Interim Inspection Report

Date of Inspection: 1 September 2010
Length of inspection: 7.5 hours
Inspectors:
Mim Glenn Lead inspector
Ellie Suthers Inspector
Sara Parlett Inspector
Roup Kaur Quality Assurance Officer

Inspection details:
The report covers the pre-inspection analysis, the visit and information received about the centre between 16 June 2010 and 17 November 2010

Date of Executive Licensing Panel: 17 November 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 Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	The Leeds Centre for Reproductive Medicine
Centre Number	0314
Licence Number	L0314/1/b
Centre Address	Seacroft Hospital, York Road, Leeds, LS14 6UH
Telephone Number	0113 206 3100
Person Responsible	Mrs Vinay Sharma
Licence Holder	Professor Peter Bellfield
Date Licence issued	25/01/2010
Licence expiry date	13/12/2011
Additional conditions applied to this licence	None

Contents

Report to the Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

At the time of the inspection improvements were recommended in relation to:

- Documentation of consent to the disclosing of identifying information on the HFEA register;
- Documentation of competence to perform witnessing in the nursing team.

The PR has responded to these recommendations and no further action is required in relation to these non compliances.

Recommendations were also made in relation to the following:

Major areas of non compliance:

- Validation of critical equipment and critical processes;
- Setting of quality indicators, audit and corrective actions;
- Continued development of the evaluation and reporting arrangements for the centre's third party agreements with satellite centres;
- Provision of information to the HFEA in line with the requirements of Directions 0005 including timely submissions and error corrections.

Other areas of practice that require improvement:

- The ability of staff to interrogate the centres "bring-forward" system for the storage of gamete and embryos;
- Evaluation and reporting arrangements for the centre's third party agreements with satellite centres.

The person responsible (PR) has provided assurances and where relevant, action plans for the implementation of these recommendations.

The inspector recommends that the Executive Licensing Panel requires that the person responsible (PR) complies with these recommendations within the timeframes set out in this report.

Details of inspection findings

Brief description of the centre and its licensing history:

The Leeds Centre for Reproductive Medicine is located within the Leeds Teaching Hospitals NHS Trust. Following a new premises/centre inspection it was granted its first HFEA licence on 25 January 2010 for a period of two years with no additional conditions.

The centre was formed as a result of the merger of the Reproductive Medicine Unit Leeds General Infirmary (centre 0052) and Assisted Conception Unit, St James' University Hospital Leeds (centre 0063). All stored material, records, scientific and treatment services have been transferred to the new facility and both these centres have now been closed and licences revoked (October 2010).

The new centre operates seven days a week and provides a full range of licensed treatment to both self-funded and NHS patients.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 25/01/2010 – 01/08/2010*
In vitro fertilisation (IVF)	395
Intracytoplasmic sperm injection (ICSI)	412
Frozen Embryo transfer (FET)	178
Donor insemination (DI)	38
Egg Donation (IVF - non-egg share)	12

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 25/01/2010 – 01/08/2010. 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.

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** Before treatment and/or storage services are offered the centre gives the person seeking treatment or storage and their partner (if applicable) a personalised costed treatment plan. The centre provides personalised costed treatment plans to its self funding patients prior to the start of treatment as part of a comprehensive information pack. An individualised '*schedule of fees'* 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 '*schedule of fees'* was seen to detail the main elements of the treatments, investigations, possible tests and necessary drugs. Patients are provided the opportunity to discuss this in detail at the first consultation. Information is repeated by the nurses at subsequent consultations (Guidance 4.3). **Legal Parenthood** The centre provides information to people seeking treatment about legal parenthood issues. Staff provided a description of the legal implications for parenthood, the necessary consent forms to be completed and the process to take if there is a withdrawal of consent by any party. The legal implications for parenthood are, where relevant, discussed at the initial patient consultation and then again at the mandatory counselling session. The relevant staff have undergone training in the use of the new HFEA legal parenthood consent forms. Meeting minutes seen from June and September 2009 demonstrated that the new consent forms had also been discussed with staff at the centre's satellite centres (Standard Licence Conditions T60, T61, T64 and T65).
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 does seek patient consent to identifying information from the HFEA Register being disclosed to medical and non-medical researchers. On the day of inspection an audit of 12 sets of patients and partner records showed that the HFEA consent to disclosure of information had been completed appropriately in all consent forms (Guidance 5.27d). **Storage** The consultant embryologist reported that he was confident that there was effective consent for the storage of all cryopreserved gametes and embryos currently in store, as they had just completed a comprehensive audit of all stored material which included the validity of consent. A copy of the audit results were provided and discussed at the time of inspection. The centre will be performing bi annual audits of all stored material (HFE Act 1990 (as amended) Schedule 3, 8(1)). The consultant embryologist described the documented bring-forward system in place to ensure that patients are provided with sufficient notice prior to the end of the consented storage period (Guidance 17.17). The centre provided a documented Standard Operating Procedure (SOP) for taking and recording consent which includes a description of the cooling off period and the procedure to follow if one gamete provider withdraws their consent to embryo storage (Guidance 5.35).
What they could do better. **Consent to disclosure of identifying information to researchers** In three sets of patient records discrepancies were noted between the consenting decisions in the patient records and those entered on the HFEA register via the electronic data interface (EDI) (Standard Licence Condition T41 & Directions 0005). **Storage** The centre does have a documented bring forward system but it is reliant on a computerised database that contains all the relevant details and prompts. At the time of inspection the PR reported that this database could not be accessed by centre staff as they don't have the resources of a data analyst to monitor and extract the necessary information.

