Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years at renewal. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 30 April and 1 May 2013
Purpose of inspection: Renewal of a licence to carry out 'Treatment with Storage'.

Inspection details:

The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Date of Executive Licensing Panel: 2 August 2013

Centre name	Cambridge IVF
Centre number	0051
Licence number	L/0051/14/a
Centre address	Kefford House, 2 Maris Lane, Trumpington, Cambridge, CB2 9LG
Person Responsible	Mr Raj Mathur
Licence Holder	Miss Amanda Cahn
Date licence issued	1 October 2011
Licence expiry date	30 September 2013
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the Centre and its licensing history:

Cambridge IVF was formerly The Rosie Hospital which was licensed by the HFEA from 1992 for the storage of sperm only. Application to vary the centre's licence to reflect a change of centre name and premises, along with licence renewal and variation to achieve a full Treatment with Storage licence was approved by the ELP in September 2011. The centre was granted a two year licence as standard for a new Treatment with Storage licence.

Cambridge IVF is registered with the Care Quality Commission (CQC) and is part of the Cambridge University Hospitals NHS Foundation Trust. The centre is situated at Kefford House, a new, purpose built stand alone unit on the outskirts of Cambridge. Accommodation is arranged over two floors with a reception and waiting area, laboratory facilities, operating theatres and sperm production room on the ground floor. The upper floor is accessible via a lift or stairs. This area houses consultation and scan rooms, offices and a spacious seminar room where patient information evenings take place. All areas are accessible to wheelchair users.

The centre provides a full range of fertility services and has capacity to provide up to 100 intra uterine insemination (partner / donor) and up to 700 IVF / ICSI / FET treatment cycles per annum to both NHS and self funded patients. 109 cycles of treatment (excluding partner intrauterine insemination) were provided in the 12 months to 31 March 2013. In relation to activity levels this is currently a small centre. The low activity levels relative to the planned capacity for this centre was explained by the PR as being due to commissioning contracts for surrounding Care Commissioning Groups (CCGs) still being in place with other providers and that activity is unlikely to increase significantly until such time as other contracts are agreed or existing service provision contracts are re-allocated locally. The centre currently continues to act as a satellite to Oxford Fertility Centre 0035 as part of this commissioning arrangement.

Activities of the centre:

Type of treatment	Treatment cycles performed in the year to 31 March 2013
In vitro fertilisation (IVF)	50
Intracytoplasmic sperm injection (ICSI)	37
Frozen embryo transfer (FET)	18
Donor insemination (DI)	4
Partner insemination (IUIP) (01/01/2012 – 31/12/2012)	8

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓

Outcomes*

For IVF and ICSI, HFEA held register data for the period January 2012 to December 2012 show the centre's success rates are in line with national averages.

In 2012 the centre reported eight cycles of partner insemination with two pregnancies, this is consistent with the national average.

Between 1 October 2011 (the point at which the centre's initial Treatment with Storage licence was issued) to 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 6%: this represented performance that was not likely to be statistically different to the no greater than 15% multiple live birth rate target for this period.

*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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the PR is suitable and he has discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major and eight 'other' areas of non-compliance or poor practice.

Since the inspection and prior to this report being presented to the ELP the PR has provided evidence that the following recommendations have been implemented:

'Other' areas of non-compliance or poor practice that require improvement:

- The PR should review the centre's process for checking and recording the consented storage period to ensure that both gamete providers consent recorded is consistent and that centre records in the bring forward system accurately reflect this.
- The PR should ensure that quality indicators are established to monitor the effectiveness of the selection and screening procedures for known donors.

- It is acknowledged that recall is likely to be infrequent, however should a recall be necessary, staff should have clear instruction for how to proceed, the PR should ensure that a suitable procedure is established.
- The PR should provide a list of the equipment still to be validated including the date of validation or the planned date by which validation is expected to be complete.
- The PR should ensure that centre staff are aware of the requirement to provide donor goodwill and pen portrait information. The related SOP should be updated to reflect this requirement.

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

Major areas of non compliance:

- The PR should review mechanisms in place to ensure the approved standard operating procedure (SOP) is followed and that consent to legal parenthood records are in place and retained in the patient's primary medical record.
- The PR should review witnessing procedures to ensure all required witnessing steps are conducted and recorded.

