Licence Committee - minutes

Centre 0017 (Newcastle Fertility Centre at LIFE)
Executive Update - Variation of Licensed Activities to include Mitochondria Pronuclear Transfer (PNT)

Thursday, 7 September 2017

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

Committee members	Lee Rayfield (Chair) Ruth Wilde Kate Brian Anita Bharucha	
Members of the Executive	Dee Knoyle	Secretary
Legal Adviser	Dawn Brathwaite	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.

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:

Papers enclosed:

- Executive update
- The PR's response to the Licence Committee's concerns regarding counselling provision
- Revised patient information sheet regarding mitochondrial donation treatment
- Revised donor information sheet regarding mitochondrial donation treatment
- Licence Committee Minutes of 13 July 2017
  - Executive update to Licence Committee 13 July 2017
- Licence Committee minutes of 9 March 2017- licence variation application PNT
  - Cover sheet for Licence Committee, 9 March 2017, Licence variation application from centre 0017
  - Report of licence variation inspection at centre 0017, provided to the Licence Committee on 9 March 2017
  - Licence variation application form and additional supporting information (Annex II document)
  - Executive Licensing Panel minutes 20 May 2016 - Interim inspection
  - Executive Licensing Panel minutes 30 May 2014 - Renewal inspection

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 treatment (including embryo testing) and storage licence is due to expire on 31 July 2018. The centre also has a research licence for project R0152, entitled 'Towards improving assisted reproductive technologies for the treatment of infertility and prevention of disease' under which its research into mitochondrial donation techniques has taken place.

March 2017

1.2. The Licence Committee approved the centre's application to vary its treatment licence to include mitochondrial donation using Pronuclear Transfer (PNT) at its meeting on 9 March 2017. The committee noted that recommendations for improvement were made for six major areas of non-compliance and two other areas of practice. The recommendations for the two other areas of non-compliance relating to donor screening and information had been fully implemented at the time of the meeting. The committee requested a full update on the progress of all the recommendations to be considered at its meeting in July.

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1.3. The Licence Committee considered the Executive update at its meeting on 13 July 2017. The Executive reported that recommendations for three of the major areas of non-compliance had been addressed relating to:

- premises (air quality);
- counselling (patient and donor information, implications counselling and qualifications of the Counsellor);
- staff training.

1.4. The Executive also reported significant progress on the other three major areas of non-compliance relating to:

- equipment (validation of the time-lapse embryo incubator);
- CE Marking (safety testing of non-CE marked media batches;
- Third Party Agreements (signing of third party agreements with two external testing laboratories).

1.5. The committee was satisfied with the progress made to address the major areas of non-compliance with the exception of counselling and patient and donor information. 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. The committee relayed, in some detail, its expectations and asked for evidence that the Counsellor meets the requirements of the HFEA Code of Practice.

2. Consideration of application

2.1. The committee noted that the centre worked swiftly to address the concerns raised by the Licence Committee at its meeting on 13 July 2017.

2.2. The committee noted that the Person Responsible (PR) has provided evidence describing further actions to complete the implementation of recommendations to address the outstanding major areas of non-compliance. These actions include advising the Executive when the safety testing of non-CE marked media is completed and when the final signed third party agreement is received.

2.3. The committee noted that the PR has responded to its concerns regarding patient and donor information and counselling provision.

2.4. The Executive considers that the revised patient and donor information sheets submitted by the PR have addressed the committee's concerns and the documents provided illustrate the centre's commitment to support patients and donors at all stages of treatment associated with mitochondrial donation.

2.5. The committee noted that implications counselling with an experienced, appropriately accredited Counsellor at the centre, who has undertaken specific training in the mitochondrial treatment pathway, will be offered to all patients and donors as part of the treatment pathway and they are encouraged to accept this offer. Therapeutic counselling is also offered at multiple points in the patient pathway. A discussion on the implications of treatment is provided by a senior member of the nursing/clinical team.

