competencies are not re-evaluated (Licence Condition T12). | **Further action required.** |

# Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions 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. | | | | | |

## 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 and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| Quality indicators have not been established for all activities.<br><br>Licence Condition T35. | The PR should ensure quality indicators are established for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence.<br><br>The list of established quality indicators should be submitted to the Executive by 30 June 2011. | Quality indicators for all activities are being established across the CARE group overseen by CARE's quality management team.<br>The time frame for this submission is not practical especially as the executive committee will not meet to review the inspection until the 24th of June. Should the committee feel this recommendation should be undertaken a more realistic time frame would be within 3 months of the committee meeting. | The PR's comments are notes.<br>The action required was to be taken three months from the date of inspection.<br><br>Action required. |
| Audits have not been performed for all activities.<br><br>Licence Condition T36. | The PR should ensure that all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, are audited against compliance with approved protocols, regulatory requirements and quality indicators. | This is being undertaken and a CARE-wide framework for this is being set up by the Quality Management team.<br>As far as I am aware it is for the licence committee to state specific requiremnets | The PR's comments are notes.<br><br>Inspectors make recommendations for action required |

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| | By the time of the next inspection.<br>The PR should submit a detailed action plan of the audits to be completed, by the time the PR responds to this report.<br>It is recommended that the Executive monitors implementation of this plan. | for the clinic and therefore such an action plan will be submitted if required when asked to do so by the committee. I am unsure of the significance of the last paragraph. I cannot understand why the executive needs to be advised to 'monitor this closely' and resent the implications of this. | Decisions on licensing are taken by panel of the Authority's staff.<br><br>Monitoring of the action required, within the time stipulated, is a standard HFEA compliance process within the compliance cycle. |
| An audit of consents to identifying information from the HFEA register being disclosed to researchers against that recorded on the HFEA register found | The PR should audit the consent to disclosure in the patient records against the consent decisions which have been submitted to the HFEA via EDI.<br>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.<br>The Executive recognises that this audit will be time consuming and recommends completion by 30 September 2011. The audit | This audit is being carried out at the moment with a third of notes auditted and discrepancies corrected.<br>Does the third paragraph indicate a decision by the executive prior to submission or anticipation | As PR was unable to be present at inspection, the lead inspector provided feedback of the inspection findings post inspection to the PR.<br>At this stage, the PR said that as a result of the inspections findings, the centre |

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| discrepancies between the consenting decisions in the patient records and those entered on the HFEA register.<br><br>Directions 0005, paragraph 8.<br><br>Directions 0005, paragraph 9. | report should be submitted to the Executive by 30 September 2011.<br><br>The PR should ensure that in 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. | on behalf of the inspector?<br><br>The time frame for completion is realistic. | was undertaking a complete audit of the submission of this data.<br><br>Action required. |
| The laboratory that carries out the PGS is not accredited by Clinical Pathology Accreditation (CPA) UK Ltd or an alternative body accrediting to an equivalent standard<br><br>Licence | The PR should submit a plan to the Executive documenting the estimated timeline for achieving compliance with this recommendation by the time the PR responds to this report. | Genesis Genetics has submitted its application for CPA accreditation and is due to be inspected in August 2011 | The PR should inform the Executive the findings of the CPA inspection. |

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| conditionT21. | | | |

### 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<br>Reference | Action required<br>Timescale for action | PR Response | Executive Review |
|---|---|---|---|
| The centre does not have a SOP to follow for providing patient information for:<br>• The procedure to follow if consent to parenthood is withdrawn.<br>Licence Condition T33 (b). | The PR should ensure that the centre has a documented procedure to follow for providing patients with the information regarding withdrawal of consent to parenthood.<br><br>The documented procedures should be submitted to the Executive by 30 June 2011. | This SOP has been provided to the inspector with my comments to the draft report.<br>A copy of CARE Manchester's patient information document is sent with this reply as requested. | The SOP has been reviewed and states the procedure to follow if this consent is withdrawn.<br><br>No further action required. |

| Area of practice<br>Reference | Action required<br>Timescale for action | PR Response | Executive Review |
|---|---|---|---|
| Not all staff could provide documented evidence of the assessment of their competence in the performance of their designated tasks.<br><br>Licence Condition T15 (a).<br>Not all staff competencies are re-evaluated.<br>Licence Condition T12.<br>At inspection, staff were unable to explain the circumstances when the withdrawal of consent form may be used (T64 (b)) and were unsure of whether there is a process to follow. | The PR should ensure that all staff can provide documented evidence of the assessment of their competence in the performance of their designated tasks.<br><br>The PR should ensure that the competency of staff is re-evaluated at appropriate intervals.<br><br>By the time of the next inspection.<br><br>The PR should submit a detailed plan, including a summary of all staff and the competence assessments they need to complete, including timeframes, by 30 June 2011. | Whilst I agree that competences should be assessed I would question the need for the submission of such a plan and timeframe for this as this report will not be presented to the Executive until the 24th of June. Again it is surely their decision as to whether this is necessary or not. In my opinion the submission of the quarterly report is | The PR's comments relating to the decision making have been addressed above.<br><br>There is no request for submission of quarterly reports. The action is for submission of a detailed plan of competency assessments.<br><br>The evidence of the competency assessments will be reviewed at the next inspection.<br><br>Further action required. |

