Executive Licensing Panel Minutes

Centre 0102 (Guys Hospital)

Renewal Inspection Report

Date:	1 June 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Helen Crutcher (Chair) Anna Coundley Niamh Marren	Risk and Business Planning Manager Policy Manager Regulatory Policy Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood	Licensing Manager

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 considered the papers, which included a completed application form, inspection report and licensing minutes for the last five years.

1.2. The panel noted that Guys Hospital has held a licence with the HFEA since 1992 and provides a full range of fertility services including gamete and embryo storage and embryo testing.

1.3. The panel noted that, in the 12 months to 30 November 2020, the centre provided 1310 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre. The figure for the previous year was 2880 cycles; the reduced activity level is primarily due to the Covid-19 pandemic.

1.4. The panel noted that, HFEA register data, for the year to 31 January 2021, show the centre's success rates for IVF and ICSI are in line with the national averages.

1.5. The panel noted that, in 2020, the centre reported 17 cycles of partner insemination, with no pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.6. The panel noted that, HFEA register data, in the year ending 31 January 2021, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is significantly lower than the 10% multiple live birth rate target for this period.

1.7. The panel noted that the centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

1.8. The panel noted that the Executive Licensing Panel (ELP) considered the centre's interim inspection in June 2019 and the minutes stated 'the panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued, supporting the inspection team's recommendation that a further targeted inspection should occur within the next 12 months to ensure that corrective actions taken to implement the recommendations made in the report generally, and specifically related to the legal parenthood consent non-compliance, have been effective in achieving and maintaining compliance.'

1.9. The panel noted that the centre was visited by HFEA inspectors four times between 2 December 2019 and 6 March 2020, investigating concerns raised by a 'whistleblower' about an inappropriately high treatment activity level for the staffing resources available and the safety of the cryostorage facilities. These inspections also provided opportunities to follow up the centre's actions to address the non-compliances identified at the previous interim inspection.

1.10. The panel noted that the Person Responsible (PR) at the time, and centre staff, provided all requested documentation and assistance during the inspection visits. The inspectors received reassurance from the hospital's Chief Executive Officer, Clinical Director and Clinical Lead for Women's Health that actions were being taken to address concerns which the centre had already identified and was responding to, which included the concerns raised by the 'whistleblower'.

1.11. The panel noted that the centre's action plan included: the recruitment of a lead embryologist at consultant level as well as several other laboratory workers, a limit on treatment activity to a level commensurate with the staffing resources available, an emphasis on improved treatment activity planning across the senior management team, improving governance arrangements to

encompass sensitivity to staff concerns, upgrading gamete and embryo storage systems to significantly increase storage capacity while reducing the equipment 'foot-print' in the cryostore; and progressing plans for a second cryostore to provide further increases in storage capacity. The inspectors concluded, after a second visit on 18 December 2019, that the centre was taking appropriate actions to address the concerns identified.

1.12. The panel noted that the implementation of the action plan was monitored closely through visits to the centre on 18 December 2019, 6 March 2020 and 13 March 2020, then remotely after the Covid-19 pandemic began in March 2020. These activities raised no concerns, providing the inspectors with reassurance that the centre had implemented appropriate actions to address issues, that had been recognised and acknowledged, by the PR and the centre's management team. The inspectors also concluded that effective actions had been taken within expected timeframes to address the non-compliances identified by the previous interim inspection in February 2019.

1.13. The panel noted that a scheduled interim inspection was due to occur in April or May 2020 at which the implementation of the action plan was to have been a focus, and the inspection team had then planned to draft a joint report for the ELP of the inspections in response to the concerns raised and the planned interim inspection. The Covid-19 pandemic, the centre being closed to treatment for periods in 2020 and early 2021 and the suspension of HFEA inspections, prevented this plan from being progressed.

1.14. The panel noted that, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), was conducted for the centre's licence renewal. Following this, it was established that any items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology, rather than an on-site inspection. This process removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic. As the centre was also last inspected in March 2020, a visit to the clinic was not needed for the HFEA to fulfil its legal obligations.

1.15. The panel noted that a DBA, followed by a virtual inspection, was conducted on 15 February 2021, which included videoconferencing with key members of staff.

1.16. The panel noted that the safety of the centre's service was a focus at the renewal inspection generally, but it also specifically looked at the staffing resources available and their matching to the treatment activity planned, the cryostorage facilities and the implementation of the action plan identified by the centre in December 2019. Other areas for review included legal parenthood consent, gamete and embryo storage consent and treatment data submission to the HFEA, areas where significant concerns had been raised by the interim inspection in February and March 2019.