2.6. The committee noted that an error was made in the Executive's licence variation report presented to the Licence Committee at its meeting on 9 March 2017. The report stated that the centre's Counsellor was accredited by the British Infertility Counselling Association (BICA) whereas the Counsellor is in fact, accredited by the British Association for Counselling and Psychotherapy (BACP). The committee noted that evidence for the equivalence of the Counsellor's BACP accreditation with that of the BICA accreditation scheme was reviewed by the Executive during and after the centre's previous renewal inspection in 2014. The committee noted that the minutes of the Licence Committee meeting on 9 March 2017 correctly described the Counsellor as a member of BACP who has attended a BICA introductory course in infertility, as stated in the licence renewal minutes of the Executive Licensing Panel Meeting on 30 May 2014, which also formed part of the variation application.

2.7. The committee noted that evidence for corrective actions, provided after the renewal inspection in 2014, indicated that the Counsellor's BACP accreditation, along with other activities she had undertaken, provided equivalence to BICA accreditation and therefore the Counsellor's accreditation was considered compliant with the HFEA Code of Practice guidance 2.12 and 2.13. The committee noted that the Executive has confirmed with the Counsellor that her activities, together with her BACP accreditation, continue to demonstrate equivalence to BICA accreditation.

3. Decision

3.1. The committee was satisfied with the centre's progress on the major areas of non-compliance.

3.2. The committee acknowledged the centre's swift response to concerns raised at its meeting in July 2017, especially given that the minutes of that meeting were distributed to the centre later than usual and the response time was limited.

3.3. The committee was satisfied with the revised patient information submitted.

3.4. The committee was satisfied with the evidence provided to demonstrate that the Counsellor meets the requirements of the HFEA Code of Practice.

3.5. The committee reiterated the importance of implications counselling for patients who in some cases, may be quite vulnerable at the time of seeking treatment. The committee also agreed that giving patients the opportunity to attend counselling with a professional Counsellor, not involved in the patient's treatment, is best practice.

3.6. The committee was pleased with the centre's response and satisfied that its concerns raised at its meeting on 13 July 2017 have been addressed.

3.7. The committee acknowledged the centre's efforts to achieve compliance in order to carry out pioneering treatment in the UK for the benefit of patients with mitochondrial disease.

4. Chair's signature

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

Signature

Name

Lee Rayfield

Date

27 September 2017

Executive Update for Licence Committee
7 September 2017

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

Further 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 as an embryologist assessed as competent to undertake PNT.

2. 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. The Committee requested a full update on all recommendations to be presented at their July meeting.

3. The Executive update on 13 July 2017 described that three major recommendations had been addressed, concerning the premises (air quality), counselling and staff training. It also outlined significant progress regarding the other three major non compliances, such that the only issues remaining outstanding were validation of the time-lapse embryo incubator, safety testing of non CE marked media batches and signing of third party agreements with two external testing laboratories.

4. The minutes of the Committee on the 13 July 2017 acknowledged the update but expressed concerns regarding the counselling non compliance:
   '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.'

5. Moreover, the minutes set out in some detail the Committee's expectations in that regard.

6. The minutes of the Committee on the 13 July 2017 were only published to the centre late, on 22 August 2017 – outside the usual performance standards. That said, the centre worked to address the Committee's concerns and provided further

information to the Executive, finalised on 1 September 2017. As such, the Executive consider it is reasonable to the centre to provide an update report to the (next scheduled) Licence Committee on the 7 September 2017. The Executive apologises for the late submission of the papers and greatly appreciate the Licence Committee's understanding in this matter.

Update

7. The PR at centre 0017 has provided revised patient and donor information sheets. These are included in the Committee papers. The Executive has reviewed these against the concerns expressed about them in the minutes of the Committee on the 13 July 2017. The Executive considers that the revisions have addressed those concerns (Annex 1).

8. The PR has also provided a response to the Committee's remaining concerns regarding counselling provision, again included in the Committee papers. This document illustrates the centre's commitment to support patients and donors at all stages of treatment associated with mitochondrial donation. Implications counselling will be provided to all patients and donors as part of the treatment pathway and therapeutic counselling is offered at multiple points in the pathway, which patients and donors are encouraged to accept. Some implications counselling is provided by a senior member of the nursing/clinical team and therapeutic counselling, which will address implications, will also offered and provided by an experienced, appropriately accredited counsellor at the centre, who has undertaken specific training in the mitochondrial treatment pathway.