Other' areas of non-compliance or poor practice that require improvement:

- The PR should ensure that all TPAs are reviewed to ensure compliance with Standard Licence Condition (SLC) T114 where appropriate.
- The PR should investigate the causes of the potential system errors identified with the 3rd party software supplier which may affect the accuracy of information submitted electronically to the HFEA register.
- The PR should review procedures for submitting patients' consent to disclosure to researchers to the HFEA.

Recommendation to the Executive Licensing Panel

The centre demonstrates good clinical practice; has suitable premises and equipment for the treatment services offered and has a quality management system (QMS) in place to continually improve the quality and safety of the service it provides in accordance with good practice. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The inspection team recommends the renewal of the centre's Treatment with Storage licence for a period of four years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed Centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient, and children born following treatment

Witnessing and assuring patient and donor identification (Guidance note 18)

What the centre does well.

The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are broadly compliant with HFEA requirements with the exception noted below. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better.

An audit of 10 witnessing records conducted on inspection showed that in two instances the record of witnessing steps was incomplete. In one case a manual witnessing step at embryo transfer was not recorded but was recorded electronically. In a second instance there was no witnessing step recorded for thaw to culture dish. Laboratory staff confirmed that these steps are witnessed but that it was not recorded in this instance. (SLC T71). See recommendation 2.

Patient and Donor selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for donors (Guidance note 13)
- Donor assisted conception (Guidance note 20)

What the centre does well.

Screening of patients and / or donors

The centre's procedures for screening patients and donors are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors

The centre does not recruit donors or provide monetary compensation to known donors.

Donor assisted conception

People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre is fully in line with the requirements of the HFEA to ensure the donor conceived will be able to receive this information.

What the centre could do better.

The centre has not established quality indicators or quality objectives relevant to the selection and recruitment of donors (known to the patient or otherwise). (SLC T35). See recommendation 4.

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)

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

The progress in reducing the clinical multiple pregnancy rates suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target.

Process Validation (Guidance note 15)

The centre has fully validated all critical processing procedures to ensure that these procedures are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Traceability (Guidance note 19)

The centre's procedures are compliant with HFEA requirements to ensure it has the ability -

(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,

(b) identify the donor and recipient of particular gametes or embryos,

(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and

(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (Guidance note 23)

The centre has a quality management system in place that is compliant with HFEA requirements. The centre uses its quality management system to ensure optimum outcomes and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)

The centre has agreements in place which cover the:

(a) procurement, testing or processing of gametes or embryos on behalf of the licensed

centre, or
(b) supply of any goods or services (including distribution services) to the licensed centre which may affect the quality or safety of gametes or embryos.

Equipment and materials (Guidance note 26)
All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff with the exception noted below.

Premises (Guidance note 25)
The centre conducts all of the licensed activities in an appropriate environment, in line with good clinical practice. All diagnostic testing is carried out in a suitable, accredited laboratory.

Adverse incidents (Guidance note 27)
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all of the adverse incidents that have occurred and shares the lessons learned in order to continuously improve the services it offers.

What the centre could do better.

Equipment and materials (Guidance note 26)
The majority of critical equipment has been validated with a small number of exceptions. (SLC T24). See recommendation 7.

Third party agreements (Guidance note 24)
The content of one third party agreement with a laboratory conducting diagnostic testing, audited against CoP requirements, did not include a description of how any results are relayed to the centre, including sign off and confirmation that the result applies to the correct sample. (SLC T114f). See recommendation 6.

Quality management system (Guidance note 23)
The 'Collecting and Recording Information for HFEA' SOP does not record the need to forward pages 3 and 4 of donor information forms to the HFEA. Page 3 and 4 of donor information forms potentially hold additional personal information (including: occupation; skills; reason for donating; goodwill message; pen portrait; religion or belief system) that is of great value to donor-conceived people. The pages should be forwarded to the HFEA even if a donor has not completed these pages, so that the HFEA is able to respond to requests for information regarding the donor without needing to refer back to the clinic for information.

An audit of form submissions against information held on patient and donor files included four donor information form submissions. In each instance additional information was found to be available on the donor's file but this had not been forwarded to the HFEA. See recommendation 9.

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA PR Entry Programme (PREP - number T/1028/7).

Staff (Guidance Note 2)
The centre has suitably qualified and competent staff to carry out all of the licensed activities and associated services.

What the centre could do better.
Nothing noted at this inspection.

Welfare of the Child (Guidance note 8)

What the centre does well.

The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. The centre takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth.

