

Interim Inspection Report



Date of Inspection: 15th October 2009

Length of inspection: 4.5 Hours

Inspectors Dr Vicki Lamb
Mrs Gill Walsh
Mrs Mim Glenn (observer)

Inspection details:

The report covers the pre-inspection analysis, the visit and information received from 24th October 2007 – 15th October 2009

Date of Executive Licensing Panel: 11 March 2010

Purpose of the Inspection report

The purpose of the inspection is to assess 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 Licence Committee/ Executive Licensing Panel which make the decision about the continuation of the centre's licence.

Centre details

Centre Name	London Women's Clinic, Darlington
Centre Number	0075
Licence Number	L0075/13/c
Centre Address	Woodlands Hospital, Morton Park Darlington County Durham, DL1 4PL
Telephone Number	01325 371 070
Person Responsible	Dr Kamal Ahuja
Licence Holder	Mrs Shailaja Nair
Date Licence issued	01/10/2009
Licence expiry date	31/03/2011
Additional conditions applied to this licence	No additional conditions imposed

Version: 0

Trim:

Contents

Page

Centre details 1

Contents 2

Report to Licence Committee/Executive Licensing Panel..... 3

Recommendation to the Executive Licensing Panel

Details of Inspection findings..... 5

Brief description of the centre and its licensing history
Activities of the Centre
Updated actions since the centre was inspected
Focus of inspections for 2010-12
Changes / improvements since the last inspection
Areas of concern

Areas of practice that require the attention of the Person Responsible..... 16

Critical area of non compliance
Major area of non compliance
Other area of practice that requires consideration

Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

In considering overall compliance, the inspectorate considered that it had sufficient information drawn from documentation submitted by the centre prior to the inspection and from observations and interviews conducted during the inspection visit to conclude that:

- The PR has largely discharged his duties effectively under Section 17 of the HFE Act. Centre staff acting under the supervision of the PR are suitably trained and qualified for their designated roles. Patients report satisfaction with the treatment they have received
- The existing premises and equipment inspected are suitable for the treatment procedures for which the centre is licensed
- The centre has been proactive in the further development and implementation of the quality management system under the direction of the recently appointed quality manager. Documentation seen by the inspection team provided evidence of compliance with the majority of HFEA requirements.
- The centre has established quality objectives and a schedule of audit was seen to be in place. Documentation to support the ongoing validation of equipment and processes was seen and considered to be appropriate.
- The inspectorate is satisfied that the centre largely demonstrates appropriate practices in respect to air quality monitoring, laboratory, clinical and administrative procedures.
- Improvements should be considered relating to the following aspects of the centre's practice:
 - the availability of mandatory training, update training, annual appraisals, professional development, and the assessment of staff competency
 - staff knowledge in relation to legal parenthood provisions, patient consent to disclosure of information held on the HFEA register, for use in research.
 - witnessing procedures should be reviewed to ensure compliance with HFEA requirement T71 and guidance note 18 of the 8th Code of Practice.
 - the centre should ensure that only gametes and embryos with appropriate consent are retained in storage.
 - the PR should ensure that the caseload of the centre is regularly reviewed to ensure that it does not exceed staff resources available.
 - validation of equipment and processes for both laboratory and clinical areas should be conducted

- some third party agreements remain outstanding following a corporate review.
- full implementation of the multiple birth minimisation strategy.

The executive recommends that the Executive Licensing Panel requires that the Person Responsible address the recommendations made in this report within the timeframes specified.

The executive consider there was sufficient information available overall to recommend the continuation of this centre's licence without additional conditions.

Details of Inspection findings

Brief description of the centre and its licensing history:

The London Women's Clinic, Darlington is a small, privately owned centre and is part of a four centre group. The centre offers a comprehensive range of licensed assisted conception treatments to self funding patients. The centre has a good history of compliance with HFEA regulatory requirements

The centre is a stand alone unit located within the BMI Woodlands Hospital, Darlington. There have recently been a number of key staff changes at a senior level in both the laboratory and nursing service. The Senior Embryologist post is to be filled early in November 09 and candidates for the Senior Nurse post were being shortlisted at the time of inspection. Quality Management is directed corporately with a new Quality Manager for all hospitals in the group having been appointed within the last six months.