Multiple births

What the centre does well.

The centre has been operational since 25 January 2010 and therefore it is too early to assess the centre's compliance with the HFEA multiple birth target for 2010/2011. The PR reported a multiple pregnancy rate of 13% since the centre opened in January 2010.

In accordance with Directions 0003 the centre has a documented record of their multiple birth minimisation strategy and is maintaining a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer (SET). The updated policy was reviewed in the course of the inspection. The strategy was seen to include guidance on:

- How the centre identifies suitable cases for SET, including criteria in relation to embryo assessment and patient selection criteria (General 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% (General Directions 0003 5(b)).

It was also noted that in cases where multiple embryos were transferred to patients meeting the criteria for SET, the reasons for this had been recorded in the patient medical records.

The centre has also maintained a summary log of every treatment cycle which involves the placing in a woman of three embryos. This log was provided during the inspection. The ages of the patient were documented (all above the age of 40) and the log also stated the reasons for the multiple transfers were age related and because of previous treatment failures.

The centre provided documented evidence that they have carried out an audit and regular evaluation of the progress and effectiveness of their strategy since the opening of the centre in January 2010.

What they could do better.

Nothing noted at the time of inspection.

Validation of critical equipment and processes
What the centre does well. With the exception of one piece of equipment (dry shipper) the embryologist provided evidence that all critical equipment and technical devices have been validated. Evidence was seen of qualification reviews of existing equipment including a class II cabinet; incubator and the freeze machine (Standard Licence Condition T24). Some of the centre's critical processes have been validated. Completed validation documentation was seen for semen analysis, sperm preparation and egg collection (Standard Licence Condition T72).
What they could do better. **Validation** Validation of the dry shipper has not been undertaken and there is no ongoing maintenance or monitoring being undertaken (Standard Licence Condition T24). Not all critical processes have been validated (Standard Licence Condition T72).

Witnessing

What the centre does well.

The centre is in the process of implementing an electronic witnessing system and is running electronic and manual witnessing in parallel.

The centre provided evidence of a comprehensive risk assessment for the electronic witnessing system in November 2009 including documented plans in the event of equipment failure (Guidance 18.31 & 18.32). Following evaluation the electronic witnessing system has been used independently for sperm preparations for treatment for approximately two months.

The centre has a witnessing SOP in place 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. Evidence was provided that these checks are completed and recorded at the time the relevant clinical or laboratory process/procedure takes place and a record made in the patients records (Standard Licence Conditions T33b and T71).

Direct observation by the inspector of three procedures using both electronic and manual witnessing and an audit of five sets of patient records demonstrated that all witnessing steps are recorded appropriately. The inspector was satisfied that the identification of samples and the patients/donors to whom they relate is witnessed appropriately by two members of staff at all critical points of the clinical and laboratory process. A senior embryologist confirmed that all steps are witnessed contemporaneously, including the storage location (Standard Licence Condition T71).

The embryologist induction training record was seen for one embryologist and included evidence of assessment of competency in witnessing. Laboratory staff confirmed that prior to performing any process the embryologist must have documented evidence of their competence (Standard Licence Condition T15a).

Witnessing

The witnessing checks were seen to be documented in all sets of records reviewed on the day of inspection but it was noted that this documentation did not include the name and status of the person who performed the activity or the person who witnessed the procedure Standard Licence Condition T71 requires that that witnessing records “must be kept in each patient’s/donor’s records. These records must include the name, status and signature of the person performing the activity and the name, status and signature of the person who witnesses the procedure”. The Senior Embryologist explained that a separate list is maintained which includes the name, status and signature of each member of the embryology team (Guidance 18.8).