What the centre could do better.
Nothing noted at this inspection.

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit the inspectors spoke to two patients who provided very positive feedback on their experiences. A further three patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was fairly positive, with one of the 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:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better.
Nothing noted at this inspection.

Treating patients fairly

What the centre does well.

Counselling (Guidance note 3)
The centre's counselling staff and procedures are compliant with HFEA requirements, ensuring that counselling support is available to patients before and during the consenting process and treatment.

Egg sharing arrangements (Guidance note 12)
The centre does not practice egg sharing.

Surrogacy (Guidance note 14)
The centre does not provide treatment involving surrogacy.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. The centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Treating patients fairly (Guidance note 29)
The centre treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors.

What the centre could do better.
Nothing noted this inspection.

Information

What the centre does well.
The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

Provision of costed treatment plans (Guidance note 4)
The centre provides an individual costed treatment plan to all of its self funding patients.

This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed or not.

What the centre could do better.
Nothing noted at this inspection.

Consent

What the centre does well.
The centre's procedures for obtaining consent are broadly compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research
The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA.

What the centre could do better.
A sample audit of five sets of embryos in store nearest to the end of consented storage showed that all samples are being stored within their consented period. However, in one instance the consented storage period stated in each gamete provider's consent form differed from that stated in the 'bring forward' letter generated by the centre. (SLC T46). See recommendation 3.

An audit of medical records on inspection showed that the WP consent form was missing in one instance where the couple had consented to legal parenthood. See recommendation 1.

To determine whether the register properly reflects the consent given by patients and their partners for the use of register information for research purposes, a sample of 20 completed patient and partner disclosure consents were reviewed against disclosure consent data submitted to the register.

Discrepancies were found between three completed patient/partner disclosure consents on patient files and the related consent data submitted by the centre for inclusion on the register.

In two further instances the 'Consent to Disclosure' Part 1 – general purposes form has been completed instead of the full form. The part 1 form does not include the questions regarding consent to the use of register information for research purposes. See recommendation 8.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well.

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- Licensed activities only take place on licensed premises.
- Only permitted embryos are used in the provision of treatment services.
- Embryos are not selected for use in treatment for social reasons.
- Embryos are not created by embryo splitting.
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman.
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better.

Nothing noted at this inspection.

Storage of gametes and embryos

What the centre does well.

The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

The centre's renewal application states vitrification of eggs is a proposed activity, however the centre have not yet begun preparing to perform this activity but anticipate that they will be in a position to offer this service in the coming year. The PR has agreed that before this activity commences patient information, evidence of training and process validation will be provided to the HFEA.

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers.

What the centre could do better.

Nothing noted at this inspection.

Distribution and / or receipt of gametes and embryos

What the centre does well.

The centre's procedures for distributing and / or receiving gametes and embryos are broadly compliant with HFEA requirements. This ensures that all gametes / embryos sent to other licensed centres within or outside the UK are appropriately labelled and relevant information is sent to the other centre to ensure the continued quality and safety of the gametes and embryos. The centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in a way that does not comprise their quality and safety.

What the centre could do better.

The centre does not have a procedure in place which:

- defines the responsibilities and actions required when cryopreserved material has to be recalled;
- directs the handling of returned gametes and embryos that includes their reacceptance into the inventory;
- directs the investigation of any recall of cryopreserved material as an adverse incident.

(CoP Mandatory Requirement 15C). See recommendation 5.

Use of embryos for training staff (Guidance note 22)

What the centre does well.

The centre's renewal application states embryos are to be used for biopsy training. At the time the application was submitted the PR stated that the centre had intended to apply for embryo biopsy to be added to their licence. After further consideration the PR has declined this stating that application to vary the centre's licence to include embryo biopsy will be made at some time in the future and that embryos will not be used for biopsy training until such time as the licence variation is granted.

The centre's procedures for using embryos for training staff are compliant with HFEA requirements. This ensures that embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

The centre only uses embryos to train staff in activities authorised by the Authority.

What the centre could do better.

Nothing noted at this inspection.

4. Information management

Record keeping and submitting information to the HFEA

What the centre does well.

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this Register, Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

To confirm that data submitted by the centre for inclusion on the register accurately reflects that found in source records on-site a sample of 53 assorted form type data submissions were reviewed against source documentation held on patient and donor files.