Opening hours at the centre are Monday - Friday 8.30am – 4.30pm and Saturday 8.30am – 12.00.

The PR is appropriately qualified to discharge his duties and responsibilities in accordance with section 17 of the HF&E Act and has successfully completed the HFEA Person Responsible Entry Programme.

The centre was last inspected by the HFEA in October 2007.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01/04/08 to 31/03/09
Intra Cytoplasmic Sperm Injection ICSI	86
In Vitro Fertilisation IVF	165
Insemination (Donor)	24

Other licensable activities	
Storage of eggs	Yes
Storage of sperm	Yes
Storage of embryos	Yes
Research	No

*These data were extracted from the HFEA register for the period 01/04/08 to 31/03/09. 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.

Version: 0

Trim:

1. Focus of inspections for 2010-12

Witnessing
<p>Evidence of how the centre demonstrates compliance with the requirement to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. (Guidance Note 18)</p> <p>The laboratory witnessing process does not fully comply with licensing condition T71;</p> <ul style="list-style-type: none">▪ The signature of the person performing the activity and the signature of the person witnesses the activity are not recorded, only the person's initials are recorded.▪ The time the procedure is conducted is not recorded▪ The disposal of gametes and / or embryos is witnessed but not documented has having been witnessed. <p>.</p>
<p>What the centre does well.</p>
<p>What they could do better.</p> <p>The centre's witnessing SOP and practice should be reviewed to ensure compliance with licence condition T71</p>

Legal Parenthood
<p>Evidence of how the centre demonstrates compliance with the requirements in relation to legal parenthood (Guidance Note 6)</p> <p>While staff did describe circumstances in which patients had been provided with information on parenthood the staff interviewed were unable to effectively demonstrate a detailed understanding of the application of the changes to the provision of legal parenthood post April 2009. The inspection team were satisfied that patients who have received treatment since the change in legislation have received appropriate information but were concerned that the level of understanding may have an impact should more complex parenthood issues arise.</p>
<p>What the centre does well.</p>
<p>What they could do better.</p> <p>Staff should be trained and assessed as to their understanding of the broader ethical, legal</p>

Version: 0

Trim:

and regulatory context of their work, to ensure they provide the correct information in relation to legal parenthood to patients in compliance with licence conditions T60 to T65.

Such training should be documented in each individual staff member's training record.

Information about the cost of treatment

Evidence of how the centre demonstrates that it has introduced personalised costed treatment plans for all patients (Guidance Note 4.3)

During the course of the inspection the centre was able to present evidence to demonstrate that several centre specific costed treatment plans for patients have been introduced in compliance with guidance 4.3.

What the centre does well.

Costed treatment plan documents viewed were clear and easily understood.

What they could do better.

N/A

Patient consent to the disclosure of information, held on the HFEA Register, for use in Research

Evidence of how the centre demonstrates that it provides information to patients about the use of information, held on the HFEA Register, for use in research. (Guidance Note 5 27 (d)).

During the course of the inspection, staff interviewed were unable to demonstrate effective knowledge regarding patient consent to the disclosure of information held on the HFEA register for use in research.

What the centre does well.

What they could do better.

The PR should ensure that staff are educated and assessed as to their understanding of the broader ethical, legal and regulatory context of their work, and are providing appropriate information to patients, as to the patient's right to decide what identifying information held on the HFEA register, may be used in research and to whom it should be disclosed, when

Version: 0

Trim:

obtaining their consent in accordance with Schedule 3, 3 (1) (b) of the Act and guidance 5.27 (d).

Such training should be documented in each individual staff member's training record.

Consent issues in relation to the storage of embryos (including cooling off period)

Evidence of how the centre demonstrates compliance with the requirements relating to the withdrawal of consent to storage of embryos intended for use in treatment.(Guidance Note 5 (H)).

During the course of the inspection, staff interviewed were unable to demonstrate effective knowledge about patient consent implications regarding the 'cooling off period' relating to the storage of embryos.

What the centre does well.

What they could do better.