| Area of practice<br>Reference | Action required<br>Timescale for action | PR Response | Executive Review |
|---|---|---|---|
| | | unecessarily<br>onerous. | |

| Additional Information from the Person Responsible |
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| Having read the report fully I would firstly like to question why the areas of 'non-compliance' have been categorised as 'major'. Using the HFEAs definition of 'major area of non-compliance' I do not believe that the documented areas of concern constitute any risk to patients, gametes or embryos, whether indirect or not. Neither do they constitute a major shortcoming from statutary requirements, a failure of myself as PR to carry out my duties or a combination of factors leading to 'major' non compliance. Whereas as a clinic we are aware that we have not established quality indicators for all activities or auditted all activities, which is a huge task for a clinic as large as CARE Manchester, the wording of the report is mis-leading in that it implies quality indicators have not been established or audits carried out at all. This is certainly not the case. Progress has been made in both areas which is not reflected in this report<br>The HFEA inspectors were aware at the time of the inspection that CARE Manchester was undertaking an audit of data provided by EDI with reference to consent to disclosure Again I do not believe this fits the criteria for 'major' non-compliance and the fact that the clinic is aware of this and is remedying the situation should be emphasised.<br>The SOP for consent and its withdrawal is already in place and provided to the inspector in my reply to the original draft report.<br>CPS accreditation is being applied for by Genesis Genetics.<br>In general the time frames in the report and the recommendations to submit reports and timescales seem unrealistic. I feel the |

need for so many submissions is unecessarily onerous and would detract from the day to day, smooth running of the clinic

# HFEA Executive Licence Panel Meeting

**24 June 2011**

21 Bloomsbury Street London WC1B 3HF

## Minutes – Item 1

**Centre 0185 (CARE Manchester) – Interim Inspection Report (Treatment and Storage)**

| Members of the Panel: | Committee Secretary: |
|---|---|
| Mark Bennett, Director of Finance & Facilities (Chair)<br>Nick Jones, Director of Compliance<br>Juliet Tizzard, Head of Policy | Joanne McAlpine |

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

**The Panel also had before it:**

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

**Consideration of Application**

1. The Panel noted that this centre is part of the CARE fertility group and is housed within the Manchester Lifestyle Clinic.

2. The Panel noted that the centre was first established in 1999, and provides self-funding treatments to patients referred from all areas of the North West and occasionally from other regions of the UK. and overseas.

3. The Panel noted that this centre has links with The Beaumont Hospital, Bolton; Assisted Conception Unit, Leigh Infirmary; Calderdale Assisted Conception Unit; and operates as a satellite centre for CARE Nottingham.

4. The Panel noted that the Person Responsible (PR) has been in post since 1999, is the person with overall clinical responsibility for the centre and is registered with the GMC.

5. The Panel noted that the centre's licence was renewed in 2009 for five years, when pre-implantation genetic diagnosis (PGD), pre-implantation genetic screening (PGS) and laser hatching were added.

6. The Panel noted that the Licence Committee recommended in 2009 that a further visit to the centre take place within a year to focus on consent for storage, an issue identified in the inspection in 2009. The Panel noted that on the recent inspection the Inspectorate was satisfied that there was sufficient evidence that this recommendation had now been implemented.

7. The Panel noted that, at the time of the inspection, the Inspectorate identified four major and three other areas of non-compliance or for improvement.

8. The Panel noted that a number of the areas identified were the same as had been identified within the Self Assessment Questionnaire (SAQ).

9. The Panel noted that since the inspection the PR has given a commitment to implement the recommendations. However, the Panel noted the PR points regarding HFEA definitions of non-compliance categories and whether it is for the inspector or ELP to make recommendations.

10. The Panel considered these points but saw no merit in altering the definitions of categories, which are intended to be applied consistently in reviews of clinic performance in line with policy and procedure. The Panel was also clear that, in general terms, inspection reports are more valuable with recommendations from the Inspectorate but equally it is

for the Panel, or Licence Committee, to make a judgement based on the evidence before it, including the response from the PR.

11. The Panel noted the centre's success rates are in line with the national average.

12. The Panel noted the timeframe for implementing quality indicators and auditing, and that the PR feels three months is not a sufficient amount of time. However, the Panel noted that the resources of the CARE Group are being deployed, which should have enabled a plan to be produced and progress to be made.

13. The Panel noted the need for the PR to continue the auditing of consents, with a view to completion by 30 September 2011.

14. The Panel noted the progress made with accreditation of the laboratory, and endorsed the other areas identified within the report.

15. The Panel noted the progress made and the comments from the PR, and encouraged the PR to work with the Inspectorate to ensure needed improvements are implemented in a timely manner, which, if agreed, need not wait ELP confirmation.

16. The Panel noted the Inspectorate's recommendation to the continuation of the centre's licence with no additional conditions.

**Decision**

17. The Panel noted the evidence before it and agreed to the Inspectorate's recommendation to continue the centre's licence, with no additional conditions. The Panel agreed to the Inspectorate's recommendations within the report and the associated timescales.

18. The Panel encouraged the Inspectorate to monitor progress on implementing the recommendations with the PR and to use its discretion to decide upon appropriate action, for example management review, if progress appeared insufficient.

Signed: Date: 6 July 2011
Mark Bennett (Chair)