No critical errors or omissions were found in the data (i.e. errors that would prevent the authority fulfilling its statutory obligations).

The centre's procedures for submitting information, about licensed activities, to the Authority are broadly compliant with HFEA requirements and ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

What the centre could do better.

Our review of a sample of form submissions against source documentation held on site identified two areas of potential system error affecting pregnancy outcome and donor information forms. The sample of forms examined was not large enough to conclude that the error resulted from system error however. Additionally a small number of minor errors were identified. (SLC T9(e) / T41 Direction 0005) See recommendation 10.

Section 3: Monitoring of the Centre's performance

Compliance with recommendations made at the time of the last inspection

Following the storage licence renewal and licence variation inspection in July 2011, there were no areas of practice that required improvement in relation to the centre's existing storage licence. There were however a number of areas of practice that required improvement in relation to the application to vary the activities for which the centre is licensed. Recommendations for improvement were made in relation to two areas of major non-compliance and 12 'other' areas of non-compliance.

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

On-going monitoring of success rates

In the last year, the centre has received no alerts from the HFEA Risk Tool regarding its treatment success rates and the Executive has no concerns regarding the centre's performance.

Areas of practice requiring action

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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. 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	Executive Review
None		NA	

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 to a 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	Executive Review
1. An audit of medical records on inspection showed that	The PR should review mechanisms in place to ensure	Staff have been reminded of the process on appropriate	The Executive notes the PR’s action in response to this

a WP consent form was missing in one instance where the couple had consented to legal parenthood. (SLC T36)	the approved SOP is followed and that consent to legal parenthood records are in place and retained in the patient's primary medical record. The PR should inform the lead inspector when this is done and advise her in writing of the changes made. The centre's inspector will liaise with the PR regarding the scope of their planned audit. A copy of the audit should be provided to the centre's inspector by 1 September 2013.	consenting for legal parenthood and there is a QC checkpoint at the time of booking to ensure that all appropriate consents are now in place. These consent forms have been included in our notes audit; the next audit is planned for July 2013.	recommendation and will await the audit report as planned.
2. An audit of 10 witnessing records conducted on inspection showed that in two instances the record of witnessing steps was incomplete. In one case a manual witnessing step at embryo transfer was not recorded but was recorded electronically. In a second instance there was no witnessing step recorded	The PR should review witnessing procedures to ensure all required witnessing steps are recorded. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA. By 1 August 2013.	The first point raised was concerning a manual witnessing step which was not recorded on the Embryo Transfer Record Form, but was recorded electronically. **The SOP for embryo transfer has now been amended** to include a comment with reference to completing paperwork post transfer; and this is to include all witnessing	The PR has provided confirmation and evidence of the implementation of this recommendation. No further action is required.

for thaw to culture dish. (SLC T71)		signatures. It is the embryologists' responsibility to obtain the required signature from the clinician or nurse that was present at the time when the patient confirms their name and date of birth just prior to the procedure. The second point raised was concerning the witnessing step at the time of thaw. Our first frozen blastocyst transfer was performed with a manual witness step (this is recorded on the thaw sheet.) The labelling of the straw was checked against the label on the 'warming dish' by 2 operators. The witnessing diagram was then modified to include an electronic witness point at the time of thaw (entry point). Two operators are required to check the straw details and the label on the 'warming dish'. All FET procedures since then have included this electronic double witness point. It should also be noted that the	

		CAPA for point 2 was in place BEFORE the HFEA inspection and that the witness signature for the ET is recorded electronically in RI Witness.	

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	Executive Review
3. A sample audit of five sets of embryos in store nearest to the end of consented storage showed that all samples are being stored within their consented period. However, in one instance the consented storage period stated in each gamete provider's consent form differed from that stated in the 'bring forward' letter generated by the centre. (SLC T46)	The PR should investigate as to how this anomaly came about and the centre's process for checking and recording the consented storage period be reviewed to ensure that both gamete providers' recorded consent is consistent and that centre records in the bring forward system accurately reflect this. The PR should inform the centre's inspector as to the outcome of the investigation, corrective actions agreed and when they were implemented.	This anomaly came about because there was a discrepancy between the consented storage period between the two partners, and we took the earlier of the two dates. Staff education has been implemented to stress the importance of both partners agreeing on the same storage period. Our nursing checklist includes a check to confirm this.	The Executive notes the PR's response and implementation of this recommendation. No further action is required.

