Interim Licensing Report

Centre name: **Bristol Centre for Reproductive Medicine**
Centre number: **0295**
Date licence issued: **19/12/2010**
Licence expiry date: **18/12/2014**
Additional conditions applied to this licence: **None**
Date of inspection: **06/12/2012**
Inspectors: **Douglas Gray (lead), Gill Walsh**
Date of Executive Licensing Panel: **15/03/2013**

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 positive comments made by patients in relation to their experience.

The team has made recommendations for improvement and these should be implemented within the time specified.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to one 'critical' area of non-compliance, two 'major' areas of non-compliance and four 'other' areas of non-compliance as follows:

'Critical' areas of non compliance:

- **The Person Responsible (PR) should continue to make progress to either obtain written consent to storage or, allow samples to perish if the statutory storage period has been exceeded or if there is no effective consent to storage.**

'Major' areas of non compliance:

- The PR should develop a comprehensive schedule for the audit and/or revalidation of practices and procedures that could impact on their clinical pregnancy rate following frozen embryo transfers (FETs).
- The PR should ensure that treatment outcomes are continually monitored in line with their current multiple births minimisation policy.

'Other' areas of practice that require improvement:

- The PR should ensure that records of consent to disclosure identified on inspection as being inaccurately reported to the HFEA are corrected with immediate effect, and determine whether the consent discrepancies noted on inspection are isolated occurrences or are more prevalent.
- The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification and take corrective action where appropriate.
- The PR should take remedial action to ensure compliance with the data submission requirements of Direction 0005.
- The PR should report to the HFEA as an adverse incident the disposal of storage consent forms for patients with gametes in storage, and if appropriate, report as an adverse incident the continued storage of gametes for which consent forms have been destroyed.

Since the inspection, the PR has provided assurance that recommendations have been fully implemented relating to multiple births, and labelling of containers at egg collection. Progress towards implementing the remaining recommendations is on-going.

Information about the centre

The Bristol Centre for Reproductive Medicine is located at Southmead Hospital, Bristol and has held a HFEA licence since December 2007 following the amalgamation of two other HFEA licensed centres located in Bristol. The centre's current licence was granted in December 2010 for a period of four years.

The centre provides a full range of fertility services. The centre provided 1194 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2012. In relation to activity levels this is a large centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes that are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law:

Outcomes[1]

HFEA held register data for the year ending July 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages, with the following exception:

Clinical pregnancy rate for FET cycles following IVF or intra-cytoplasmic sperm injection (ICSI) in patients aged 16-39 are lower than average; this is at a level that is statistically significant (see recommendation 2).

For the year 2011 the centre reported 174 cycles of partner insemination with 33 pregnancies. This equates to a 19 % pregnancy rate and is consistent with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 21 %: this represented performance that was not likely to be statistically different from the 20 % live birth rate target.

[1] 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.
[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

For the time period April 2011 to September 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 26 %: this represents performance that is likely to be statistically different from the 15 % live birth rate target.

Data held by the HFEA show that the centre's clinical multiple pregnancy rate has increased since 2010. The inspection team therefore has concerns that the centre may not meet the 10 % multiple live birth rate target that became effective on 1 October 2012. On inspection, the PR confirmed that in September 2012 the centre implemented a single embryo/blastocyst transfer policy and its effectiveness would be monitored on a monthly basis and audited in spring 2013 (see recommendation 3).

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: active identification of the patient at egg collection, transfer from tubes to dishes at egg collection, thawing of gametes and sperm preparation. Tubes used to collect follicular fluid which are then transferred to the laboratory were not labelled with patient identifying information (see recommendation 5). All other procedures observed were witnessed in accordance with the HFEA requirements using a manual system. The centre has recently installed an electronic witnessing system which will be validated during 2013.

The inspection team was able to review 10 witnessing records that were present in the laboratory and concluded that records of manual witnessing are maintained at all critical time points.

