HFEA Executive Licensing Panel Meeting

14 November 2014

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

Minutes – Item 5

Centre 0295 – (Bristol Centre for Reproductive Medicine) – Progress Report – Treatment & Storage Centre

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Director of Strategy & Corporate Affairs (Chair) Rachel Hopkins – Head of HR Hannah Verdin – Head of Regulatory Policy	Dee Knoyle

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel 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 the Report

1. The Panel considered the papers, which included an Executive Summary and licensing minutes for the past three years.

Background

2. The Panel noted the background information from the previous meeting papers.

3. At its meeting on 5 September 2014, the Executive Licensing Panel had endorsed the Inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions. However, given the volume and seriousness of the non-compliances identified on inspection, the Panel asked that a progress report should be submitted to the Executive Licensing Panel shortly after 25 September 2014.

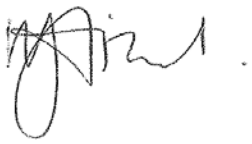
Update

4. The Panel received confirmation from the Inspectorate that the Person Responsible had fully completed six recommendations. The actions still remaining were the completion of process and equipment validations, eight audits and ensuring the website update is completed.

5. The Panel noted that progress in implementing these recommendations will continue to be monitored by the Inspectorate.

Decision

6. The Panel was satisfied with the centre's progress to date and encouraged the centre to continue to stay fully engaged through to completion of the recommendations and actions required.



Signed: Date: 25 November 2014
Juliet Tizzard (Chair)

Executive Summary for Executive Licensing Panel

Centre number	0295
Centre name	Bristol Centre for Reproductive Medicine
Person Responsible	Dr Valentine Akande

Progress report following up on recommended actions relating to non-compliances identified at renewal inspection, as requested by ELP

1. The ELP met on the 5 September 2014 to consider the centre's application to renew their treatment and storage licence. The minutes recorded the following::
    - *The Panel also agreed that given the volume and seriousness of the non-compliances a progress report should be submitted to the Executive Licensing Panel shortly after 25 September 2014.*

2. The ongoing monitoring of post inspection actions by the centre's inspector has enabled a progress update to be provided in the table below. The progress updates are noted in the Executive Review column.

3. The Executive can confirm that the PR has implemented all the required actions and recommendations to date, and within the prescribed timescales with one exception (see recommendation 8 below in relation to the centre's website).

4. Six recommendations are fully complete. The actions still remaining are the completion of process and equipment validations (due by 25 December 2014), eight audits (due by 25 December 2014, 25 January 2015 and 25 June 2015) and ensuring the website update is completed. Progress in implementing these recommendations will continue to be monitored.

Karen Conyers
Inspector

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, General 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
1. On the day of the inspection the centre did not have effective consent for the storage of cryopreserved sperm for nine patients and embryos for two couples (Schedule 3, 8(1) HF&E Act 1990 (as amended)). This is in addition to samples identified from previous inspections.	The inspector advised the PR both during the inspection and immediately thereafter that he should take immediate actions to resolve this non-compliance. The PR should provide the HFEA with an update on how many gametes and embryos remain in store without effective consent by the time this report is considered by a Licensing Committee.	Please see the PR comment section for further information. Noted & agreed	The lead inspector acknowledges the PR's immediate responses and actions taken to resolve this non-compliance. The PR has confirmed that no samples remain in storage without effective consent, with the exception of two which have been subject to legal challenge by the gamete providers.

This was identified as a non-compliance at the last inspection.	Also by the time this report is considered by a Licensing Committee, where gametes or embryos remain in store without effective consent, a plan should be submitted to the centre's inspector documenting the PR's intended actions and the anticipated timescale for their implementation. The PR should provide monthly updates to the centre's inspector on progress in implementing the proposed actions. The PR should review the bring-forward systems and procedures for auditing storage of cryopreserved material. Summary reports of the findings of both reviews including corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 25 September 2014. Within three months of the implementation of corrective actions, the centre should conduct an audit of consent to storage and a summary report of the findings of	Noted & agreed. Noted & agreed. Noted & agreed. Noted & agreed.	The PR has also provided a review of the centre's bring forward system and has confirmed that corrective actions which were identified have already been implemented. Further action is required in relation to the completion of the audit **Update 24 October 2014** The planned audit is due on 25 December 2014.

	the audit should be provided to the centre's inspector by 25 December 2014. The PR is reminded of guidance issued by the HFEA in CH(03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	Noted & agreed.	

