Licence Committee - minutes

Centre 0017 (Newcastle Fertility Centre at LIFE),

Executive Update following a variation of licence to permit Pronuclear Transfer (PNT)

13 July 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Lee Rayfield (Chair) Ruth Wilde Kate Brian	
Members of the Executive	Dee Knoyle Paula Robinson	Committee Secretary Head of Planning & Governance
Legal Adviser	Philip Grey	Mills & Reeve LLP
Specialist Adviser		
Observers		

Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this Item, however they did want to declare the following:
  - Ruth Wilde has served on the Executive of the British Fertility Society (BFS) alongside the current Person Responsible.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Executive update
- Revised information provided to patients and donors
- Licensing minutes up to the centre's last renewal inspection:
  - 9 March 2017 - Variation of licence to permit mitochondrial donation
  - 20 May 2016 - Interim inspection
  - 30 May 2014 - Licence renewal

1. Background

1.1. Newcastle Fertility Centre at LIFE, centre 0017 has held a treatment (including embryo testing) and storage licence with the HFEA since 1992 and provides a full range of fertility services. The centre's current licence is due to expire on 31 July 2018. The centre also holds a research licence.

1.2. In December 2016 the centre applied to vary its treatment (including embryo testing) and storage licence to include Mitochondrial Donation using Pronuclear Transfer (PNT). The licensing process for this treatment requires the HFEA to make 'express provision' in the licence to permit mitochondrial donation treatments using PNT. This type of application also requires a named embryologist, competent in PNT, to fulfil the role of Mitochondrial Donation Practitioner and to be added to the licence.

1.3. Once a patient has been assessed as suitable for PNT by the centre's multi-disciplinary team the Person Responsible (PR) is required to make a separate application to the HFEA for permission to allow PNT in the individual patient and this application will be considered case by case by the HFEA's Statutory Approvals Committee. Following approval, a suitable donor will undergo stimulation and egg collection. The procedure will then take place using fresh donor eggs, and thawed eggs from the patient. Embryos created through PNT will be transferred to the recipient patient or frozen for future use.

1.4. On 9 March 2017, the HFEA Licence Committee approved the variation of the centre's current licence for treatment (including embryo testing) and storage to include mitochondrial donation using PNT. The committee also agreed to add Dr Louise Hyslop as the named embryologist, assessed as competent to undertake PNT to the licence.

1.5. There were six major areas of non-compliance and two 'other' areas of practice that required improvement. The 'other' areas of non-compliance had been fully implemented at the time of the Licence Committee on 9 March 2017 and the PR had committed to implement all of the recommendations within the agreed timeframes. The Licence Committee requested a full update on implementation of these recommendations.

1.6. The committee also made a number of comments in relation to counselling and the patient and donor information.

2. Consideration of application

2.1. The committee noted the progress made to address the six major areas of non-compliance, which were outstanding since the last report.

2.2. The committee noted that the Executive had reported that three of the major recommendations relating to premises, counselling and staff training had been fully implemented and that it was satisfied that appropriate progress is being made to implement the three other recommendations relating to equipment, CE marking and third party agreements.

3. Decision

3.1. The committee was satisfied with the progress made to address the major areas of non-compliance with one exception. The committee was not convinced by the amendments to the patient and donor information on the provision of counselling and felt that patients should be encouraged to take up counselling with a counsellor who is competent to explore all the implications of mitochondrial donation treatments using PNT. The patient information should set out the benefits of seeing a counsellor prior to treatment or donation and make it clear that it is expected that mitochondrial donation treatment patients and donors will have counselling before treatment or donation starts.

3.2. The committee agreed, taking into account the fact that this is a new procedure, that ideally implications counselling should be included routinely in the process of preparing patients and donors for mitochondrial donation treatments using PNT. This should be independent of any discussions with the medical and nursing team. It should allow patients and donors to explore their feelings about the treatment and potential post-treatment scenarios, and should be carried out by a qualified counsellor (meeting the requirements of the Code of Practice sections 2.12 – 2.14) in a confidential setting. The committee recalled the discussions at the HFEA Authority when the decision was made to authorise mitochondrial donation treatments: the Authority expected that patients and donors would have implications counselling with a counsellor before undergoing this procedure. The committee agreed that patients and donors should all have the opportunity to participate in implications counselling to ensure they are emotionally prepared and able to fully explore all the issues for them, about either having mitochondrial donation treatment or donating eggs for the procedure.

