Executive Licensing Panel Minutes

Centre 0159 (Royal Surrey County Hospital)

Interim Inspection Report

Change of Centre Name

Date:	23 March 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Anna Coundley	Director of Strategy and Corporate Affairs Communications Manager Policy Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood India Hickey	Licensing Manager Research Officer (Induction)

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:

- 9th edition of the HFEA Code of Practice.
- Standard licensing and approvals pack for committee members.

1. Consideration of Application

1.1. The panel noted that The Royal Surrey County Hospital is located in Guildford and has held a licence with the HFEA since 1995. The centre holds a storage only licence and provides a sperm storage service to patients who are undergoing treatment that may impair their fertility.

1.2. The panel noted that the centre stores sperm for approximately two patients per week. In relation to activity levels this is a very small centre.

1.3. The panel noted that an application to change the centre's name would also be for consideration at this meeting.

1.4. The panel noted that, due to the Covid-19 pandemic, this interim inspection was conducted by means of a Desk Based Assessment and Risk Based Approach (DBA/RBA). This took into account the centre's own assessment of its service, the progress made in implementing the actions identified at the last inspection, alongside the on-going monitoring of the centre's performance. An onsite inspection of areas of concern or uncertainty identified during the DBA/RBA, and where they could be safely reviewed, was conducted on 2 December 2020.

1.5. The panel noted that at the time of the inspection, there was one critical area of non-compliance concerning consent to storage. There were three major areas of non-compliance regarding the quality management system (QMS), procuring, processing and transporting gametes and embryos, and staff. One 'other' area of non-compliance surrounding procuring, processing and transporting gametes and embryos was also identified. Since the inspection, the Person Responsible (PR) has fully implemented the non-compliances concerning the QMS and the procuring, processing and transporting gametes and embryos (both the major and 'other'). The PR has given a commitment to fully implementing the non-compliances concerning the consent to storage and staff.

1.6. The panel noted that, due to the level of concerns raised regarding storage activities at the centre and in accordance with the HFEA's Compliance and Enforcement Policy, a management review meeting was held on 8 December 2020 to consider the extent of the critical non-compliance and to determine whether any informal or formal regulatory action was required. Whilst it was considered that there were no immediate risks to patients, staff or stored sperm, the critical non-compliance regarding consent to storage was deemed significant. The PR was provided with detailed guidance and information about the HFEA statutory storage regulations and was asked to consider what actions he needs to take to address this area of concern.

1.7. The panel noted that the centre stores sperm for fertility preservation purposes, so there is the risk that, should the providers want to use their samples in the future, they may not be able to because the samples may have been stored unlawfully.

1.8. The panel noted that there were some concerns that the PR has failed to discharge his duty because he has either failed to understand or to apply the regulations in relation to extended storage. The executive has been provided with reassurance by the PR, during the onsite inspection and in correspondence received following the inspection, which shows understanding of the regulations and of the impact of the centre's non-compliance. The PR has also committed to take the necessary actions to address this area of concern, has liaised with senior management at the Trust and received their support to take all actions necessary to achieve compliance.

1.9. The panel noted the centre is reasonably well led and provides a good level of patient support.

1.10. The panel noted that an initial recommendation, to continue the centre's licence, was conditional on the PR developing and implementing effective action plans to address the non-compliances in the interim report and providing suitable assurances to the satisfaction of the executive.

1.11. The panel noted that the PR has provided a commitment and assurances that he has started to develop and implement effective actions; therefore, the executive recommends continuation of the centre's storage only licence. However, given the level of concern regarding the consent to storage recommendation, the executive further recommends a focused inspection to be performed within one year of the meeting's decision, to ensure that the processes implemented have been effective in ensuring that there is valid consent for all gametes being stored at the centre.

2. Decision

2.1. The panel was satisfied the centre was fit to have its storage only licence continued, endorsing the executive's recommendation that a focused inspection should be performed within one year of the meeting's decision, to ensure that the processes implemented have been effective in ensuring that there is valid consent for all gametes being stored at the centre.