The PR must ensure that all staff authorised by the centre to seek consent have been trained and assessed as to their competence to provide information to patients regarding consent issues in relation to the storage of embryos, (including cooling off period) in accordance with licence conditions T58 T59 and guidance note 5. The centre should also ensure that their patient information has been updated to reflect this change.

Multiple Births

Evidence of how the centre demonstrates compliance with Guidance Note 7 of the Code of Practice relating to multiple births: (Guidance Note 7).

In compliance with Directions 0003, the centre has a documented strategy to minimise multiple births and will be conducting regular audits to assess progress with reducing the

Version: 0

Trim:

centre's multiple birth rate. The centre has yet to fully implement their strategy and eSET policy. All multiple embryo transfers are logged with accompanying rationale recorded. Not all patients are currently subject to eSET criteria.

What the centre does well:

What they could do better:

The centre should ensure that they are implementing and monitoring the efficacy of their multiple birth minimisation strategy in accordance with HFEA Directions 0003 .

2. Changes / improvements initiated since t

Area for improvement	Action required	Action taken as evidenced during this inspection
Security of premises	Review of security arrangements at the centre.	All external entrances to the centre have now been fitted with self locking keypads, as have several internal doors including the administration office, where patient files are stored. (Observed) S16(2)(d) of the Act -
Staff reporting lines	The organisational chart was not in evidence prior to inspection	An organisational chart which clearly demonstrates staff roles and reporting lines was seen on inspection. Licence Condition T11 met
Storage of gametes and embryos – safety of gametes, embryos and personnel	Fitting of an audio or visual alarm on the outside of the cryostore	An audible alarm has been fitted and appropriate safety signage was seen at the time of the inspection. Guidance 25.7 met
Quality management (QM) – completeness and accuracy of health records.	Medical notes should be audited to ensure that they are complete and accurate	The QM manager confirmed that an audit has been completed on certain aspects of patient’s medical notes, (eg consent and witnessing), the results of which were seen. have also been included in the centres quality indicators and audit schedule. Licence Condition T35 & T36 met
Document control	Documents in current use	Evidence presented demonstrates

Version: 0

Trim:

	<p>should be appropriately reviewed and document controlled.</p>	<p>there is now an effective document control system in place. This includes the development and introduction of a document control SOP's (Document Control SOP v1 00417) and templates. A master index (Darlington Master Index Office 2003 version 15Oct09) is accessible to all staff via the centres quality drive.</p> <p>Licence Condition T34 met</p>
--	--	--

2. Focus of inspection

The analysis of the previous inspection report, 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 that were focused on during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement.
<p>Air quality The quality of air in which gametes and embryos are manipulated had not previously been established.</p>	<p>Documentation was seen on inspection that demonstrates daily air quality testing. Testing results seen confirmed that the air quality was compliant with T20.</p>	<p>The actions taken by the centre now demonstrate compliance with Licence Condition T20.</p>
<p>Traceability Monitoring of traceability of items used in the laboratory was incomplete.</p>	<p>Staff interviewed and a review of the documentation submitted for inspection demonstrated effective traceability of materials and solutions coming into contact with gametes and embryos as part of the assisted conception process.</p>	<p>The actions taken by the centre demonstrate compliance with Licence Condition T99(b)</p>
<p>Welfare of the Child (WoC) Welfare of Child assessments needed to be documented in patients treatment records.</p>	<p>Staff interviewed confirmed that WoC assessments are conducted and documented in patients' notes and are signed on review. Evidence of this was seen in the patient records sampled.</p>	<p>The actions taken by the centre demonstrate compliance with Licence Condition T56</p>
<p>Third party agreements Not all third party agreements were in place.</p>	<p>Staff interviewed stated that all third party agreements for the group are in the process of being managed centrally. It was stated that during this transition period a small</p>	<p>The centre does not currently demonstrate compliance with Licence Conditions T113, T114, T115 & T116 The centre must establish written</p>