What they could do better.

Quality indicators
The centre has not established quality indicators or objectives relevant to witnessing. The centre could not provide any documented evidence of the audit of witnessing (Standard Licence Conditions T35).
On inspection it was noted that there is a variation between actions described in the witnessing SOP and actual practice. (Standard Licence Condition T36).

Competency assessments
Nursing staff participate in procedures where witnessing is required outside the laboratory, but they have not been assessed as to their competency to perform this task (Standard Licence Condition T15a).

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

The centre has an active egg donation and sharing programme with approximately 20 egg donors recruited this year. Sperm donor recruitment is largely through known donors and some importation from a UK and European sperm bank. The centre plans to start an active recruitment programme in the coming year.

The donor coordinator described the process for recruitment, screening and counselling of donors which is also described in a documented SOP with detailed checklists completed for every donor. Donor information material includes all the requirements of HFEA guidance 11.24.

The checklist includes all of the investigations and screening tests that must be conducted and copies of these checklists were seen to be included in all donor records audited. Donors are not allowed to progress through the process without all checks being performed.
Four sets of donor records (egg donors) were audited during the course of the inspection. Verbal and written evidence provided by staff and an audit of a sample of records demonstrated that:

- Donors are being selected on the basis of their health and medical history, provided in a questionnaire by the centre and through a personal interview and physical examination performed by a qualified and trained medical professional.
- Donors are being screened in accordance with the screening requirements of relevant professional bodies[1].
- Screening tests have been carried out by a qualified laboratory which has appropriate accreditation. Evidence of CPA accreditation was seen on individual results forms returned to the centre and stored in the donor records.

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

What the centre does well.

There is no requirement to quarantine imported or transferred sperm but locally recruited sperm, egg and embryo donors are screened and material quarantined in line with professional guidelines.

Staff provided documented evidence that all reimbursements and expenses are logged on a donor payment sheet, along with the rationale for the payments. These arrangements are compliant with Directions 0001.

During consultations and counselling the recipients of donor gametes are advised about the importance of informing any resulting child at an early age that the child results from the use of donated gametes. The donor coordinator commented that most treatments are with donors already known to the recipients and the welfare of the child assessment includes telling any child born of their donor conception (Standard Licence Condition T63 a).

What they could do better.

Quality indicators and audit
The centre has not established quality indicators or objectives relevant to the recruitment, screening, processing or providing information to donors or conducted regular audits of activity (Standard Licence Conditions T35 & T36).

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

What the centre does well.

Not applicable for this centre

What they could do better.

Embryo testing (if applicable)

What the centre does well.

Not applicable for this centre

What they could do better.

2. Changes / improvements since the last inspection on

This is the centre's first inspection visit since the issue of their first licence in January 2010. The Licence Committee that granted the licence on the 24 of December 2009 imposed no further requirements.

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
SAQ 2 – Staff The response indicated that the centre was not operating at a full staff complement.	At the time the PR submitted the SAQ the centre had four vacant nursing posts. These had subsequently been filled and all are due to start at the beginning of October 2010.	No further action is required
SAQ 2 – Staff The response indicated a discrepancy in whether all staff could provide documented evidence of competency assessments. Section 2 (Staff) noted that all staff could provide evidence of competency assessments. Subsequent individual sections of the SAQ noted not all members of staff could provide evidence.	The PR, senior nurse and consultant embryologist provided detailed documented evidence of all staff having completed competency assessments in all aspects of the centres activity. Annual appraisals, linked competency to the NHS Knowledge Skills Framework, training portfolios, continued professional development and relevant registrations were all provided.	No further action is required

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
SAQ 22 – Research and Training The response indicated that the centre has a research licence.	The centre does not carry out research and does not have a licence to do so. This was an error in completing the SAQ.	No further action is required.
SAQ 23 – Quality Management System The response indicated that the centre has not established quality indicators in some areas.	The centre has not developed quality indicators in relation to: witnessing; consent, record keeping and data submission.	Further action is required. The PR should establish quality indicators for all licensed activities and other activities carried out in the course of providing treatment services that do not require a licence (Standard Licence ConditionT35).