3. Variation of Name

3.1. The panel noted that the centre's PR had also submitted an application to change the centre's name.

3.2. The panel noted that the centre's name is presently Royal Surrey County Hospital and the centre now wishes to be known as Royal Surrey Hospital NHS Foundation Trust.

4. Decision

4.1. After considering the recommendation of the inspectorate and all supporting documentation, the panel changed the name of the centre to Royal Surrey Hospital NHS Foundation Trust.

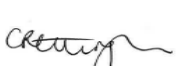
5. Chairs signature

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

Signature

Clare Ettinghausen

Name



Date

29 March 2021

Interim Licensing Report

Centre name: Royal Surrey County Hospital
Centre number: 0159
Date licence issued: 1 April 2019
Licence expiry date: 31 March 2023
Additional conditions applied to this licence: None
Date of inspection: 2 December 2020
Inspectors: Desk based assessment undertaken by Julie Katsaros and Karen Conyers. On-site inspection undertaken by Andrew Leonard
Date of Executive Licensing Panel: 23 March 2021

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLCs).

This is a report of a short notice interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

This inspection was conducted via a Desk Based Assessment and Risk Based Approach (DBA/RBA), combined with onsite inspection of areas of concern or uncertainty, identified by the DBA/RBA process, where they could be safely reviewed.

Variation to Licence

The executive received an application from the PR to vary the licence to change the centre's name to Royal Surrey Hospital NHS Foundation Trust. The PR requests that the committee consider the interim inspection report and the licence variation at the same time.

Summary for the Executive Licensing Panel

Summary for licensing decision

Taking all findings into account the executive concluded that the centre's licence should continue.
An initial recommendation to continue the centre's licence was conditional on the PR developing and implementing effective action plans to address the non-compliances in this report and providing suitable assurances to the satisfaction of the executive.

The PR has provided a commitment and assurances that he has started to develop and implement effective actions and therefore the executive recommends continuation of the centre's licence, however, given the level of concern regarding the consent to storage recommendation, the executive further recommends a focussed inspection to be performed within one year of the ELP's decision, to ensure that the processes implemented have been effective in ensuring that there is valid consent for all gametes being stored at the centre.

The centre is reasonably well led and provides a good level of patient support.

The ELP is asked to note that this report makes recommendations for improvement in relation to one critical, three major and one 'other' area of non-compliance or poor practice.

Since the inspection visit the following recommendations have been fully implemented:

Major areas of non-compliance:

- The PR should ensure that the Quality Management System (QMS) is coordinated across all aspects of the centre's activities.
- The PR should ensure with immediate effect that each patient's travel history is reviewed and the need for additional testing is considered, so that sperm can be safely stored and used in line with licence condition requirements and professional body guidance.

'Other' area of non-compliance:

- The PR should ensure the centre's relevant standard operating procedure (SOP) is updated to define the responsibilities and actions required when a distribution is recalled.

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

Critical area of non-compliance:

- **The PR must ensure that there is effective consent to storage for all cryopreserved sperm**.

Major area of non-compliance:

- The PR should ensure that staff complete their mandatory safeguarding training within the specified timeframes.

Due to the level of concerns raised regarding storage activities at the centre and in accordance with the HFEA's Compliance and Enforcement Policy, a management review meeting was held on 8 December 2020 to consider the extent of the critical non-compliance and to determine whether any informal or formal regulatory action was required. Whilst it was considered that there were no immediate risks to patients, staff or stored sperm, the critical non-compliance regarding consent to storage of cryopreserved materials was deemed significant. The PR was provided with detailed guidance and information about the HFEA statutory storage regulations and was asked to consider what actions he needs to take to address this area of concern.

The centre stores sperm for fertility preservation purposes, so there is the risk that should the providers want to use their samples in the future, they may not be able to because the samples may have been stored unlawfully.