Version: 0

	number of agreements were being revised and that this process was to be completed within two months.	agreements with all third parties who provide goods and services that influence the quality and safety of gametes and embryos and ensure compliance with the licence conditions detailed above.
<p>Quality Management System The centre had previously not established an effective Quality Management System.</p>	<p>Staff interviewed and a review of the documentation submitted at the time of inspection showed that an effective Quality Management System is now fully in place.</p> <p>A new, full time Quality Manager has been recently employed at corporate level to oversee the activities in Quality Management on all four sites with local 'link' personnel at each centre in the group.</p> <p>Quality indicators have been set (Darlington v1 doc. 75005) and an audit schedule is now in place.</p>	<p>The actions by the centre demonstrate compliance with Licence Conditions T32 T33(a)(b)(c) & T34 and T35</p> <p>.</p>
<p>Staff</p> <p>The centre could not demonstrate how staff competence and confidence in performing their designated tasks was assessed.</p> <p>Staff had not had timely</p>	<p>Staff interviewed and individual training logs observed demonstrated that mandatory training had not been conducted during appropriate timescales for staff currently in post.</p> <p>There was no evidence in personnel training files of documentation of competency assessment.</p>	<p>The centre cannot fully demonstrate compliance with Licence Condition T12 T13 and T15.</p> <p>The PR should ensure that all personnel are provided with appropriate induction to the organisation and to their roles.</p>

<p>appraisal of the performance, review of the job profiles or CPD planned.</p> <p>Planned mandatory training was not conducted / attended within time scales specified.</p>	<p>The quality manager stated that the majority of human resource functions and appraisal mechanisms were in the process of being centralised which, when complete, would afford better control to ensure all staff have planned appraisal, CPD and training conducted in a timely and effective manner.</p> <p>Competency assessment, appraisal and CPD planning is planned to recommence with the appointment of the key posts currently vacant.</p> <p>Staff were able to demonstrate that mandatory training was scheduled for November 2009 and an induction programme for the new staff anticipated is in progress.</p>	<p>Training needs must be evaluated and adequate opportunity for relevant professional development and mandatory training conducted. The competency of staff in post must be assessed and evaluated at appropriate intervals.</p>
--	---	---

Areas identified during the course of the inspection visit that require further examination and or will require follow up.

Area of concern identified during the course of the inspection	Inspection findings	Action(s) needed to be taken to meet requirements
<p>Staff Resources</p>	<p>During the course of the inspection it was noted that the centre currently has two key staff vacancies, that of Senior Embryologist and a Senior Nurse.</p> <p>The PR stated that a Senior Embryologist has been appointed and takes their up post at the beginning of November 2009, the PR also stated that a short list of candidates for the Senior Nurse Post had been decided and that they were confident an appropriate appointment would be made shortly.</p>	<p>The PR must ensure that until such time as these posts are filled and candidates fully inducted in the role, that the activities of the centre are regularly monitored to ensure that personnel in the centre are available in sufficient number and be qualified and competent for the tasks they perform in accordance with Licence Condition T12.</p>
<p>Sperm and Embryos stored beyond consent</p>	<p>During a 'spot check' audit of the dewars, five samples of cryo-preserved sperm and 10 cryo-preserved embryos, were found to be stored beyond their consent period.</p> <p>It was also noted that the centre's SOP relating to this does not reflect current HFEA guidance and the centre's Licence Conditions.</p>	<p>The PR should take immediate action to ensure that storage of embryos and gametes is compliant with the requirements of the Act.</p> <p>The centre should establish appropriate documented procedures to ensure that all storage and handling of gametes and embryos complies with licence conditions, regulations and relevant patient and donor consent. (G17.1) and</p>

	<p>Section 3 (3) (c) of the Act states that (c) a licence cannot authorise keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use. Section 4 (2) of the Act states that a licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use. Section 41 of the Act states that a person who does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence, is guilty of an offence.</p>	<p>Licence Condition T33 (b).</p>
--	---	-----------------------------------

Areas of practice that require the attention:

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 identified at this inspection					