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
SAQ 23 - Quality Management System The response indicated that the centre has not undertaken audits in some areas.	The centre has not undertaken audits in the following areas of practice: Witnessing; provision of information; consent; donor recruitment, assessment and screening, procurement, processing and transporting gametes and embryos; confidentiality and privacy; data submission	Further action is required. The PR should undertake audits to determine if all licensed activities or activities carried out in the course of providing treatment services that do not require a licence compliance with the approved protocols, the regulatory requirements (Standard Licence Condition T36).
SAQ 24: Third-party agreements The response indicated that the centre is almost compliant with the requirement for the evaluation of the ability of the third party to meet required standards and whether they comply with standard licence conditions.	The centre has a third party arrangement with the Leeds Teaching Hospitals NHS Trust procurement division/ department who purchase consumables and other goods and services. The centre has four satellite arrangements. The centre has not carried out an evaluation of their ability to meet the required standards of licence conditions. However the PR is in the process of developing an evaluation tool and process for evaluation and regular reporting as required by Standard Licence Conditions.	Further action is required. The PR should continue to develop the evaluation and reporting arrangements. (Standard Licence Conditions T112 & T 116)

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
SAQ 31 Record keeping and document control The centre has a high error rate and slow correction rate in their submission of data via EDI to the HFEA	The PR reported that the centre does not have sufficient resources to clear the backlog of errors and are finding it difficult to submit data as required by Directions 0005.	Further action is required The PR should ensure that information is provided to the HFEA in line with the requirements of Directions 0005.

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 identified at this inspection					

Areas of practice that require the attention of the Person Responsible

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
Discrepancies were noted between the consenting decisions in the patient records regarding consent to the disclosing of identifying information to researchers and those entered on the HFEA register via the electronic data interface (EDI) Standard Licence Condition T41 & Direction 0005	The PR should ensure the accuracy of data provided via the EDI system regarding consent to the disclosure of identifying information to researchers. By 01/12/2010	We have looked into this matter and discovered that for the satellite patients, our LCRM nurses were having to complete the HFEA registration forms without having a copy of patient's consents when in order to avoid error they completed this section as not having consented. Now this process has been amended and LCRM will only accept patients for treatment with copies of the HFEA consent so that these sections can be accurately completed.	No further action is required. Will be monitored via the compliance cycle.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Not all critical processes have been validated. Standard Licence Condition T72 Validation of the dry shipper has not been undertaken and there is no ongoing maintenance or monitoring being undertaken. Standard Licence Condition T24	The PR should ensure that all critical processes are validated. By 01/09/2011 The PR should provide quarterly reports to the inspector on the progress of the action plan. The PR should ensure that all critical equipment and technical devices are validated. By 01/12/2010	Please find enclosed a report from the Senior Embryologist regarding work done to date regarding the critical equipment. The dry shipper validation is to be completed soon. Some of the critical processes have been validated and others are to be actioned soon. The Senior Embryologist has advised that validation of all critical processes and equipment will be complete by the end of this year. This is also the time of renewed inspection, servicing and validation of critical equipment for the coming year.	Further action is required. A validation action plan has been submitted to the inspector. This will be monitored via the compliance cycle.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The centre has not established quality indicators or objectives relevant to the recruitment, screening, processing or providing information to donors or conducted regular audits. The centre has not developed quality indicators in relation to: witnessing; consent, record keeping and data submission. Standard Licence ConditionsT35 & T36	The PR should establish quality indicators or objectives relevant to the recruitment, screening, processing or providing information to donors and conducted regular audits By 01/01/2011	This is 'work in progress'. We now have appointed a full time data officer who will work in our department for this sole purpose from November 2010, will be managed by the LTHT IT department and who will have access to senior database programmers and analysts for support and help when needed. Currently we have a senior data officer seconded to us and she after performing a thorough assessment of the existing processes has put in a number of improvements and a training plan in place for those in need. She is writing the standard operating procedures for the data officer. Additionally the IT department have seconded another senior data analyst to create the reports for quality indicators identified by us in the clinical/scientific field. I expect that preliminary steps would have been taken by the end of this month and by the end of this year we should be able to generate regular Further the data officer will also produce the regular analysis of 'Patient Satisfaction Questionnaires' which will cover the non-scientific part of the quality indicators.	Further action is required. This will be monitored via the compliance cycle.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The centre has a high uncorrected error rate in their submission of data via EDI to the HFEA. The PR should ensure that information is provided to the HFEA in line with the requirements of Directions 0005 including timely submissions and error corrections.	The PR should continue to correct errors.	This matter has been dealt with to a very large extent. **For centre 0052**: Out of 1875 errors identified in May 2010, there are now 19 remaining errors to resolve. **For centre 0063**: Out of 758 errors identified in May 2010, there are now nil left to resolve. **For centre 0314**: Out of 1001 errors identified in May 2010, we have 138 errors left to resolve. Most of these are programming errors and we are waiting for the data programmer Richard Cannon to resolve these. Subsequent to this correction which is expected by the end of this month the centre 0314 errors should plummet.	Further action is required An error correction report has been submitted that shows a substantial reduction in error rates and corrections being made within the required timeframe. This will be monitored via the compliance cycle.

