Interim Licensing Report

Centre name: Royal Surrey County Hospital
Centre number: 0159
Date licence issued: 01/03/2011
Licence expiry date: 31/03/2015
Additional conditions applied to this licence: None
Date of inspection: 24/10/2012
Inspectors: Janet Kirkland Machattie, Andy Glew
Date of Executive Licensing Panel: 11/01/2013

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note: the information and support given to patients attending the centre and the PR's positive response to the inspection report and adoption of recommendations.

The Executive Licensing Panel is asked to note that at the time of the inspection there was one recommendation relating to a **'critical'** area of non-compliance, two **'major'** areas of non-compliance and three **'other'** areas of non-compliance.

Since the inspection, the PR has provided assurance that the following recommendations have been fully implemented:

'Other' area of practice that require improvement:

- The PR should ensure that each patient record contains patient's first name, surname, date of birth age and sex and that all documents relating to the patient are maintained in a secure format.
- The PR to ensure that patients are screened for Hepatitis B core antigen antibody (anti-HBc).

Since the inspection, the PR has given a commitment to fully implement all of the following recommendations:

'Critical' area of non-compliance:

- The Person Responsible (PR) should ensure that two unique patient identifiers are used to positively identify the patient and his gametes at all critical points in the clinical and laboratory process.

'Major' area of non- compliance:

- The PR should ensure that the documentation of the disposal of samples includes the signatures of the person doing the procedure, the witness and the time of the procedure.

'Other' area of practice that require improvement:

- The PR should ensure that their systems of audit are robust and should include whether practices are compliant with regulatory requirements.
- The PR to assess for each patient whether any additional testing is required as per licence condition T50.ie. HTLV-1, RhD,,Malaria CMV,T.cruzi .

Information about the centre

The centre is part of the Royal Surrey County Hospital in Guildford and operates within that NHS Trust and has held a licence with the HFEA since 1994. The centre's current licence was granted on 1 March 2011 for a period of four years with no additional conditions.

The centre provides a sperm storage service for both self funding and NHS patients most commonly for the preservation of fertility prior to urological surgical procedures or chemo/radiotherapy treatment.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law. It is however recognised that certain themes for this inspection do not apply to the service provided by this centre and where this is the case, this is indicated in the report.

Outcomes[1]

This theme does not apply as this centre holds a storage only licence and does not provide treatment services.

Multiple births[2]

This theme does not apply as this centre holds a storage only licence and does not provide treatment services.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. There were no laboratory activities on the day of the inspection so witnessing practices and procedures could not be directly observed on the day of inspection. An evaluation of patient identification and witnessing practices and procedures was made on the basis of discussions with staff and a review of documentation.

The inspection team was able to review five patient records and concluded that records of manual witnessing are maintained.

The form 'Cryopreservation of Semen' used for the active identification of the patient and documentation of all witnessing steps for the processing, storage and disposal of gametes constitutes the primary patient record. This form records the patient's name and signature but does not record the patient's date of birth or other unique identifier. This leads the inspection team to conclude that it is not possible for the centre to have adopted witnessing procedures compliant with the requirements of T71 and CoP guidance at 18.4 which

recommends the cross-check of information marked on dishes and tubes against the patient's or donor's records at critical stages (see recommendation 1).

Documentation such as laboratory results and the patient's medical history are stored together loosely in a plastic wallet specific to each patient. Wallet files seen appeared to be complete but it was felt that storing records in this way may present a risk that loose documents may be displaced and or lost (see recommendation 4).

The documentation of disposal of samples does not include the signature of the witness or time of the procedure (see recommendation 2).

Consent: Disclosure to researchers

Since 1 October 2009, the HFEA has been able to release patient-identifying information regarding their treatment held by the HFEA to researchers if patients give their permission. As this centre does not provide treatment services consent to disclosure to researchers is not sought therefore this theme does not apply.