	By 1 August 2013.		
4. The centre has not established quality indicators or quality objectives relevant to the selection and recruitment of donors. (SLC T35)	The PR should ensure that, quality indicators are established to monitor the effectiveness of the selection and screening procedures for known donors. By 1 August 2013.	A Quality Indicator (QI) in respect of this had already been established and it is subject to Audit in April 2014 as part of the Audit Schedule.	The Executive notes the PR's response and is satisfied that the recommendation has been implemented. No further action is required.
5. The centre does not have a procedure in place that: • defines the responsibilities and actions required when cryopreserved material has to be recalled; • directs the handling of returned gametes and embryos that includes their reacceptance into the inventory; • directs the investigation of any recall of cryopreserved material as an adverse incident. (CoP mandatory requirements 15C).	It is acknowledged that recall is likely to be infrequent but in consideration that should a recall be necessary, staff should have clear instruction for how to proceed. The PR should ensure that a suitable procedure is established and a copy provided to the HFEA. By 1 August 2013.	The SOP's for receipt and transfer of frozen gametes and embryos to/from other units were amended on 1/5/13 at the time of the inspection, as required. A copy of the SOP is attached.	The Executive notes the PR's response and implementation of this recommendation. No further action is required.
6. The content of one third party agreement with a laboratory conducting	The PR should ensure that all TPAs are reviewed to ensure compliance with T114 where	The third party concerned has been contacted and the required amendments to the	The Executive is satisfied with the PR's response to this recommendation and will await

diagnostic testing, audited against CoP requirements, did not include a description of how any results are relayed to the centre, including sign off and confirmation that the result applies to the correct sample. (SLC T114f).	appropriate. A summary report of the findings of the review should be submitted to the lead inspector. By 1 August 2013.	TPA are being put in place to meet the requirements. The expected completion date is 31 Jul 2013.	the summary as planned.
7. A number of small items of equipment have not been validated. (SLC T24).	The PR should provide a list of the equipment including the date of validation or the planned date by which validation is expected to be complete. HFEA will ask for a sample of validation documents to be submitted for review. By 1 August 2013.	The list of the equipment including the date of validation is attached. All items had been validated but the centrifuge's calibration certificates had not been received although requested. This has been followed up and replacement calibration certification has been requested for the centrifuges. On going verification of equipment will be implemented into our IQA strategy. Documented evidence of validation, verification and maintenance records for small equipment are compiled and stored per item of equipment which collectively forms the necesseary paperwork for the IOQ process'	The Executive notes the PR's response and is satisfied that the recommendation has been implemented.

8. To determine whether the register properly reflects the consent given by patients and their partners for the use of register information for research purposes, a sample of 20 completed patient and partner disclosure consents were reviewed against disclosure consent data submitted to the register. Discrepancies were found between three completed patient/partner disclosure consents on patient files and the related consent data submitted by the centre for inclusion on the register. In a further two instances the 'Consent to Disclosure' Part 1 – general purposes form has been completed instead of the full form. The part 1 form does not include the questions regarding consent to the use of register information for research purposes.	The PR should review procedures for submitting patients' consent to disclosure to researchers to the HFEA. A summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective actions should be submitted to the lead inspector by 1 November 2013. Three months after the implementation of corrective actions the centre should audit a random sample of ten sets of patient records to ensure that consent to disclosure to researchers taken from patients has been correctly transferred to the HFEA register. The records audited should have had this consent completed within the previous three months. This audit should be submitted to the HFEA for cross reference against the records held by the HFEA. The HFEA may require the	The procedures have been reviewed and the root cause of this issue was as a result of human error in interpreting the forms in our first few cycles. This has since been rectified through staff education. We have specifically targeted all staff taking consent and recording consent on our electronic patient database system. An audit of this process is planned for July 2013 and the results will be submitted to the lead inspector.	The Executive is satisfied with the PR's response to this recommendation and will await the audit as planned.