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
2. Blood samples from egg share donors are not obtained within a timeframe specified by the Authority, i.e. at the time of donation. SLC T53b	The PR should review the centre's practices to ensure that blood samples are obtained in the timeframes specified by the Authority (see Clinic Focus March 2013). A summary of the findings and proposed corrective actions should be submitted to the centre's inspector in responding to this report. Updates in training on screening timescales should be provided to relevant staff and confirmation of this submitted to the centre's inspector by 25 September 2014.	Noted & agreed. Noted & agreed. Noted & agreed.	The PR confirmed that the review of the centre's practices has been completed. The PR also confirmed that corrective actions and staff training have already been implemented. Further action is required in relation to the completion of the audit. **Update 24 October 2014** The planned audit is due on 25 December 2014.

	The PR should ensure that the revised screening processes are audited 3 months after implementation and a summary of the findings should be submitted to the centre's inspector by 25 December 2014.		
3. The centre undertakes diagnostic semen analyses however the laboratory is no accredited by CPA or equivalent. SLC T21	The PR should ensure that the laboratory which undertakes diagnostic semen analysis is accredited by CPA or equivalent, or provide evidence to support a status equivalent to accreditation. Evidence of CPA accreditation, or equivalent should be forwarded to the centre's inspector by 25 September 2014.	Noted & agreed. Noted & agreed	The lead inspector acknowledges the PR's response. Further action is required in relation to the submission of the requested evidence of CPA accreditation or equivalence. **Update 24 October 2014** Evidence of equivalence to CPA accreditation has been provided. The required actions have been completed. No further action is required.

4. The centre could not provide evidence that they had complied with all the requirements of General Direction 0006 (Schedule 3, 1c) for one of three gamete/embryo import cases reviewed.	The PR should review the centre's procedures for import and export of gametes and/or embryos to ensure that evidence required demonstrating compliance with General Direction 0006 is obtained before gametes and/or embryos are imported or exported. A summary of the review and any changes implemented as a result should be provided to the centre's inspector by 25 September 2014. The PR should audit the records relating to imports and exports of gametes or embryos six months after the implementation of corrective actions against compliance with General Direction 0006 and forward a summary of the audit to the centre's inspector by 25 December 2014.	Noted & agreed. Noted & agreed. Noted & agreed.	The lead inspector acknowledges the PR's response. Further action is required in relation to the completion of the review and the subsequent audit. **Update 24 October 2014** The centre provided a summary of the review and copies of new patient consent forms, checklists and a SOP being implemented to ensure all requirements of General Directions 0006 will be met. The planned audit is due on 25 December 2014.
5. The following critical equipment has not been validated: tube warmers,	The PR should ensure that all critical equipment is validated and submit an action plan	Noted & agreed. Action plan submitted with response.	The lead inspector acknowledges receipt of the action plan for

lasers, suction pump, fridges. SLC T24	listing all critical equipment, the date of validation and /or the expected date by which validation will be achieved, to the centre's inspector when responding to this report. The PR should ensure all critical equipment is validated and that all validations are completed by 25 December 2014. On completion of the validations the centre's inspector will ask for a sample of validation documents to be submitted for review.	Noted & agreed Noted & agreed	validation of equipment and will request a sample of the validation documents for review in due course. Further action is required. **Update 24 October 2014** The action plan confirmed all required critical equipment will be validated by 25 December 2014, as required. Since the report was considered by the ELP, an example of an equipment validation was provided: this was reviewed and considered sufficient. Further action is required.
6. Documentation of process validations was not sufficiently detailed to provide assurance to the inspection team that all critical processes had been appropriately validated.	The PR should ensure that all critical processes and any proposed new activities are adequately validated and an action plan listing all critical processes, the date of validation and /or the expected date by which validation can	Noted & agreed. Action plan submitted with response.	The lead inspector acknowledges receipt of the action plan for process validations and will request a sample of the validation documents for review in due course.