There were some concerns that the PR has failed to discharge his duty because he has either failed to understand or to apply the regulations in relation to extended storage. The executive have however been provided with reassurance by the PR during the onsite inspection and in correspondence received following the inspection, which shows understanding of the regulations and of the impact of the centre's non-compliance. The PR has also committed to take the necessary actions to address this area of concern and has liaised with senior management at the Trust and received their support to take all actions necessary to achieve compliance.

Information about the centre

The Royal Surrey County Hospital is located in Guildford and has held a licence with the HFEA since 1995.

The centre holds a storage only licence and provides a sperm storage service to patients who are undergoing treatment that may impair their fertility. The centre stores sperm for approximately two patients per week. In relation to activity levels this is a very small centre.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes

Treatment services leading to pregnancies are not provided at this clinic.

Multiple births

Treatment services leading to pregnancies are not provided at this clinic.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of sperm samples and that identification errors do not occur.

This area of practice was assessed via DBA which indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes are stored in accordance with the consent of the gamete providers.

This area of practice was assessed via a DBA and the 'bring-forward' system was discussed with staff during the onsite inspection. These activities indicate that the centre's processes for storing sperm in line with the consent of the gamete providers are not effective for the following reasons.

- The centre does not take into consideration the date of the Medical Practitioner's Statement (MPS) when calculating the expiry date of samples in storage for more than 10 years.
- Centre staff are not aware that a MPS has a 10 year life span if signed after October 2009 so, for samples stored for more than 10 years, a new MPS forms has to be signed within 10 years of the last one and, if it is not, that the period of absence of a valid MPS is likely to be irreconcilable with lawful storage.
- The inspection team is concerned that some samples may have been in storage for longer than the statutory storage period of 10 years, without evidence of compliance with the 2009 storage regulations being recorded in the patient records.
- The centre's bring-forward system has not been updated to take into account the additional two years of statutory storage available to patients meeting the requirements of The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020.

See recommendation 1.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

This area of practice was assessed via a DBA and during onsite inspection. Staffing levels in the clinic appeared suitable for the activities carried out.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: infection control; witnessing and consent to storage.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements because:

- Outstanding actions noted in previous meeting minutes have not been addressed

See recommendation 2.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- information provision;
- extension of storage consent;
- screening;
- the use of CE marked medical devices.

The centre is effective in implementing learning from their audits and guidance from the HFEA, with the exceptions noted in this report (see recommendations 1 and 3).

Medicines management

The centre does not provide treatments requiring medicines therefore this area of practice is not relevant to this inspection.

Prescription of intralipid 'off label'

The centre does not provide treatments requiring medicines therefore this area of practice is not relevant to this inspection.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

Infection control practices were assessed via a DBA and were found to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with sperm are approved for the provision of fertility treatment, to ensure the safety of those samples generally and when used in patient treatment. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of all medical devices used by the centre was confirmed by the PR during the DBA. The centre was found to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback, however, because of the nature of the activities undertaken by patients at this clinic, it is not relevant for this group of patients. The centre obtain their own patient feedback and the most recent patient survey responses were reviewed: 38 out of 42 patients attending the centre since January 2020 have provided feedback via the centre's patient experience questionnaire. All questionnaires were fully completed with 100% satisfaction, no areas of improvement were identified.

Due to the ongoing Covid-19 pandemic patients were not approached by the inspector during the onsite inspection.

On the basis of this feedback and the information reviewed via a DBA, it was possible to assess that the centre:

- treats patients with privacy and dignity;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment, the DBA and observations during the visit to the centre, indicate that the centre is fully compliant with HFEA requirements with the following exceptions.

- Although the centre's staff ask about a patient's travel history they do not undertake additional testing depending on the patient's travel and exposure history. See recommendation 3.
- A member of staff had not completed a safeguarding update within the timeframe specified by the Trust and they subsequently failed to attend a pre-arranged safeguarding training session. See recommendation 4.
- Although the SOP for transporting sperm discusses a sample's recall it does not document the recall procedure or define the responsibilities and actions required when a distribution is recalled. See recommendation 5.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2018, recommendations for improvement were made in relation to one major and four 'other' areas of non-compliance or poor practice. All were addressed within appropriate timescales with the exception of the QMS non-compliance noted in this report.