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 10 patients (and their partners) were reviewed during the inspection. The consent forms were completed, but for one patient an error had been made by the centre when reporting the consent decision through the EDI system (see recommendation 4). In the patient's records, consent to disclosure had not been given by the patient but the centre reported that consent had been given. Errors of this kind represent a significant risk that patient information could be disclosed contrary to the patient consent.

Consent: To the storage of cryopreserved material

There are consent issues relating to cryopreserved sperm. This issue was known to the HFEA following on-site inspections in both 2009 and 2010 and largely relates to samples stored before the formation of Bristol Centre for Reproductive Medicine following the merger of two centres in 2007.

Following the inspection in 2010, a commitment was made by the PR to complete an audit of cryopreserved material and to discard any of those samples without effective consent to storage. A summary of the final audit and corrective actions identified was expected from the centre by February 2011, but given the scale and complexity of this task, and changes in legal advice provided independently to the centre, this was not made available to the HFEA until the time of this on-site inspection.

The audit identifies a number of complex scenarios applying to 142 patient samples; based on the information provided in the audit summary, 36 samples remain in storage without appropriate consent, and a decision is still pending for eight samples (see recommendation 1). A further 22 samples were placed in storage prior to the 1991 HFE (Statutory Storage) Regulations. All remaining samples identified in the audit are considered to have appropriate consent to storage.

The summary also identified that a number of historic patient files, including copies of storage consent forms, have been destroyed. The HFEA requires records to remain traceable for a period of 30 years after their clinical use (see recommendation 7).

In addition to monitoring compliance with previous recommendations, the on-site inspection also focused on the robustness of the centre's current storage system. A review of the centre's records of consent to storage of embryos showed that embryos currently in store are being stored in accordance with the consent of the gamete providers and are within the consented storage period. The storage periods for three sets of embryos recently placed into storage as recorded on the centre's database were cross checked against the consent given by the gamete providers. The storage period had been accurately recorded in all cases.

The centre operates a bring forward system to ensure sufficient advance notice is given to patients that the end of the consented storage period is approaching; this system, as it applies to recently stored material, was discussed on inspection and was considered by the inspectors to be robust.

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: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit we spoke to three patients who provided feedback on their experiences and we observed interactions between centre staff and patients. A further 62 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive with 51 of the 62 individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- gives prospective and current patients 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 during the visit to the centre, the inspection team identified no non-compliances. However, a discussion was held with centre staff regarding their diagnostic semen analysis activities:

- Centre staff explained that they have decided not to seek CPA accreditation. The centre considers that they have status equivalent to that conferred by CPA accreditation on the basis that they have: a HFEA reviewed quality management system; validated procedures and equipment; staff suitably qualified to perform and interpret the tests; and that they participate in the National External Quality Assessment Scheme (NEQAS) for semen analysis. The centre also holds an ISO 9001:2008 certificate. The PR has provided assurance that the HFEA will be informed if they cease to participate in NEQAS.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2010, a recommendation for improvement was made for one area of critical non-compliance in relation to the storage of gametes without consent discussed elsewhere in this report. Further recommendations for improvement were made in relation to nine areas of major non-compliance and four 'other' areas of non-compliance. Whilst not completed within the given times due to a focus of efforts on the critical non-compliance, the PR provided evidence prior to the inspection that these remaining recommendations were now fully implemented.

On-going monitoring of centre success rates

Since the introduction in April 2012 of an automated system of email alerts based on HFEA held register data, the centre has received three alerts relating to multiple pregnancy rates. The centre responded to these alerts to the satisfaction of the inspector and the centre's action in relation to multiple births is discussed elsewhere in this report.

HFEA held register data for the year ending July 2012 show the centre's clinical pregnancy rate for FET in patients aged 16 -39 are lower than average; this is at a level that is likely to be statistically significant. During the inspection, the centre described proactive steps they have taken to audit some practices in this area. The centre has committed to implementing a number of corrective actions identified from their audits including changes to their embryo

freezing policy and have provided a commitment to keep under review the success rates in this treatment group (see recommendation 2).