9. The Executive notes an error was made in the licence variation report presented to the Committee in March 2017. It stated that the centre's counsellor was British Infertility Counselling Association (BICA) accredited. The counsellor is in fact accredited by the British Association for Counselling and Psychotherapy (BACP). The Executive apologises for the inaccuracy in the licence variation report but notes that the minutes of the Committee in March 2017 correctly describe the counsellor as BACP accredited.

10. Evidence for the equivalence of the counsellor's BACP accreditation with that provided by BICA was reviewed by the Executive during and after the centre's previous renewal inspection in 2014. Evidence for corrective actions provided after the inspection indicated that the counsellor's BACP accreditation, along with other activities she had undertaken, provided equivalence to BICA accreditation, as per the relevant HFEA Clinic Focus article (January 2013: 'Counselling qualifications and equivalence') which sought to clarify this issue. Thus the counsellor's accreditation was considered compliant with CoP guidance 2.12 and 2.13.

11. The inspection team which addressed the licence variation application, confirmed with the counsellor that her activities continue to support the equivalence of her BACP accreditation. Hence the Executive update report provided on 13 July 2017 stated: '…The PR has included information in her response to the Committee's

concerns, provided in the papers, in support of the equivalence of the counsellor's BACP accreditation as well as her more recent training regarding the mitochondrial treatment pathway.

12. The PR has also provided evidence to the Executive describing further actions to complete the implementation of recommendations to address the final three outstanding major non compliances. These are discussed in Annex 2.

13. In summary, the remaining actions necessary to fully implement the licence variation report's recommendations are:
    - the PR should advise the Executive when the safety testing of non CE marked media is completed;
    - the PR should advise the Executive when the final signed third party agreement is received

Andrew Leonard, Senior Inspector
1 September 2017

Annex 1: Do the revised patient and donor information sheets address the concerns expressed by the Licence Committee on 13 July 2017?

The concerns expressed in the July Committee minutes	Executive review of revised information sheets
1) The Committee 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 revised patient and donor information sheets make clear that implications counselling with a senior member of the nursing/clinical team is an integral part of the treatment pathway. Therapeutic counselling with an appropriately accredited and trained counsellor is also offered, which can also address all implications of the treatment pathway. Both patients and donors are encouraged in the information documents to make use of the therapeutic counselling service. The Executive considers that the revised information sheets address the Committee's concern.
2) The patient information should set out the benefits of seeing a counsellor prior to treatment or donation.	The revised patient and donor information sheets now make clear the benefits of the implications and therapeutic counselling available. The Executive considers that the revised information sheets address the Committee's concern.
3) Patient and donor information should make it clear that it is expected that mitochondrial donation treatment patients and donors will have counselling before treatment or donation starts.	All prospective patients and donors must be given a suitable opportunity to receive proper counselling before providing consent to a licensed activity (e.g. CoP interpretation of mandatory requirements 11C or Schedule 3 of the HF&E Act). There is no legal or CoP requirement or guidance that all patients and/or donors must undertake counselling, neither generally or specifically in the CoP guidance regarding mitochondrial donation. The Executive notes that the revised information sheets encourage patients and donors to use the therapeutic counselling service and discuss its