▶ Major area of non compliance

A major are of non compliance is a non critical are 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
Storage of gametes and embryos without consent	Section 3 (3) (c) of the Act states that (c) a licence cannot authorise keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use. Section 4 (2) of the Act states that a licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use. Section 41 of the Act states that a person who does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence, is guilty of an offence.	Whilst it is recognised that the centre have made all attempts to contact the gamete and embryo owners, the PR should take immediate action to ensure that storage of embryos and gametes is compliant with the requirements of the Act.	Immediate action required.		<p>Email confirmation from the Laboratory Manager has been received by the HFEA stating that since inspection Consent to extend storage has been secured for 4 samples: 11 samples have been discarded in accordance with Section 3 (3)c of the act.</p> <p>No gametes or embryos remain in store without valid consent.</p>
Witnessing	<p>Licence Condition T71</p> <p>Principle 10</p> <p>18.4(j), 18.6, 18.7 &</p>	The PR should ensure that the centre's SOP and practice for witnessing are compliant with licence conditions.	Within 3 months of date of this report or by 31st	The Witnessing Record has been updated to be more compliant with the 8 th Code of Practice {Document number 00673}.	No further action required.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
	18.8 of the 8 th CoP		January 2010		
Parenthood	Licence condition T15(d) T60, T61, T62, T63, T64, T65	The PR must ensure that staff have been trained and assessed as to their understanding of the broader ethical, legal and regulatory context of their work, to ensure they provide the correct information in relation to legal parenthood to patients to ensure compliance with licence conditions.	Within 3 months of date of this report or by 31st January 2010	Further training will be given and documented by 31 st January 2010.	Confirmation that training in this area was conducted on 19 January 2010 has been received from the centre's Quality Manager. The centre states that further update training is also scheduled for 8 March 2010.
Disclosure of information held on the HFEA register, for use in research	HFEA Act 1990 (as amended) Section 15 (2); 12 (1) (d) and (g) GN5.27 (d)	The PR must ensure that staff have been trained and assessed as to their competencies in providing information to patients, as to the patients right to decide what identifying information, held on the HFEA register, is use in research, and to whom it should be disclosed,	Within 3 months of date of this report or by 31st January 2010	Further training will be given and documented by 31 st January 2010.	Further follow up with the centre Quality Manager confirms that the first of 2 scheduled staff training sessions was conducted on 19 January 2010 and the second is scheduled for 8 March 2010.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
		when obtaining their consent in accordance with guidance 5. 27 (d).			
Consent in relation to the storage of embryos (including cooling off period)	HFEA Act 1990 (as amended) Schedule 3 4A GN5 (h)	The PR must ensure that all staff involved with obtaining consent have been trained and assessed as to their competencies in providing information to patients as to consent issues in relation to the storage of embryos (including cooling off period) in accordance with Guidance 5 (h).	Within 3 months of date of this report or by 31st January 2010	A new competency framework template has been introduced for all departments as well as a competency record for Nurses which includes the issue of obtaining consent. This will be instigated and discussed at each of the staff appraisals by 31 st January 2010.	As above, in addition the Quality Manager has confirmed that with the appointment of new line managers for laboratory and nursing, confirmation of competency by assessment and joint appraisal has begun.
Third Party Agreements	HFEA Act 1990 (as amended) Section 2(A)(2) Licence Conditions T111 to T117	The centre must establish written agreements with all third parties who provide goods and services that influence the quality and safety of gametes and embryos and ensure compliance with the licence conditions.	Within 3 months of date of this report or by 31st January 2010	The Purchasing Department is based in the LWC London offices and a Third Party Agreement is being issued now for all suppliers that LWC London purchases for LWC Darlington. The Agreements with the individual suppliers have been reviewed and are being pursued by the LWC Purchasing	To be monitored by lead inspector