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The centre currently has a number of register submission issues as follows:

- At the time of inspection a significant number of data submissions were outstanding. This has an impact upon the effectiveness of HFEA tools to monitor clinical and multiple pregnancy rates and potentially the HFEA's ability to fulfil statutory obligations to donor-conceived offspring (see recommendation 6).

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 centre does not have written effective consent for all cryopreserved sperm. HF&E Act (1990, as amended) 17(1)(c) and Schedule 3(8).	The PR should continue to make progress to either obtain written consent to storage or, where the centre has followed its own procedures and determined that it is appropriate, should allow samples to perish when the statutory storage period has been exceeded or if there is no effective consent to storage. The PR should ensure that samples placed in storage prior to the 1991 HFE (Statutory Storage)	We would wish the report to indicate more clearly that the stored samples involved in the critical area of non compliance were placed into storage and managed at a previous clinic and not as a result of any mis-management by the BCRM. We also question whether this matter fits the definition of a critical incident, as the HFEA definition of a critical incident [as stated above]: 'an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or	This non-compliance is catagorised as a 'major' in the Executive's 'Compliance Framework'. It is recognised that it does not fit the definition of a 'critical' non-compliance, but in accordance with the framework it has been escalated to this category because this continues to be an issue from the previous two inspections. The inspection team appreciates the PR's commitment to resolve these

	Regulations are stored pursuant with Chair's Letter CH(01)06 and the Code of Practice (guidance note 5). The PR should supply the HFEA with monthly updates until the issues are resolved.	child who may be born as a result of treatment services. Furthermore, during the inspection the centres current system for ensuring consent and storage was investigated and shown to be a robust system which is working well; this is not the impression the report would represent to patients or others. A critical area of non compliance requires immediate action to be taken by the Person Responsible'. We have been transparent concerning our efforts to resolve this historical anomaly and have allocated susbtantial resources towards rectifying the situation. We remain very open about the ongoing progress and will continue to update the HFEA about all the steps we have take. We consider this an area where appropriate action is taking place and is managed by fully engaged staff. We also are fully aware that samples stored without effective	long-standing issues and recognises the robust systems in place currently. The inspection team will continue to work closely monitoring the progress in resolving this issue on a monthly basis. The executive expects this issue to be fully resolved within nine months.

		consent is in breach of the law, as such we have taken legal advice and believe we are working in the best interest of the patient who stored samples many years ago at a different centre. We would ask the HFEA to consider reporting current practices rather than representing those inherited from a different centre. We have provided the HFEA with all the information regarding current procedures for the disposal of these samples. We are happy to provide monthly updates until the matter is resolved.	

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. HFEA held data shows the clinical pregnancy rate following FET in women aged 16-39 is lower than the national average at a level that is likely to be statistically significant. SLC T36 & T72	The PR should develop a comprehensive schedule for the audit and/or revalidation of all practices and procedures that could impact on their clinical pregnancy rate following FETs. A copy of the plan should be provided to the inspection team by 6 March 2013, and summary reports of the audit findings should be provided on a monthly basis. Where corrective actions are implemented, SOPs should be updated and provided to the inspection team; update training should be provided to relevant staff and confirmation of receipt of the training should be provided. The PR should ensure that the impact of any corrective actions is audited and summary reports of those audits should be	A report has previously been sent to the HFEA about this. We are currently evaluating, validating other cryopreservation systems using samples donated for training purposes. Workshop/update training arranged for 8th February 2012.	A summary of the centre's recent audits of clinical pregnancy rates following FET was received in December 2012. The inspection team accept the PR's

	sent to the inspection team on a monthly basis.	Monthly updates: we do not feel that any meaningful results will be shown by monthly updates, but after careful consideration we consider tri monthly updates would provide larger data sets in which monitor progress in this area. Although as stated during the inspection any changes implemented are unlikely to impact CPRs significantly for many months if not years. We still have the ethos that patients should have some choice in storing and thawing of their embryos. Therefore Patient choice in terms of embryos frozen or the thawing strategies will have a huge impact on	rationale for providing three monthly up-dates. The inspection team will continue to monitor the centre's outcomes and progress with revalidation of processes relating to FET. Clarification has been received that embryos are being used for training purposes compliant with T93.