1.17. The panel noted that, at time of the inspection, there were three major areas of non-compliance concerning medicines management (controlled drugs), the Quality Management System (QMS) and record keeping and document control. There were also three 'other' non-compliances regarding donor screening, payment to donors and satellite services. Since the inspection, the PR has fully implemented the recommendation surrounding satellite services. The PR has given a commitment to fully implementing the recommendations concerning medicines management (controlled drugs), the QMS, record keeping and document control, donor screening and payment to donors.

1.18. The panel noted that the centre is well led and provides a good level of patient support. Some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to continue to use the QMS to best effect to monitor and improve their success rates and the quality of the service offered to patients.

1.19. The panel noted that the inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

1.20. The panel noted that the centre submitted a 'treatment and storage' licence application form in error, rather than one for a 'treatment (including embryo testing) and storage' licence; the PR has confirmed his intention was to apply to renew the 'treatment (including embryo testing) and storage' licence and email confirmation had been received.

1.21. The panel noted that, as a result of the UK's departure from the European Union (EU) a relicensing exercise is currently under way. This follows approval by the Licence Committee of a variation without application on 4 March 2021. This means that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021. Due to this, and assuming this application is approved, the offer licence provided to the centre for renewal will also constitute the offer licence for the licence condition changes related to EU exit.

1.22. The panel noted that the inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence, for a period of four years, without additional conditions, subject to the recommendations in the report being implemented in the prescribed timescales.

1.23. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to section 24(4AD). Such certificates are generally synchronised to the centre's HFEA licence. The executive therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

2. Decision

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

2.2. The panel noted that the premises to be licensed are suitable for the conduct of licensed activity.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge her duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel commended the centre on its low multiple birth rate of 3%, endorsing the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

2.5. The panel endorsed the executive's recommendation to renew the ITE's import certificate, in line with the centre's licence.

3. Chair's signature

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

Signature

Name

Helen Crutcher

Date

2 June 2021

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors.

The report provides information on the centre's application to renew its existing licence. Licensed centres usually receive a licence to operate for up to four years, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law).

The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 15 February 2021

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage.

Inspection details:

Centre name	Guys Hospital
Centre number	0102
Licence number	L/0102/16/c
Centre address	Assisted Conception Unit, 11th Floor, Tower Wing, Guy's Hospital, London, SE1 9RT
Person Responsible	Mr Tarek El-Toukhy
Licence Holder	Dr Simon Steddon
Date licence issued	01 July 2017
Licence expiry date	30 June 2021
Additional conditions applied to this licence	None

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

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented. These

methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

The DBA/RBA for this clinic allowed the inspection team to do this. The inspection team concluded that the items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic. This centre was also last inspected in March 2020 so a visit to the clinic was not needed for the HFEA to fulfil its legal obligations.

In summary, this inspection was carried out by DBA followed by a virtual inspection, which included videoconferencing with key members of centre staff.

Inspectors: Andrew Leonard (Lead), Julie Katsaros and Louise Winstone

Date of Executive Licensing Panel: 1 June 2021

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Guys Hospital has held a licence with the HFEA since 1992 and provides a full range of fertility services including gamete and embryo storage and embryo testing.

The centre provided 1310 treatment cycles (excluding partner intrauterine insemination) in the 12 months to 30 November 2020. The figure for the previous year was 2880 cycles. The reduced activity level is primarily due to the Covid-19 pandemic.

This current licence has been varied to reflect the following changes:

- A change of Licence Holder on 10 March 2020
- A change of Person Responsible (PR) on 8 September 2020

The ELP in June 2019, which considered the report of the last interim inspection at the centre in February and March 2019, noted in the minutes: 'The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued, supporting the inspection team's recommendation that a further targeted inspection should occur within the next 12 months to ensure that corrective actions taken to implement the recommendations made in the report generally, and specifically related to the legal parenthood consent non-compliance, have been effective in achieving and maintaining compliance.'

The centre was visited by HFEA inspectors four times between 2 December 2019 and 6 March 2020, to investigate concerns raised by a 'whistleblower' about an inappropriately high treatment activity level for the staffing resources available and the safety of the cryostorage facilities. These inspections also provided opportunities to follow up the centre's actions to address the non compliances identified by the previous interim inspection.