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
				Manager.	
Staff: Basic/initial and mandatory training	HFEA Act 1990 (as amended) Schedule 3A 5 Licence Condition T15	The PR must ensure that all staff are provided with initial/basic and mandatory training in accordance with licence conditions.	Within 4 months of date of this report or by 31 March 2010	Mandatory training was carried out in November and was recorded for each staff member on their training record. There is also a company Induction Manual (currently undergoing its annual review) and an Induction Health and Safety checklist which details induction training requirements.	To be monitored by lead inspector
Staff - Annual joint review, with their line manager.	HFEA Act 1990 (as amended) Schedule 3A 5 Licensing condition T15 Staff (2) 2.1(c) & 2.2(j) 2.3 of the 8 th CoP	The PR must ensure that all staff have participated in an annual performance review, with a manager and a plan for CPD established in accordance with licence conditions.	Within 6 months of this report or 30 June 2010	Staff appraisals are taken seriously. All appraisal appointments have been set for end of January 2010. A new Appraisal SOP has been implemented which details how staff's requirements for training will be assessed and identified for action.	Confirmation has been received from the Quality Manager that with following the appointment of two new key Managers a schedule of staff appraisal has been set.
Staff – Assessment of competencies	HFEA Act 1990 (as amended) Schedule 3A 5	The PR must ensure that all personnel have demonstrated competence in the	Within 4 months of date of this	Approved Competency Framework records will be instigated at the next scheduled Appraisal	Confirmation that this process has begun and is ongoing has been

Version: 0

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
	Licence Conditions T12 & T15(a) 2.2(e) of the 8 th COP	performance of their designed tasks. Assessments undertaken should be documented in each individual staff members training records.	report or by 26 February 2010 (ongoing)	appointments – due end of January 2010	received from the centre's Quality Manager.
Validation of equipment and processes	HFE Act 1990 (as amended) 17(1)(b) Schedule 3A Licensing conditions T24 & T25	The PR should ensure that all critical equipment and technical devices are identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions.	Within 3 months of date of this report or by 31st January 2010	The newly appointed Senior Embryologist is committed with her team to complete the validation process within 3 months.	Confirmation has been received from the centre's Quality Manager that this process has commenced and is ongoing.

▶ **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
Staff Resource	Licence condition T12	The PR should ensure that until such time as the vacant posts are filled and candidates fully inducted to their roles, the activities of the centre are regularly monitored to ensure that personnel in the centre are available in sufficient number and be qualified and competent for the tasks they perform in accordance with Licence Condition T12.	Ongoing	The PR has taken steps to immediately rectify the situation: 1. 2 Fertility Nurses have now been appointed 2. A new Senior Embryologist has now been appointed 3. The PR and the QA Coordinator have committed themselves to review this at the regular Clinic and Quality Management Review meetings.	No further immediate action required. To be monitored

Additional Information from the Person Responsible

We are thankful for the inspecting team's courteous and fair assessment of our Clinic and program. The key points that have been identified have been acted upon and we are confident that the attached timetables will not be compromised.

Version: 0

Trim:

HFEA Executive Licensing Panel Meeting

11 March 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

London Women's Darlington (0075) Interim Report

Members of the Panel:

Peter Thompson, Director of Strategy & Information (Chair) Committee Administrator:
Joanne McAlpine

Mark Bennett, Director of Finance & Facilities

Ian Peacock, Analyst Programmer

Declarations of Interest: members of the Panel 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 (33 pages)
- no papers were tabled for this item

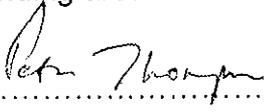
The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel noted that this application is for an interim and considered the papers that consisted of an interim inspection report and previous licence committee minutes.
2. The Panel noted that the centre's inspection took place on the 15 October 2009 and lasted for four and half hours.
3. The Panel noted that this is a small privately owned centre and is part of a four centre group.
4. The Panel noted the inspectorate's recommendation that the licence should continue without any additional conditions.
5. The Panel noted that the inspection report recorded that the centre has taken steps to address various areas such as parenthood, validation of equipment.
6. The Panel noted the appropriate response from the Person Responsible and that he has addressed most of the outstanding areas or is working towards implementing them.
7. The Panel endorsed the executive's recommendation that the centre implements its multiple births minimisation strategy; but noted that there was not evidence within the report setting out the current rate of multiple births at the centre.

The Panel's Decision

8. The Panel agreed to continue the centre's licence with no additional conditions, endorsed the inspectorate's recommendations and requested the inspectorate to continue to monitor completion of the outstanding areas identified in the report.

Signed..........
Peter Thompson (Chair)

Date..... 22 / 03 / 10