		clinical pregnancy rates	
3. The centre did not meet the 15 % target rate for multiple live births, and the inspection team has concerns that the centre may not meet the 10 % multiple live birth rate target that became effective on 1 October 2012. SLC T123; General Direction 0003	The centre implemented corrective actions in September 2012 and as a result, no further recommendations are considered necessary pending monitoring of the impact of the changes to practice. The centre should ensure that they continue to monitor treatment outcomes in line with their current multiple births minimisation policy, and HFEA risk tool data in order to determine whether any further adjustments are required.	MBR – policy has already been amended; impact will begin to be noticed and is continually reviewed. Can we suggest consideration is given to the wording of the report to refelct this, as currently it suggests we have not been monitoring our multiple birth rate.	The inspection team acknowledges the PR's response and will continue to monitor this area.

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. An audit of decisions for consent to disclosure to researchers	The PR should ensure that records of consent to disclosure identified on inspection as being inaccurately reported to the HFEA are corrected with immediate effect.	The Quality Manager has reviewed the errors with the member of staff who entered the data and only one error, rather than three were identified. This has now been amended. As suggested, an audit of sample patients is	The inspection team can confirm that only one error was identified during the audit and the centre has now

held in patient notes against that submitted to the HFEA showed an error. General Direction 0007	The centre should audit a sample of patient and partner consents to disclosure of information to researchers documented in patient records, against the consent decisions submitted to the HFEA, to determine whether the consent discrepancies between these sources noted on inspection are isolated occurrences or are more prevalent (SLC T36). The PR should ensure that a summary report is submitted to the inspection team. By 6 June 2013.	underway and any corrective actions and a summary report will be forwarded to the HFEA before 29th March 2013.	corrected this. We await the summary report and will work with the PR should further action be required.
5. Egg collection tubes are not labelled with patient identifying information. SLC T101	The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification and take corrective action where appropriate. Action could include the introduction of a check step to confirm that critical work areas are cleared in between egg collection cases. The risk assessment and details of any action taken should be submitted to the centre's inspector by 6 March 2013.	A risk assessment has been undertaken and the introduction of a checkbox to confirm that critical work areas are cleared in between egg collection cases has been implemented. The paper work was forwarded to Dr Gray on 20th December 2012 prior to receipt of this report. The information forwarded previously will be included at the end of this report.	The inspection team is satisfied with the PR's response. The PR is asked to submit a copy of the risk assessment by 6 March 2013.

6. At the time of inspection a significant number of data submissions were outstanding. General Direction 0005 SLC T9(e) & T41	The PR should take remedial action to ensure compliance with the data submission requirements of Direction 0005. The PR should review the centre's procedures for the submission of information to the HFEA's register and provide a summary to the inspection team of that report and any relevant corrective actions. Where corrective actions are implemented, SOPs should be updated and provided to the inspection team; update training should be provided to relevant staff and confirmation of receipt of the training should be provided to the inspection team. By 6 March 2013 The PR should audit the submission of forms since the implementation of corrective actions and submit to the inspection team a summary of the findings. By 6 June 2013	A review of the procedures for submission of data is currently taking place. Any corrective actions will be forwarded to the HFEA. An audit of any corrective actions will be undertaken and a summary of any report will be sent to the HFEA on the 6th June 2013	We await the summary report and will work with the PR should further action be required.
7. Patient consent forms have not been	The PR should report to the HFEA as an adverse incident the loss or disposal of storage consent forms for patients with gametes in	As stated previously this is an inherited issue and no consent for patients of the BCRM centre 0295 has been destroyed. If this is ever happened this would be reported to the HFEA.	The inspection team acknowledges that this issue was identified as a result of the centre's