On-going monitoring of centre success rates

Treatment services that result in success rates monitored by HFEA are not provided at this centre.

Provision of information to the HFEA

The centre is not required to provide information to the HFEA.

Legal parenthood

Treatment services that might need a person to consider providing consent to legal parenthood are not provided at this centre.

Leadership

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Whilst the executive was concerned that the PR lacked an understanding of his responsibilities regarding storage regulations he has been proactive in seeking to address this issue.

The centre is compliant with HFEA guidance regarding effective leadership.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the inspection team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be made.

Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical non-compliance requires immediate action to be taken by the Person Responsible.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Consent to storage The centre's processes for storing sperm in line with the consent of the provider are not effective because: • The centre does not take into consideration the date of the MPS when calculating the expiry date of samples in	The PR must ensure that there is effective consent to storage for all cryopreserved sperm. The PR must provide a report of the number of patients for whom sperm remains in store without appropriate records to support its lawful storage including, for each sample, a	Agree to your points, these will be actioned and responses provided. Bullet 3 bottom of page number 9. I feel this is not correct as we had started informing patients. The SOP was updated and available for inspection. Since	The executive notes the PR's response and his commitment to fully implementing this recommendation. The executive notes that actions are being taken to contact patients advising them of the potential additional statutory storage period under the

storage for more than 10 years. • Centre staff are not aware that a MPS has a 10 year life span if signed after October 2009 so, for samples stored for more than 10 years, a new MPS forms has to be signed within 10 years of the last one and, if it is not, that the period of absence of a valid MPS is likely to be irreconcilable with lawful storage. • The inspection team is concerned that some samples may have been in storage for longer than the statutory storage period of 10 years, without evidence of compliance with the 2009 storage regulations being recorded in the patient records. • The centre's bring-forward system has not been updated to take into account the additional two years of statutory storage available to patients meeting the requirements of The Human	summary of the consent documents available and an explanation why storage is likely to be unlawful. In all cases where there has been a failure to comply with the statutory storage regulations, the PR must seek independent legal advice from a legal representative conversant with the HF&E Act 1990 (as amended), the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, and The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020, on how to proceed. Legal advice should guide the development of a documented action plan, with timescales for implementation, to ensure all samples are lawfully stored. If lawful storage cannot be assured or reconciled, actions must be taken to advise the	the inspection we have written to majority of our patients.	Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020. However, it is not clear in the centre's SOP what actions are to be taken when a response is received, specifically with regards to updating the centre's bring-forward system. The executive is particularly concerned as the centre had not previously taken date of the MPS into consideration in their bring-forward system when calculating the expiry date of samples in storage for more than 10 years. Further actions are required to ensure the centre's bring forward system includes consideration of any relevant changes in patient's consent to storage particularly MPS and/or CVS forms. The PR should ensure that the requested review of the centre's procedures for storage consent also includes consideration of how the HFEA CVS form will be

Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020. HF&E Act (1990) as amended, Schedule 3, 8(1). Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020.	sperm providers of the situation and of the options available to them. A copy of this action plan should be provided to the centre's inspector by 2 March 2021. The PR must review procedures for storage consent and ensure they are robust and effective in ensuring written effective consent and a valid MPS where necessary, are in place for all cryopreserved sperm. The PR must provide a summary report of this review including the corrective actions taken, to the centre's inspector by 2 March 2021. Three months after the review, the PR must audit storage consent procedures to ensure that corrective actions have been effective in achieving compliance. A summary report of this review should be		incorporated into the bring-forward system. **26 February 2021** The PR confirmed that all samples held in storage have been audited and 6 patients samples have been identified as not having valid consent in place, for which the PR has sought legal advice. The PR has provided a report, which includes the legal advice received by the PR and sets out the actions that he is going to take. One patient has been able to update their consent in line with the Coronavirus Regulations 2020, whilst the remaining 5 are due to be contacted by letter and further actions are to be taken accordingly. The PR has reviewed the centre's procedures CVS forms in the centre's bring forward system.

	provided to the centre's inspector by 2 June 2021.		The PR has put additional interim measures in place so only experienced staff at the clinic will undertake the actions required in response to the centre's bring forward system. Following discussions with the Hospital Trust, the Trust has committed to working with the PR to produce/procure a suitable replacement data base and financial support for the project has been included in the business planning for next year. Further action is required.