SLC T72	be achieved should be submitted to the centre's inspector in responding to this report. It is expected that validation will be prioritised on the basis of risk associated with the procedure and that validation will be complete by 25 December 2014. On completion of the validations the centre's inspector will ask for a sample of validation documents to be submitted for review.	Noted & agreed. Noted & agreed	Further action is required. **Update 24 October 2014** The action plan confirmed all required validations of critical processes will be completed by 25 December 2014, as required. Three sample summaries of process validations were submitted and these were reviewed. The summaries indicated that the proposed method of process validation is likely to be sufficient. Further action is required.
7. Patient information states that potential donors of eggs through an egg sharing agreement could donate all eggs during their first cycle, and receive their next cycle free of charge. The centre confirmed that their policy does not take account of what medical reasons might prevent a donor from	The PR should ensure egg donors who receive a benefit through their egg sharing programme, are provided with that benefit during the course of the donation cycle unless there is a medical reason why this cannot be. The PR should consider reviewing the centre's SOPs and patient information to	Noted & agreed. The Centre would like to make the Authority aware that no patients have received benefit in kind in a subsequent cycle while being an egg share donor. Noted & agreed.	The lead inspector acknowledges the PR's response. Further action is required in relation to completion of the review and updates to staff. **Update 24 October 2014** The centre provided a summary and evidence of

receiving the intended benefit during the course of their donation cycle. General Direction 0001	ensure they accurately reflect the requirements of General Direction 0001. A summary of that review and any consequent changes should be provided to the centre's inspector by 25 September 2014. The PR should ensure that any changes made are communicated to staff effectively and inform the centre's inspector when this is done by 25 September 2014.	Noted & agreed. Noted & agreed.	the actions taken in response to this non-compliance; confirmation that all staff had been informed, individual training for specific staff involved in the egg share programme and revised egg share documentation. No further action is required.
8. Information provided to patients regarding the following matters did not fully comply with regulatory requirements: parenthood laws for patients using donated gametes, (SLC T60), use of gametes/ embryos in training (SLC T97c and d) and success rates on the centre's website (Chairs Letter CH(11)02).	The PR should ensure that patient information fully incorporates the regulatory requirements and provide the centre's inspector with a summary report of the changes and copies of the updated patient information by 25 September 2014.	Noted & agreed	The lead inspector acknowledges the PR's response. Further action is required in relation to the summary report and providing copies of updated information to the lead inspector. **Update 24 October 2014** Patient information on parenthood laws and use

This puts the centre at risk of failing to provide proper information to patients/donors giving consent, as required by the HF&E Act 1990 (as amended), Schedule 3 (1) (b).			of gametes/ embryos in training have been submitted and were considered suitable. The inspector has been assured that the website update is underway but not yet completed. Progress in implementing this recommendation will be monitored. Further action is still required.
9. In one of the patient files reviewed, the screening test laboratory results for the male partner were not present. It was noted that emails confirming the screening test result status were present but the laboratory test results were not. SLC T46g	The PR should review the centre's practices to ensure that all clinical and laboratory test results are obtained prior to procurement or processing of gametes and /or embryos. A summary of the findings and proposed corrective actions should be submitted to the centre's inspector by 25 September 2014. The PR should ensure that the revised screening processes are audited 3 months after	Noted & agreed. This Centre would like to inform the Inpectors that this finding does not reflect accepted practice within the centre. Noted & agreed	The lead inspector acknowledges the PR's response. Further action is required in relation to the completion of the review and the subsequent audit. **Update 24 October 2014** The centre confirmed that this did not reflect standard or documented practice at the centre and that all staff have been reminded of the