	benefits. The accredited counsellor's contact details are provided for patients and donors to use to make appointments. The Executive considers that the patient and donor information sheets satisfy CoP requirements and guidance to provide a suitable opportunity to receive proper counselling.
4) The patient and donor information sheets are still inaccurate and do not reflect the Code of Practice in places: • 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 Executive notes that the information provided in the revised patient and donor information sheets about legal issues concerning parenthood now appears accurate, i.e. that mitochondrial donors are not legal parents to any child and have no specific rights or responsibilities in relation to your family. In relation to CoP 33.28, the Executive notes that the revised patient and donor information sheets accurately describe the information about the donor, which can be provided to the person conceived through mitochondrial donation, as discussed in CoP guidance 33.28. The Executive notes that the information provided in the revised patient information sheet now encapsulates CoP guidance 33.20. The Executive considers that the revised information sheets addresses the Committee's concerns on these matters.
5) 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. • specifically recommend or mention counselling on the implications of treatment	The Executive notes that the revised patient and donor information sheets now discuss an implications counselling session with a senior member of the nursing/clinical team in the treatment pathway. They also discuss therapeutic counselling with an accredited counsellor, which will include implications counselling. Patients and donors can arrange counselling sessions if they want to and are encouraged within the information sheets to do so. The content and benefits of implications and counselling are described, including consideration of the implications of treatment specifically.

• describe the benefits of implications counselling or provide information on counselling generally	The Executive considers that the revised information sheets address the Committee's concerns.
6) 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 Executive notes that the revised donor information sheet now discuss implications counselling within the donor treatment pathway and information on the counselling service is more specific to donor requirements. The Executive considers that the revised donor information sheet addresses the Committee's concerns.
7) 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.	Interpretation of mandatory requirements 11C states: 'All prospective donors must be given a suitable opportunity to receive proper counselling…' CoP guidance 3.3 discusses implications counselling regarding donation being provided separate from that provided regarding treatment. CoP guidance 3.7 discusses counselling being separate from medical assessment and the provision of information. The Executive notes that the revised donor information sheet now discusses that implications counselling with a senior member of the clinical team is part of the donor treatment pathway and therapeutic counselling attendance is encouraged. It also states 'Counselling is an integral part of all fertility treatment'. There is also discussion about the implications of donation

	separate from the implications of treatment. The content regarding implications and therapeutic counselling is also focussed on counselling rather than treatment information provision. The Executive considers that the revised donor information sheet addresses the Committee's concerns.

Annex 2:

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	Documented validations, and any supporting	2. Equipment: As detailed in the departments	We request that the centre confirms the validation of necessary critical

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.	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.	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.	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. **September 2017 update:** The PR has clarified that a new time-lapse incubator was included on the list of proposed equipment for use in the treatment but was not an absolute requirement. Incubators already in the laboratory are validated for use in the proposed treatment and will be used going forward. The Executive has no concerns regarding this matter.

			No further actions are required.
3. CE marking Documented procedures/templates to assure the safety of non-CE marked reagents (medical devices) are currently in draft format. SLC T23 and T30	Final versions of the centre's risk assessment, release specification template and associated SOP should be forwarded 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.	3. We will forward the HFEA appropriate risk assessments, release specifications and SOPs for all non CE marked 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 Executive is satisfied with the response provided, and we await the final risk assessment/SOP, followed by the outcome of testing of 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. **September 2017 update:** The PR provided evidence that safety testing of all non CE marked media is progressing and will be completed by 10 September 2017. No problems have been encountered as yet. The PR has provided assurance that she will keep the Executive updated on testing progress and that treatment will not progress until all non CE marked media has passed 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.	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.

SLC T111-114.			**September 2017 update:** All TPAs have now been signed albeit one was in transit between the third party and the centre at the time this update was prepared. The PR will confirm receipt with the Executive.
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 documents, such as patient information, amended as a consequence should be forwarded to the centre's inspector by 23 April 2017.	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 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.	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. **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. **September 2017 update:** The PR has responded in the papers submitted with this update to additional concerns raised by the Licence Committee. The Executive has reviewed the PR's responses elsewhere in this update. The Executive considers no further actions are required.
6. Staff training A nurse has not yet been identified and specifically trained or assessed as competent for their role in mitochondrial donation and treatments.	Confirmation that a nurse(s) has been trained and assessed as competent should be forwarded to the centre's inspector by 23 April 2017.	Nursing staff taking on the mitochondrial donation work come from the existing staff and therefore are well aware of the development of the programme and its course. To build on that	An appropriate training package has been put in place. Confirmation that this has been completed should be forwarded to the centre's inspector by 23 April 2017. **June 2017 update:** The centre has described how

SLC T12 and T13.		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.	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.