The PR at the time, and centre staff, provided all requested documentation and assistance during these inspection visits. The inspectors received reassurance from the hospital's Chief Executive Officer, Clinical Director and Clinical Lead for Women's Health that actions were being taken to address concerns which the centre had already identified and was responding to, which included the concerns raised by the 'whistleblower'. The action plan included: the recruitment of a lead embryologist at Consultant level as well as several other laboratory workers; a limit on treatment activity to a level commensurate with the staffing resources available; an emphasis on improved treatment activity planning across the senior management team; improving governance arrangements to encompass sensitivity to staff concerns; upgrading gamete and embryo storage systems to significantly increase storage capacity while reducing the equipment 'foot-print' in the cryostore; and progressing plans for a second cryostore to provide further increases in storage capacity. The inspectors concluded after a second visit on 18 December 2019 that the centre was indeed taking appropriate actions to address the concerns identified.

The implementation of the action plan was monitored closely through visits to the centre on 18 December 2019, 6 March 2020 and 13 March 2020, then remotely after the Covid-19 pandemic began in March 2020. These activities raised no concerns and provided reassurance to the inspectors that the centre had implemented appropriate actions to address issues that had been recognised and acknowledged by the PR and the centre's management team. The inspectors also concluded that effective actions had been taken

within expected timeframes to address the non compliances identified by the previous interim inspection in February 2019.

The inspectors had planned to undertake a scheduled interim inspection at the centre in April or May 2020, at which the implementation of the action plan was to have been a focus, and to then draft a joint report for the ELP of the inspections in response to the concerns raised and the planned interim inspection. The Covid-19 pandemic prevented this plan from being progressed, the centre being closed to treatment for periods in 2020 and early 2021, and HFEA inspections being suspended. The PR for the centre was then changed on 8 September 2020 after approval of a licence variation application by the ELP.

The safety of the centre's service was a focus at this renewal inspection generally, but we also specifically looked at the staffing resources available and their matching to the treatment activity planned; the cryostorage facilities; and the implementation of the action plan identified by the centre in December 2019. We also reviewed legal parenthood consent, gamete and embryo storage consent and treatment data submission to the HFEA, areas where significant concerns had been raised by the interim inspection in February and March 2019.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year to 31 January 2021 show the centre's success rates are in line with national averages.

In 2020, the centre reported 17 cycles of partner insemination with no pregnancies, which is in line with the national average.

Multiple births[2]

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

For treatments in the year to 31 January 2021, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is statistically lower than the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that evidence was reviewed by the inspection team to support a conclusion that the issues of concern arising from the last interim inspection in February 2019 and the 'whistleblower' inspections of December 2019 – March 2020, have all been addressed.

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

Since the inspection visit, the PR has provided evidence that actions have been taken to fully implement the following recommendation:

'Other' areas that requires improvement:

- The PR should take actions to ensure that the centre formally notifies the HFEA regarding new satellite services and provides a suitable satellite agreement for each satellite service.

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

Major areas of non compliance:

- The PR should ensure that controlled drugs are recorded in the record book in the manner required by the centre's documented procedures, drug legislation and best practice guidelines. Staff training and competence assessment to manage medicines should be undertaken at an appropriate frequency.
- The PR should ensure that the quality management system (QMS) is consistently robust, including the audit scope and methodology, recording and implementing corrective actions, document review; and reviewing third party agreements and auditing associated third party services.
- The PR should ensure that information about patients in the centre's records system is accurate and that staff verifying data with patients and entering data into the records system and ensuring its accuracy, should be identifiable.

'Other' areas that requires improvement:

- The PR should ensure that the donor recruitment protocols describe donor screening practices which are compliant with current professional body guidelines.
- The PR should ensure that donor compensation reports are collected and retained.

Recommendation to the ELP

The centre has no critical areas of concern but does have three major areas of concern.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates are below the target.

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

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to continue to use the QMS to best effect to monitor and improve their success rates and the quality of the service offered to patients.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

It is noted that the centre submitted a 'Treatment and Storage' licence application form in error, rather than a 'Treatment (including embryo testing) and Storage licence application form. The PR has confirmed that his intention is to apply to renew the 'Treatment (including embryo testing) and Storage licence, and this emailed confirmation is included in the paper set for ELP.

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

Centre 0102 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

As a result of the UK's departure from the EU, there is currently a relicensing exercise under way. This follows approval by the Licence Committee of a variation without application on 4 March 2021. This means that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021. Because of this and assuming this application is approved, the offer licence provided to the centre for renewal will also constitute the offer licence for the licence condition changes related to EU exit.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

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

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are broadly compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are broadly compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore,

donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Screening of donors (Guidance note 11)
The egg donor and sperm donor recruitment protocols discuss HTLV 1 and 2 screening in donors in an 'at risk' population. This is compliant with licence condition requirements and the HFE Act 1990 (as amended) however revised professional body guidelines released in late 2019 recommend that all donors are screened for HTLV 1 and 2. These professional body guidelines should be adhered to.