3.3. The committee agreed that the patient and donor information sheets are still inaccurate and do not reflect the Code of Practice in places. For example: Patient Information pages 9 and 10 – 'Are there any legal issues?' This is not accurate – see Code of Practice 33.28. 'What shall I tell my child about their origins?' Page 10 does not reflect the wording of the Code 33.20 about the importance of informing children of their origins from an early age. The section on the 'Counselling Service' on page 10 does not make the distinction between a thorough discussion with the medical team and implications counselling with the counsellor and what to expect from each. It also does not specifically recommend or mention counselling on the implications of treatment. This should be amended in both the patient and donor information to set out the benefits of implications counselling as well as providing the information on counselling generally. On the Donor Information Sheet, 'What happens at these visits?' page 6 does not mention that

implications counselling could/will take place at one of the visits. The section on the 'Counselling Service' appears to have been cut and pasted from the patient information sheet as it refers to feelings of isolation and confusion and the stress of fertility investigations, which are not usually associated with donating gametes. The offer of counselling to donors should reflect the Code, for example, sections 11C, 3.3 and 3.7 and make it clear that implications counselling is routine.

3.4. The committee at its meeting on 9 March 2017 had noted that it was not clear in the information submitted whether the appointed counsellor meets the requirements of the HFEA Code of Practice sections 2.12 and 2.13. The committee has not subsequently seen any evidence that the centre may have provided to the inspectorate on whether she is suitably qualified and would like to see evidence that this is the case.

3.5. The committee decided that the centre should review the patient and donor information and make amendments to ensure that information provided is accurate and robust and reflects the HFEA Code of Practice. This should be resubmitted to the Licence Committee together with the evidence that the counsellor meets the requirements of the HFEA Code of Practice. The committee would also seek reassurance that both the offer and opportunity for implications counselling for patients, donors, and their partners if relevant, is included in all Standard Operating Procedures.

4. Chair's signature

4.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Bishop Lee Rayfield

Date

22 August 2017

Executive Update for Licence Committee
13 July 2017

Centre number	0017
Centre name	Newcastle Fertility Centre at LIFE
Person Responsible	Dr Jane Stewart

Update following a variation of licence to permit pronuclear transfer (PNT).

Background

1. On 9 March 2017, Licence Committee varied the centre's current licence for treatment (including embryo testing) and storage to include mitochondrial donation (PNT), and to name Dr Louise Hyslop on the front of the licence as an embryologist assessed as competent to undertake PNT. The minutes of this meeting are available alongside this update.

2. The Committee requested a full update on all recommendations made by the executive in their inspection report to be presented at their July meeting. Recommendations for improvement were made in six areas of major non-compliance and two 'other' areas of practice. Both 'other' recommendations had been fully implemented at the time of the Licence Committee.

Update

3. A full progress update on the remaining six recommendations has been provided to the executive. A summary is presented in the executive review column in Annex 1 alongside the recommendations made by the executive.

4. Three of the major recommendations have now been fully implemented. The executive is satisfied that appropriate progress is being made to implement the remaining three major recommendations.

5. The Committee also made a number of comments in their minutes relating to counselling and information provided to patients/donors. A response to these has been incorporated into the update below.

Douglas Gray
Inspector

Annex 1:

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 action required	Action required and timescale for action	PR Response	Executive Review
1. Premises Following the refit, laboratories will need deep cleaning, and testing completed to evidence appropriate air quality. SLC T17 and T20.	Confirmation that the deep clean has taken place, and evidence of appropriate air quality in all refurbished laboratories must be provided to the centre's inspector. As this recommendation affects all treatments, not just PNT, evidence of an appropriate air quality should be forwarded before any licensed activity takes place in the laboratory.	1. Premises: We have already scheduled cleaning and validation into our refurbishment. An independent Service provider (Vega Services) that specialise in Cleanroom validation will be validating both the isolators and the rooms for air flows, viable and non viable particle counts. This data will be forwarded to the HFEA prior to PNT.	We await confirmation of the air quality before commencing licensed activity. **June 2017 update:** Evidence has been provided of air quality that satisfies the requirements of SLC T20. No further action required.