kept for a minimum of 30 years after clinical use, in an appropriate archive. SLC T48	storage. The PR should provide documented reassurance that the requirements to retain patient consent forms have been communicated to staff, both within the centre and if appropriate within relevant NHS trusts. Policies relating to this Licence Condition should be reviewed and amended as appropriate to ensure consent forms are not disposed of within the 30 year statutory period. By 6 March 2013 If the centre decides to continue to store gametes for which consent forms have been destroyed, the PR should report this as a separate incident. By 6 March 2013	Please find enclosed/ attached a SOP for the retention of records and all staff are aware of these requirements BCRM had assumed that as the historic storage of sperm without effective consent had been discussed in an ongoing manner with the Authority that this was not necessary. If deemed necessary we can report the incidents by 6th March 2013.	own audit, and that these records were not in the control of BCRM at that time. However, the inspection team have no documented record of the details relating to these consent forms being destroyed. We request that the PR retrospectively reports this incident as a point of learning to facilitate the investigation of events surrounding the loss of these documents. Pending the PRs review of stored gametes, any decision to continue storage of samples without consent is considered a new event and we request the PR reports this as an incident.
Additional information from the Person Responsible			

- The report is quoting success rates that have not been validated yet, ie to Q2 2012 when the HFEA websites have only 2010 LBs and 2011 CPs
- The BCRMs success rates are reported as being in line with the national average. In fact, some areas of treatment are statistically above the national average, as reported via the HFEA website, ie the latest Live Birth Rates for <35 and 38-39 year olds undertaking IVF or ICSI. These patient groups account for more than half of our patients.
- In the main body of the report it is mentioned that we have an HFEA reviewed QMS – Perhaps the HFEA could include/ reflect in the report that our centre holds ISO accreditation.

HFEA Executive Licensing Panel Meeting

15 March 2013

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

Minutes – Item 3

Centre 0295 – (Bristol Centre for Reproductive Medicine) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Ian Peacock – Analyst Programmer Matthew Watts – Regulatory Policy Manager	Rebecca Loveys

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 is a large centre which provides a full range of services, and has been licensed since 2007 following the amalgamation of two other HFEA licensed centres located in Bristol.

2. The Panel noted that the centre's current licence is due to expire on 18 December 2014.

3. The Panel noted that, during the 12 months to 31 October 2012, the centre provided 1194 cycles of treatment (excluding partner intrauterine insemination) and that its outcomes were within the national average, except for the clinical pregnancy rate for Frozen Embryo Transfer (FET) cycles, which was below the national average. The comments of the Person Responsible (PR) regarding success rates in some categories being higher than the national average were noted.

4. The centre's performance on multiple births was noted. In particular, the Panel noted the change in policy regarding single embryo transfer in September 2012 following the previous year's performance that was assessed as not likely to meet the target. The Panel urged the PR to keep this performance under review.

5. The Panel noted that, during the inspection, the Inspectorate identified one critical, two major and four other areas of non-compliance.

6. The Panel noted that the critical area of non-compliance, regarding the storage of cryopreserved sperm without consent, is an historic issue which the centre inherited following the amalgamation. Whilst the Panel recognised this is a legacy issue, it urged the PR to deal with this long-standing matter.

7. The Panel noted that current practices at the centre appear robust regarding consent and so the non-compliance would not become worse.

8. The Panel noted the action required with regard to the critical area of non-compliance and urged the PR to provide the Inspectorate with regular updates until the issue is resolved, so that it is resolved within nine months, as stated in the inspection report.

9. The Panel noted that the clinic holds ISO accreditation for its quality management system.

10. The Panel noted the need for formal reporting of the loss of consent to storage forms as an incident. It recognised that the loss was an inherited issue and that the reporting should have been done by 6 March 2013.

11. The Panel noted the centre's progress on some of the non-compliances highlighted in the report, as well as its commitment to resolve others which have not yet been fully addressed.

Decision

12. The Panel urged the PR to keep the Inspectorate updated as per the report and to completely resolve the long-standing issue regarding lack of consent.

13. The Panel agreed to the Inspectorate's recommendation to continue the centre's licence with no additional conditions.

Signed:  Date: 26 March 2013

Mark Bennett (Chair)