CoP Guidance 11.24; recommendation 4.

Payments for donors (Guidance note 13; General Direction 0001)
Donor compensation reports have not been provided to the centre for some imported donors (General Direction (GD) 0001, paragraph 13). For such donors, evidence held by the centre for donor compensation compliant with GD0001, paragraph 12, is based only on the relevant third party agreements and an assumption that the donor banks concerned have adhered to their terms. This is not robust or in line with the requirements of GD0001, paragraph 13 (recommendation 5).

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The inspection team determined that risks in the cryostore are well controlled, new storage equipment having been installed with a much greater storage capacity relative to

the ‘footprint’ of the equipment. Risk assessment of the storage facilities is regularly updated. The plans for an additional cryostore are progressing, though the project resources have to be agreed with the Hospital Trust management team and this is taking time. The inspection team considered that the centre has implemented the actions committed to in December 2019 to address the safety of cryostorage arrangements. The inspection team supports the plan for a second cryostorage room to ‘future-proof’ cryostorage capacity at the centre.

The centre’s premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre’s satellite/transport facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre’s laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients’ partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering, and disposing of medicines that are partially compliant with guidance.

Prescription of intralipid ‘off label’
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)

The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements, notwithstanding concerns raised above in 'Payments to donors' regarding the lack of documentation held by the centre for payments made to donors.

The HF&E Act 1990 (as amended) was amended on 1 April 2018 by the HF&E (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments in third countries, i.e. 'third country suppliers' (TCS). From 1 April 2018 until 31 December 2020, third countries included all countries outside of the European Union/European Economic Area (EU/EEA) or Gibraltar. The legal effects of EU exit mean that from 1 January 2021, for centres in Great Britain, third countries include all countries outside the United Kingdom, while for centres in Northern Ireland, third countries include all countries which are outside of the EU/EEA. Clinics must apply to the HFEA for an ITE import certificate to allow imports

from a specified clinic in a third country (i.e. a TCS), a clinic's import certificate being synchronised in lifespan with the treatment licence. Centre 0102 has been allocated an ITE import certificate and imports of gametes and embryos from TCSs have been made since the introduction of the ITE import certification scheme on 1 April 2018. No imports have been made from TCS which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements, including those associated with ITE/TCS import certificates, are partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage transport and satellite activities that are broadly compliant with HFEA requirements. This is important to ensure that activities performed by transport and satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have

occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Medicines management (Guidance Note 25)
The controlled drugs register contained entries which were not in line with the centre's SOP, relevant medicines legislation or best practice guidelines.

Some staff had not undertaken training or competence assessment in medicines management practices in the last two years. While this was in line with the trust training policy, the inspection team was concerned because of the problems with documentation in the controlled drugs register.

SLCs T2, T12 and T15; recommendation 1.

QMS (Guidance note 23)
The QMS is well developed however several non compliances detract from its robustness:

- The audit programme is wide-ranging however occasional audits were less robust because they did not review:
  - Practice against the documented procedures (e.g. consent, witnessing, some embryology practices);
  - Practice and/or documented procedures against all up to date regulatory requirements (e.g. donor screening and compensation; imports; medicines management; use of embryos in training);
  - Process outcomes and quality indicators against quality objectives;
  - Staff training and competence (e.g. medicines management);
- Some audits cited non conformances as observations only, so that corrective and preventative actions were not then appropriately documented or monitored for implementation (e.g. consent; witnessing; traceability).
- Issues related to document control and the review and audit of third party agreements, noted elsewhere in this report.

SLC T32, T34 and T36; recommendation 2.

Third party agreements (Guidance note 24)
Multiple third party agreements have not been reviewed in the last year nor have multiple third party services been audited against the requirements of the relevant third party agreements in the last two years (SLCs T34 and T36, CoP Guidance 31.9; recommendation 2).

Transport and satellite agreements (Guidance note 24; General Direction 0010)
IVF Ipswich provides satellite services to the centre but the centre has not notified the HFEA of this satellite relationship or provided a compliant satellite agreement.

The PR informed the inspection team after the inspection that IVF Ipswich provided only scanning services to patients having treatment at the centre but also that this arrangement had been cancelled on 30 April 2021.