‘Major’ areas of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise 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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
2. The quality management system Outstanding actions noted in the centre’s previous meeting minutes have not been implemented. This was identified as an area for improvement at the time of the last inspection and therefore has been recorded as a major area of non-compliance. SLC T32.	The PR should ensure that the QMS is coordinated across all aspects of the centre’s activities. The PR is asked to investigate why this area of non-compliance has recurred and to provide a summary report, including any corrective actions with timescales for implementation, to the centre’s inspector by 2 March 2021. The PR is asked to review the minutes of the meetings provided for the DBA, as well	Agree. Already actioned.	The executive notes the PR’s response and his commitment to fully implementing this recommendation. Further action is required. **26 February 2021** The PR provided the requested summary report. The PR provided the executive with meeting minutes for the last 18 months and confirmed that these had been reviewed

	as two further sets of minutes for meetings held in the last 18 months, to see if there are any other outstanding actions that still need to be addressed and to implement those actions if any are found. A report of this review and confirmation of the actions undertaken, should be provided when responding to this report.		and all outstanding actions have been addressed. No further action is required
3. Procuring, processing and transporting gametes and embryos Although the centre's staff ask about a patient's travel history they do not consider whether the information indicates that additional testing is necessary to ensure the sperm can be safely stored and used in treatment. SLC T50 (d).	The PR should ensure with immediate effect that each patient's travel history is reviewed and the need for additional testing is considered, so that sperm can be safely stored and used in line with licence condition requirements and professional body guidance. The PR should advise the centre's inspector of the actions taken to address this non-compliance by 2 March 2021. The PR should consider, with expert advice if necessary, if there is any risk to patients or	Agree, clincial staff have been reminded again and this will be actioned.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required. **26 February 2021** The PR has provided the requested information. No further action is required.

	their partners resulting from the past failure to undertake additional testing where it might have been indicated by travel history. If risk is present, appropriate risk control measures should be implemented.		
4.Staff A member of staff had not completed a safeguarding update within the timeframe specified by the Trust and they subsequently failed to attend a pre-arranged safeguarding training session. Failure to complete safeguarding training was identified at the time of the last inspection, however, there were also additional areas relevant to staff training that were identified but have not reoccurred and therefore some improvement has been achieved, resulting in the level of non-compliance not being elevated in this report. SLC T12.	The PR should ensure that staff complete their mandatory safeguarding training within the specified timeframes. It is expected that staff should complete their safeguarding training by 2 June 2021. The PR should provide evidence of this to the centre's inspector by this date.	Agree. Clinical staff have already completed, evidence will be provided.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required. **26 February 2021** The PR confirmed that one member of staff is yet to complete the relevant training. Further action is required.

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas of practice in which failings occur, which cannot be classified as either a critical or major area of noncompliance, but which indicate a departure from statutory requirements or good practice.

An ‘other’ area of non-compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
5.Procuring, processing and transporting gametes and embryos Although the centre’s sperm transport SOP discusses sample recall it does not document a recall procedure or define the responsibilities and actions required when a distribution is recalled. CoP Interpretation of mandatory requirements 15c.	The PR should ensure the relevant SOP is updated to define the responsibilities and actions required when a distribution is recalled. Confirmation that the SOP has been updated appropriately should be provided to the centre’s inspector by 2 March 2021.	Agree. Already actioned and evidence will be provided.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. Further action is required. **26 February 2021** The PR provided documentary evidence that the centre’s sperm transport SOP had been updated. No further action required.

Additional information from the Person Responsible