	implementation of any changes and a summary of the findings should be submitted to the centre's inspector by 25 December 2014.		regulatory requirements. A review of screening results will now form part of the centre's monthly patient records audit so that compliance in this area will be monitored, The planned audit is due on 25 December 2014.
10. The HFEA register audit team found some evidence of problems with the accuracy of the centre's submission of data to the Register. A small number of minor submission errors were also found at the time of inspection. SLCs T9e and T41, General Direction 0005	The PR should ensure that the treatments identified as outstanding at the time of inspection are reported to the Authority immediately. The systems and processes used for licensed treatment data submission should be reviewed to enable the reasons for non-reporting to be identified and addressed. The PR should inform the centre's inspector of the findings and corrective actions by 25 July 2014. The PR should conduct an audit six months after implementing any changes to	These treatment cycles have now been reported to the Authority. Noted & agreed. Noted & agreed	The lead inspector acknowledges the PR's response confirming that the outstanding treatments have been reported to the HFEA and the review of processes has been undertaken. Further action is required in relation to the completion of the audit. **Update 24 October 2014** The planned audit is due on 25 January 2015.

	confirm that any changes made to systems and processes are having the desired effect. A summary report of the findings of the audit should be provided to the centre's inspector by 25 January 2015.		
11. The staff at the centre were unable to locate the records for a patient with stored embryos during the inspection. SLCs T47 and T48	The PR should review the centre's SOP for retention of records and ensure staff are aware of the requirements for record keeping. A summary of the findings and any corrective actions should be submitted to the centre's inspector by 25 September 2014. The PR should conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect. A summary report of the findings of the audit should be provided to the centre's inspector by 25 December 2015.	Noted & agreed. Noted & agreed.	The PR has kept the lead inspector updated on the centre's extensive efforts to locate this record and has confirmed that the embryos are stored with effective consent. This is being actively followed up by the centre's senior management. The lead inspector will liaise with the PR on the outcome of this issue. Further action is required in relation to the completion of the review and the subsequent audit. **Update 24 October 2014** The centre confirmed that

			they have reviewed the SOP and updated staff on the requirements for record keeping. The issue regarding the missing records is still being followed up by senior management. The lead inspector will continue to liaise with the PR on this issue. The planned audit is due on 25 December 2014.

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
12. Whilst it is acknowledged that staff witness the disposal of sperm, this process is not documented in the records. SLCs T71 and T99a	The PR should review current practice to ensure the disposal of sperm is documented for traceability purposes and advise the centre's inspector of the implementation of the changes by 25 September 2014. The PR should conduct an audit six months after the implementation of any changes to practice and processes and forward a summary of the audit to the centre's inspector by 25 December 2014.	Noted & agreed. Noted & agreed	The lead inspector acknowledges the PR's response. Further action is required in relation to the completion of the review and the subsequent audit. **Update 24 October 2014** The centre confirmed that the witnessing of disposal of sperm is now being documented and updated copies of the relevant laboratory documents provided were reviewed and considered satisfactory. The planned audit is due on 25 December 2014.

13. The SOPs describing the following procedures did not adequately describe the processes and procedures used in practice (screening timeframe requirements, consent, legal parenthood, transport, distribution and recall of gametes and/or embryos). SLCs T33b, T107f, T108, CoP 15C and T122.	The PR should ensure the development of documented SOPs for these procedures. Copies of the SOPs should be provided to the centre's inspector by 25 September 2014.	Noted & agreed	The lead inspector acknowledges the PR's response and awaits copies of the updated SOPs by 25 September 2014 Further action is required. **Update 24 October 2014** Copies of all the requested SOPs were provided and reviewed and were considered to be satisfactory. No further action is required.
14. Written agreements with satellite centres do not clearly define all responsibilities. SLC T116 and General Direction 0010	The PR should review all agreements with satellite centres to ensure compliance with requirements. A summary report of the findings of the review should be provided to the centre's inspector by 25 September 2014. The report should also document any corrective actions required to ensure compliance and the anticipated timescales for the	Noted & agreed.	The lead inspector acknowledges the PR's response. Further action is required in relation to the completion of the review. **Update 24 October 2014** The centre undertook a review of all agreements with satellite centres. A