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 and Reference	Action required and timescale for action	PR Response	Executive Review
The centre does have a documented bring forward system but it is reliant on a computerised database that contains all the relevant details and prompts. At the time of inspection the PR said that this database could not be accessed by centre staff as they don't have the resources of a data analyst to monitor and extract the necessary information. Guidance 17.17	The PR should ensure that the centre can access the bring forward system in order to ensure sufficient advance notice of the end of the statutory storage period (or such shorter period as specified by a person who provided the gametes) for gametes or embryos in storage By 01/12/2010	LCRM database operates as has done in previous years on a 3 month bring forward system. This process has not been fully implemented because of a few database errors that came to light and because of long term sickness of the team member(s) delegated this responsibility. We expect that the data officer will take charge of this and ensure that timely action takes place in the future	Further action is required The PR should submit a final report of compliance on or before the 01/01/2011

Area of practice and Reference	Action required and timescale for action	PR Response	Executive Review
Nursing staff participate in procedures where witnessing is required but have not been assessed as to their competency to perform this task. Standard Licence Condition T15a	The PR should ensure and document that each member of the nursing staff have demonstrated competence in the performance of their designated task relating to witnessing. By 01/12/2010	This has been completed.	No further action is required.
Reporting arrangements with the centres third party agreements with satellite centres. Standard Licence Conditions T110 & T117).	The PR should continue to develop the evaluation and reporting arrangements for the centre's third party agreements with satellite centres	The process of regular non-administrative evaluation of the third party agreements with satellite centres is being developed. The PR has created a Self Assessment Questionnaire for the satellite centres which is to be dispatched to the satellite centres as soon as we become aware that HFEA Chair has informed the satellite centres to expect this evaluation from the primary centre. We will also start an audit programme of their notes and consents. Once completed, we have plans to undertake a formal on site evaluation on an annual basis.	Further action is required This will be monitored via the compliance cycle

Additional Information from the Person Responsible

We take compliance with the HFEA quite seriously in our unit. As a matter of evidence I enclose our own identified weaknesses at the last inspection and the action points we generate which of course will be completed.

I have also developed a SAQ for satellite centres which is modelled on HFEA's own SAQ for primary centres. This is for your information and we hope to implement this or something similar as soon as the Chair has advised the satellite centres to expect inspection/evaluation from the primary centre on an annual basis.

It has been a marathon task to merge the two large centres with understandably differing methodologies and processes. Equally it has been a considerable effort and to get everyone subscribing to a common new process and there have been some training needs. We are not completely there yet but the team has the right aptitude and sincerity with which I have no doubt that next year we would have realised the benefits of many new developments that have been enacted and are in the pipeline.

Mrs Vinay Sharma
Consultant Gynaecologist
Person Responsible

HFEA Executive Licence Panel Meeting
17 November 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0314 (The Leeds Centre For Reproductive Medicine) – Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Mark Bennett – Director of Finance & Facilities	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 Directions 0000 – 0012
- 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 located within the Leeds Teaching Hospitals NHS Trust. Following a new premises/centre inspection it was granted its first HFEA licence on 25 January 2010 for a period of two years with no additional conditions.

2. The Panel noted that the centre was formed as a result of the merger of the Reproductive Medicine Unit Leeds General Infirmary (centre 0052) and Assisted Conception Unit, St James' University Hospital Leeds (centre 0063).

3. The Panel noted that all stored material, records, scientific and treatment services have been transferred to the new facility and both these centres have now been closed and licences revoked (October 2010).

4. The Panel noted the areas of non-compliance identified in the report, but noted that none were critical, and a large number have been dealt with or are in the process of being addressed.

5. The Panel noted the positive response from the Person Responsible (PR) within the report.

Decision

6. The Panel were satisfied that the centre is largely compliant and noted the actions underway to address the areas of non compliance identified.

7. The Panel noted and endorsed the Inspectorates recommendations highlighted within the report.

8. The Panel agreed to the continuation of the centres licence with no additional conditions.

Signed: Peter Thompson Date: 3/12/10.

Peter Thompson (Chair)