Consent: To the storage of cryopreserved material

A review of the centre's records of consent to storage of gametes showed that all gametes currently in store are being stored in accordance with the consent of the gamete providers and are within the consented storage period.

The consent recorded on one patient record was referenced against the centres consent to storage data base. The consent recorded in the patient record and on the centre's storage confirmed that the patient's sample is being stored with the valid consent of the gamete provider.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out.

Patient experience

It was not possible to speak with patients on the day of the inspection and the HFEA has had no feedback from patients since the last inspection. However from discussion with the team and review of patient information material it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations and discussions with centre staff during the visit to the centre, the inspection team identified the following non-compliance:

- patients are not routinely screened for hepatitis B core antigen antibody (anti-HBc) prior to storage of their gametes (see recommendation 5).

The PR also responded negatively in the SAQ to the question as to whether additional testing is carried out as required by licence condition T50 ie: HTLV-1 antibody testing for patients living in or originating from high incidence areas and additional testing depending on the patients travel, sexual and exposure history. The PR explained that in general when patients attend for cryopreservation of the semen this is prior to the commencement of essential medical/surgical treatment and the time available to collect and store samples is limited (see recommendation 6).

The PR reported in the self-assessment questionnaire that the centre's procedures for traceability and witnessing had been subject to an audit of practice against compliance with the regulatory requirements and their own approved protocols and quality indicators. As the audit failed to identify that records did not record the patient identifiers as required by SLC T102 and necessary to ensure that witnessing requirements could be satisfied in line with the requirements of SLC T71, this suggests that the centre's audit procedures are not robust. The same observation is made in relation to the audit of screening requirements which failed to identify non-compliance with the requirement to screen for anti-HBc.(see recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2010 recommendations for improvement were made in relation to six areas of major non-compliance and three 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

Annex 1

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 required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. The 'cryo preservation of semen' form records only the patient's name and signature. This is non compliant with the requirements of SLC T46(a & b) CoP guidance 18.5 and with the traceability requirements of SLC T102. This leads the inspection team to conclude that it is not possible for the centre to have adopted witnessing	The PR should initiate changes in procedure immediately to record the additional information required by T46 and T71 The PR should review the centre's procedures and make any required changes to standard operating procedures for traceability, record keeping and document control and witnessing. A summary report	There is now a space at the top of the witnessing form where PID can be inserted either in the form of a printed hospital label or for patient to record his name and dob. The requirement to do this has also been added to the SOP Patient's name, address and dob is recorded on the request card and the witnessing form with traceability data is attached to this. Training given	The inspector has received a copy of the "cryo-preservation form "and acknowledges the PR's assurance that either a label will be applied to the form or that the patient will be asked to record their date of birth in addition to their full name. However, the PR is encouraged be more prescriptive regarding how patients details are recorded in order to reduce risk and

procedures compliant with the requirements of SLC T71 and CoP guidance at 18.4 which recommends the cross-check of information marked on dishes and tubes against the patient's or donor's records at critical stages. .	of the findings of the reviews; any corrective actions identified and a timescale for their full implementation should be provided to the HFEA by 24 January 2013. Staff should be provided with update training as required Confirmation of the provision of this training should be provided to the HFEA by 24 January 2013.	30.11.12. Minutes of meeting attached	ensure consistency. This form is also used as the primary witness form and the PR is asked to insure that at **each** witness point there is a prompt to enter the name of the witness in addition to the date and time of each witness point. Further action required

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, embryo or child who may be born as a result of treatment services
- 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	Inspection team's response to the PR's statement
2. The documentation of disposal of samples does not include the signature of the witness or the time of the procedure. CoP guidance 18.7	The PR should ensure that the disposal of samples is witnessed and documented in accordance with CoP guidance 18.7. A change in practice should be implemented immediately The PR should review the centre's procedures for witnessing and make any required changes to standard operating procedures. Staff should also be provided with update training as required. A copy of the centre's revised standard operating procedure and confirmation of the provision of training should be provided to the HFEA by 24 January 2013.	Disposal of samples has been added to the witnessing form for 2 signatures. Included in SOP (attached) Training 30.11.12. See attached	The inspector is satisfied with the response. SOP received 7 December 2012. Further action required to confirm provision of training.