Chair's Letter CH(10)05 Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007.	centre to perform an audit of individual consent records against the consent decision held by the HFEA in the future if an application by researchers is made for the release of that information. *(NB. The Centre's designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected).* By 1 November 2013.		
9. The 'Collecting and Recording Information for HFEA' SOP does not record the need to forward pages 3 and 4 of donor I information forms to the HFEA. (SLC T33b).	The PR should ensure that centre staff are aware of the requirement to provide donor goodwill and pen portrait information. The related SOP should be updated to reflect this requirement and a copy submitted to the lead inspector. The PR should liaise with the HFEA Register team to ensure that any missing pages from donor information	The SOP has been amended as required. A copy of the SOP is attached. All staff have been educated about the need to provide donor goodwill and pen portrait information as per the HFEA's Code of Practice.	The Executive notes the PR's response and the submission of the revised SOP. The HFEA Register team will monitor the submission or donor information forms.

	forms are submitted for inclusion on the register. By 1 August 2013.		
10. A review of a sample of form submissions against source documentation held on site identified two areas of potential system error affecting pregnancy outcome and donor Information forms. The sample of forms examined was not large enough to conclude that the error resulted from system error however. Additionally a small number of minor errors were identified. SLC T9(e) / T41 Direction 0005.	The PR should investigate the causes of the potential system errors identified with the 3rd party software supplier. A brief summary of the findings of the review including corrective actions and the timescale for implementation of the corrective actions to the HFEA should be provided. The action plan should include addressing affected historic register submissions. The action plan should be provided to the HFEA. Three months after the implementation of corrective actions the centre should audit a random sample of recent (i.e. post implementation of corrective actions) pregnancy outcome and donor information submissions against ten sets of patient and donor records to ensure that	The third party software supplier has been in formed and they are investigating if there is a system issue that can be addressed. Any findings will result in a review by Cambridge IVF and an action plan formulated as appropriate. In the meantime, staff have been educated to be aware of the problem and to manually correct for it and an audit has been scheduled for September 2013.	The PR's response to this recommendation is noted. The PR is to inform the centre's inspector of the outcome the investigation and any consequent actions planned. The PR is to submit a copy of the scheduled audit report to the centre's inspector when available or by 1 November 2013.

	the issues identified at the time of inspection have been effectively addressed. *(NB. Where appropriate the designated HFEA Form Returnee has been provided with the relevant patient numbers; form numbers; and error details so that necessary corrections can be made to the small number of minor errors found during the audit).* By 1 August 2013.		

Reponse from the Person Responsible to this inspection report

HFEA Executive Licensing Panel Meeting

2 August 2013

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

Minutes – Item 2

Centre 0051 – (Cambridge IVF) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Nick Jones – Director of Compliance and Information Rachel Hopkins – Head of HR	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 small centre which has held a licence with the HFEA since 1992.

2. The Panel noted that the centre was formerly The Rosie Hospital which was licensed for the storage of sperm only, and that an application to vary the centre's licence to reflect a change of centre name and premises, along with licence renewal and variation to achieve a full Treatment and Storage licence, was approved by the HFEA in September 2011.

3. The Panel noted the centre has a two year, initial licence due to expire September 2013 and the inspection took place on 30 April and 1 May 2013.

4. The Panel noted that, from January 2012 to December 2012, the centre's success rates for IVF and ICSI were in line with national averages.

5. The Panel noted that between 1 October 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all cycles and all age groups was 6%. This represented performance that was not likely to be statistically different to the target for this period.

6. The Panel noted that, at the time of inspection, two major and eight other areas of non-compliance were identified by the Inspectorate.

7. The Panel noted that, since the inspection, five other areas of non-compliance have been addressed by the Person Responsible (PR).

8. The Panel noted that the centre's renewal application states embryos are to be used for biopsy training, but that since submitting the application the PR has clarified this. An application to vary the centre's licence to include embryo biopsy will be made in the future and that embryos will not be used for biopsy training until such a variation is granted.

9. The Panel noted that the centre's procedures for using embryos for training staff are compliant with HFEA requirements and that embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

10. The Panel noted the recommendation to renew the licence for four years without additional conditions and subject to fulfilment of the remaining recommendations within the prescribed timescales.

Decision

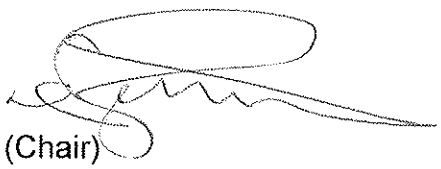
11. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

12. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities.

13. The Panel was satisfied that the licence renewal application concerns treatment or non-medical fertility services which relate to gametes intended for human application.

14. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence provided within the report.

15. The Panel agreed with the Inspectorate's recommendations made in the report and endorsed the recommendations and timescales relating to remaining non-compliances. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed:  Date: 7 August 2013

Mark Bennett (Chair)