2. Equipment Following the laboratory refit, validation or revalidation will be required for all equipment to be used during the processing and culture of embryos for the purposes of PNT, including: • isolators • micromanipulator • lasers • time lapse incubators • any other equipment required during the processing and culture of embryos creating using PNT. SLC T23 and T24.	Documented validations, and any supporting documents such as SOPs, should be forwarded to the centre's inspector. This recommendation impacts on all treatments and not just PNT. Therefore, confirmation that equipment has been validated should be provided before licensed treatments resume. However documented validations should be forwarded for all equipment to be used in PNT.	2. Equipment: As detailed in the departments Validation Master Plan and subsequent documentation, all critical equipment will be validated following the refurbishment as well as all new equipment. The validation reports will be forwarded to the HFEA prior to performing PNT.	We request that the centre confirms the validation of necessary critical equipment before recommencing any licensed treatment. The centre should then forward validations for those pieces of equipment specifically to be used in PNT before starting this procedure. **June 2017 update:** Suitable evidence of validation/revalidation has been provided for all required equipment except the time lapse incubator that has yet to be installed. Further action is required to forward the validation of the time lapse incubator.
3. CE marking Documented procedures/templates to assure the safety of non-CE	Final versions of the centre's risk assessment, release specification template and associated SOP should be forwarded	3. We will forward the HFEA appropriate risk assessments, release specifications and SOPs for all non CE marked	The executive is satisfied with the response provided, and we await the final risk assessment/SOP, followed by the outcome of testing of

marked reagents (medical devices) are currently in draft format. SLC T23 and T30	to the centre's inspector by 23 April 2017. Evidence that the first batch of the non-CE marked reagents have been assessed as suitable for release should be sent to the centre's inspector before they are used in clinical treatment.	consumables used in PNT by the 5th of April 2017. Prior to commencing PNT we will forward our inspector the completed release specification for the first batch of non-CE marked products that will be used.	the first batches of reagents. This must be received before commencing PNT. **June 2017 update:** The following documents have been forwarded for review and are considered by the executive to be suitable: • A risk assessment covering the use of non-CE marked reagents in PNT. • A protocol and template to direct the safety testing, acceptance criteria and release of non-CE marked reagents for PNT. • A counselling template that includes reference to the need to discuss the implications of using non-CE marked reagents. • Patient information that touches upon the use of non-CE marked reagents. We await confirmation that

			the first batches have passed their safety testing.
4. Third Party Agreements TPAs are required for: • the two laboratories that will test the non-CE marked reagents for sterility and toxicity; and • the Trust theatres that may be used for complex egg collections. SLC T111-114.	Copies of these TPAs should be forwarded to the centre's inspector by 23 April 2017.	4. We have attached a copy of the TPA with the Trust theatres. We will also send our inspector a copy of the TPA for the companies providing "top-up" testing for our non-CE marked products. These documents will be submitted by the 05th of April 2017.	The TPA with the Trust theatres has been received and is suitable. We await receipt of the remaining two TPAs by 23 April 2017. **June 2017 update:** Copies of the remaining TPAs have been provided but are yet to be signed by the relevant parties. We request confirmation once they have been signed.
5. Counselling The counsellor is yet to receive training in the mitochondrial donation/treatment pathway. Inspectors considered steps could be taken to facilitate the uptake of counselling by patients and donors. SLC T12 and T58(f).	The counsellor should receive appropriate training in the mitochondrial donation pathway, and confirmation should be forwarded to the centre's inspector by 23 April 2017. When responding to this report, a brief comment should be provided on the steps taken to facilitate the uptake of counselling. Any	Counsellor to attend NFCL seminar - Working Towards Clinical Mitochondrial ART. Counsellor to attend NFCL joint clinics x2 to experience the clinical work-up. Counsellor to have 1-2-1 training discussion with Dr Stewart regarding specifics of process that raises issues. Counsellor invited to attend clinics and sessions at all	An appropriate training package has been put in place for the counsellor. Confirmation that this has been completed should be forwarded to the centre's inspector by 23 April 2017. Patient information has also been updated to better promote the availability of counselling and is submitted alongside this report.