3. The centre's procedures for audit are considered unlikely to be robust. SLCT36	The PR should undertake an audit of all practices performed at the centre including traceability, documentation and witnessing in April 2013. The audits should review activities undertaken after the date of the inspection subsequent to the implementation of revised practices. The audit should evaluate whether practices are compliant with regulatory requirements. A summary report of the findings of the audits should be provided to the HFEA by 24 May 2013.	Audit to be carried out with report submitted to HFEA by 24 May 2013.	The inspector is satisfied with the response and looks forward to receiving the summary report of the findings of the audit by 24 May 2013. Further action required

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 statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
4. Each patient's documents are contained within a plastic folder. Documents are not attached to the folder and are loose within it. This could lead to documents being lost or misfiled. SLC T46,T47. T48	The PR should risk assess the current form and arrangement of patient files/results and information and consider if this could be made more secure and ensure full traceability. The PR should inform the executive of the result of this risk assessment and of any subsequent changes in practice by 24 January 2013	Patient record to be held in a secure wallet. All records will be moved to a secure wallet and HFEA informed by 24 January 2013.	The inspector is satisfied with the response. Records to be seen on next inspection. No further action required
5. Patients storing samples are	The PR informed the inspection team on	This is now occurring.	The inspector is

not routinely screened for anti-HBc SLC T50(a)	the day of the inspection that patients would be screened for anti-HBc with immediate effect.	SOP has been reviewed and changes made. Immunology are aware this test needs to be carried out.	satisfied with the response. No further action required
6. The PR response in the SAQ indicated that HTLV-1 antibody screening is not performed nor is additional screening carried out depending on the patient's travel and exposure history SLC T50 (c)(d).	On the basis of information currently available the HFEA accepts that the risks of transmission of HTLV may not be significant enough to warrant screening of patient groups other than gamete donors. The PR should make formal assessment of the risks of excluding some patient groups from screening for HTLV .The findings of the assessment should be documented and the HFEA provided with a copy of the assessment by 24 January 2013. The PR should also ensure that patients are assessed to identify whether additional screening is required depending on their travel and exposure history. Screening procedures should be reviewed and revised as appropriate and a copy of the SoP should be provided to the HFE by 24 January 2013.	Discussion to take place with oncology and immunolgy to establish a way forward.	The inspector accepts the response and looks forward to receiving the results of the discussions and updated SOP. Further action required

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

11 January 2013

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 1

Centre 0159 – (Royal Surrey County Hospital) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Nick Jones, Director of Compliance Joanne Anton, Policy Manager	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 has been licensed since 1994 and provides a sperm storage service for both self-funding and NHS patients, most commonly for the preservation of fertility prior to urological surgical procedures or chemo/radiotherapy treatment.

2. The Panel noted that the centre's current licence is due to expire on 21 March 2015.

3. The Panel noted that the centre was inspected in October 2012, and at the time of the inspection the Inspectorate identified one critical, two major, and three other areas of non-compliance.

4. The Panel noted that since the inspection visit the Person Responsible (PR) has addressed two of the other areas of non-compliance, and has given a commitment to address the other outstanding recommendations.

5. The Panel noted in particular the critical area of non-compliance that the PR should ensure that each patient record contains the patient's first name, surname, date of birth, age and sex and that all documents relating to the patient are maintained in a secure format. The Panel urged the PR to address this recommendation within the prescribed timeframe, and to inform the Inspectorate when this has been completed.

6. The Panel noted that the Inspectorate recommended the continuation of the centre's licence without additional conditions.

Decision

7. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence with no additional conditions. In particular, the Panel noted the information and support given to patients attending the centre and the PR's positive response to the inspection report.

Signed: Date: 31 January 2013
Juliet Tizzard (Chair)