	implementation of the corrective actions.		copy of an updated agreement provided assurance that the revised format clearly defined responsibilities and should ensure compliance of satellite centres with regulatory requirements. No further action is required.
15. The centre has not audited the compliance of the satellite centres against regulatory requirements and their own approved protocols and quality indicators. SLCs T36 and T112	The PR should audit the centre's satellite units' compliance with regulatory requirements and approved protocols and quality indicators. A copy of the audit including any corrective actions and timescales for implementation should be provided to the centre's inspector by 25 September 2014.	Noted & agreed.	The lead inspector acknowledges the PR's response. Further action is required in relation to the completion of the audit. **Update 24 October 2014** A copy of the audit including corrective actions and timescales for implementation was provided to the inspector by 25 September 2014. No further action is required.

16. Staff involved in donor recruitment, assessment and screening could not provide documented evidence of assessment of their competence in this area of practice. SLC T15a	The PR must ensure that assessments of competence are documented and evidence of the relevant assessment of competence should be forwarded to the centre's inspector by 25 September 2014.	Noted & agreed.	The lead inspector acknowledges the PR's response. Further action is required. **Update 24 October 2014** A copy of the centre's assessment of competence of staff involved in donor recruitment, assessment and screening was provided to the inspector by 25 September 2014. No further action is required.
17. An audit of patient consent to disclosure decisions recorded in 27 patient notes against those submitted for inclusion on the HFEA register showed that in seven instances discrepancies were found between patient disclosure consent decisions recorded in patient files and the related consent data	The PR should ensure that patient / partner consents to disclosure of information to researchers are reported accurately to the HFEA. The PR should correct the submissions that have been identified as being incorrect and review systems and processes to ensure that going forward, the patient and	Noted & agreed. Incorrect submissions have now been corrected.	The lead inspector acknowledges the PR's response confirming that the incorrect submissions have been corrected. Further action is required in relation to the completion of the review and the subsequent audit. **Update 24 October 2014**

submitted for inclusion on the register. Chair's Letter CH (10)05 Guidance supplementary to Chair's Letter CH (10)05 and General Direction 0007	partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms by 25 September 2014. A summary of that review and any consequent changes should be provided to the centre's inspector by 25 September 2014. Six months after implementing any changes to this process the PR should audit the submission of consent to disclosure data to confirm that any changes made to systems and processes are having the desired effect. A summary of this audit should be provided to the centre's inspector by 25 June 2015.	Noted & agreed.	The centre provided a summary of the review of systems and processes and the changes to practice which will be implemented. The planned audit is due on 25 June 2015.

Reponses from the Person Responsible to this inspection report

As confirmed to the Inspection team during the recent inspection, the centre immediately instigated contact procedures, where they were not already ongoing, for the patients/partners where samples were in storage without effective consent and had contacted 9 of the 11 patients within 24hours to inform them of their options. Contact was made with the two remaining patients/partners shortly thereafter.

The Centre can confirm to the authority that all samples identified during the inspection will be held with effective consent or will have been discarded at patient request/in line with regulatory requirements by 15th August 2014. Furthermore, the Centre has already forwarded a summary of findings and corrective actions to prevent future recurrence to its Inspector. Implementation of corrective actions has already commenced.

The Centre would also like to inform the Authority that it recently sought and received legal advice relating to two pre chemotherapy sperm storage patients where consent has expired but the patients have indicated that they wish to explore legal avenues in in order to ensure the samples remain in storage. The PR has therefore concluded, in line with HFEA guidance in this area and legal advice received that the continued storage of the samples for these two men is both reasonable and prudent until the situation is clarified/a Court Order is obtained and the Centre will forward further information relating to these cases seperately to the Authority.

The Centre can also confirm that all other stored samples are held with effective consent.