	documents, such as patient information, amended as a consequence should be forwarded to the centre's inspector by 23 April 2017.	stages of the pathway to acquaint herself. We hope to have additional counsellor facility as the programme progresses and we will ensure that any new staff are afforded similar provision.	**June 2017 update:** Confirmation has been provided that appropriate training has now taken place. Additional hours of counselling time have also been built into the program which will initially allow for training and then patient appointments. The counsellor will audit uptake of counselling. In addition, to address comments made by the Committee in paragraph 3.11 of their minutes, the executive can confirm that the counsellor's competence has been assessed by the PR, and the executive is satisfied the counsellor meets the requirements of the Code of Practice. No further action required.
6. Staff training A nurse has not yet been identified and specifically	Confirmation that a nurse(s) has been trained and assessed as competent should be forwarded to the	Nursing staff taking on the mitochondrial donation work come from the existing staff and therefore	An appropriate training package has been put in place. Confirmation that this has been completed should

trained or assessed as competent for their role in mitochondrial donation and treatments. SLC T12 and T13.	centre's inspector by 23 April 2017.	are well aware of the development of the programme and its course. To build on that and for the newer members of the team we have a seminar in place which will be repeated as required to acquaint the whole team with the pathways invovled. (Working Towards Clinical Mitochondrial ART). Those leading the nursing elements of the patient pathway will attend the joint mitochondrial clinic (NFCL) to understand the detailed discussions undertaken at that point and will receive specific small group teaching on the consents (HFEA and In house), implications documents and procedures. Dr Stewart will sit with those giving specific information to ensure confident and competent before signing off.	be forwarded to the centre's inspector by 23 April 2017. **June 2017 update:** The centre has described how appropriate initial training has been provided, and an outline of further training planned for the relevant nurses in the immediate future. The executive is satisfied with the update provided and require no further action.

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
7. Donor screening A documented procedure (a checklist) for screening donors required updating to reflect screening requirements of mitochondrial donors, in particular those screening tests not required in comparison to egg donors. SLC T52 (a-h) and T126; Code of Practice guidance 33B.	The centre should audit their documented procedure against the mitochondrial screening requirements, amend as appropriate, and forward a copy to their inspector by 5 April 2017.	This has already been audited please see attached a copy of the Audit on Donor Screening (Clinical/Process/4).	Appropriate action has been taken to update the documented procedure. **No further action required.** **June 2017 update:** No update required.
8. Information Written information for mitochondrial donors or patients did not explicitly cover all guidance issued in the Code of Practice.	Written information should be reviewed against the guidance issued in the Code of Practice, and amended as appropriate or consideration given to why its inclusion might not be appropriate.	This has already been audited please see attached the Audit for "Donor Information for Mitochondrial Donors (Clinical/Patient information/10).	The centre has used the inspectorate's information audit tool to audit their information against the Code of Practice. A copy of this audit was forwarded to the inspectorate alongside revised patient information.

CoP Guidance Note 33.	A summary of actions taken should be provided when responding to this report, and any amended documents forwarded to the centre's inspector by 5 April 2017.		The inspectors are satisfied that guidance in the CoP has been fully incorporated into the centre's information. All information leaflets are submitted to the Committee alongside this report. **No further action required.** **June 2017 update:** In paragraphs 3.13-3.15 of their minutes, the Licence Committee made suggestions to further improve patient information: to make counselling arrangements clearer, to update a reference to 'Infertility Network UK', and to make arrangements for storage clearer. Updated patient and donor information has been provided by the centre that addresses these points. The information (with relevant sections highlighted) is submitted alongside this update.

			No further action required.