General Direction 0010; recommendation 6

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

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

Leadership
The PR has ensured that effective actions have been implemented to address the concerns raised with the HFEA in December 2019, as discussed elsewhere in the report. He provided evidence of improved governance arrangements across the centre to ensure staff concerns are listened to and addressed, as committed to in December 2019.

The centre is compliant with HFEA guidance regarding effective 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.

Staff (Guidance note 2)
The centre has recruited a consultant embryologist and multiple other staff, including a number of experienced embryologists in the laboratory. The PR also discussed activity level controls and described a robust system to control activity at a level suitable for the staff available. The inspection team considered that the centre has implemented the actions committed to in December 2019 to address staffing resource concerns.

The centre is generally compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. It is however noted that some staff had not undertaken training or competence assessment in medicines management practices in the last two years and this is discussed above in ‘Medicines management’.

The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA;
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons;
- no embryo is tested unless the statutory tests are met i.e. that the embryo is at a significant risk of having a serious genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. 210 patients have provided feedback in the 12 months to 31 December 2020, giving an average 4.5 star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. Nearly all patients confirmed that they had paid what they expected to.

The centre's own most recent patient survey responses were also discussed with the PR. Feedback was comparable to that provided to the HFEA.

This inspection did not include an onsite visit so conversations with patients were not possible.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has staff who are supportive and professional;
- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding;
- responds to patient feedback

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non discriminatory way.

Patient support (Guidance note 3)
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.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors before they provide relevant consents.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake treatment involving egg or sperm sharing arrangements, so these requirements were irrelevant at this inspection.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

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

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

Information

What the centre does well

Information (Guidance note 4)
The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Nothing identified at this inspection.

▶ Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that one couple was affected by legal parenthood consent anomalies. This case was concluded in May 2016 following a declaration of parenthood being made by the Family Division of the High Court.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015, all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the executive.

Inspectors visited the centre in August 2016 and reviewed 30 patient records which contained consents to legal parenthood. No anomalies were identified. At the renewal inspection at the centre in January 2017, the inspection team considered the processes used to obtain consent to legal parenthood at this centre to be compliant with HFEA requirements.

The interim inspection in 2019 found errors in the completion of legal parenthood forms (WP and PP) and the PBR form ('your consent to being registered as the legal parent in the event of your death'). A critical non compliance was documented because of significant concerns regarding the competence of staff to guide the consenting process and to review the accuracy of completed forms, and also regarding the robustness of the audit of the legal parenthood consenting process. Actions to address this non compliance were reviewed by HFEA inspectors between December 2019 and March 2020 and were considered to be robust and to have removed non compliance in this area.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff, and reviewed the relevant documented procedures and reports of recent audits of legal parenthood consenting. The audits reviewed all records where donor sperm had been used in treatment and identified no non conformances in legal parenthood consents. Staff were knowledgeable about the consenting process and the use of the PBR form. The inspection team concluded that the processes used to collect legal parenthood consent are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

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

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

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
Storage of gametes and embryos was an area of critical non compliance at the interim inspection in 2019. The centre implemented corrective and preventative actions in response to the inspection report which were monitored by the centre's inspector and were considered to have corrected the non compliance.

At this inspection, the centre's procedures for storing gametes and embryos were reviewed and considered to be compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

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

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

The centre's procedures for document control are partially compliant. Good document control is necessary to ensure documents are regularly reviewed so they remain up to date and accurate.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The reporting of treatment information to the HFEA was an area of critical non compliance at the interim inspection in 2019. The centre implemented corrective and preventative actions in response to the inspection report which were monitored by the centre's inspector and were considered to have corrected the non compliance.

The centre's procedures for submitting information, about licensed activities to the Authority were reviewed at this inspection and were compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)
Patient records were not stored in a robust manner:

- Relationship status was imprecisely characterised and recorded in the patient records;
- Patient information transferred from the hospital records system to the centre's records system was not consistently verified for accuracy in a robust manner nor was the staff member entering and/or verifying data recorded.

The inspection team was concerned because these problems have the potential to impact negatively on patient care, the consenting process and the parenthood of children conceived through licensed activity.

SLCs T37 and T46, CoP Guidance 5.13 and 5.15; recommendation 3.

The centre's procedures for document control were not robust because numerous documents were beyond their review dates. It is recognised that these documents were described as predominantly being not in use. The documents are however classified as active in the centre's document management system so must be controlled and reviewed, or archived.

SLCs T34, CoP Guidance 31.9; recommendation 3.

Section 3: Monitoring of the centre's performance

Following the interim inspection in February 2019, recommendations for improvement were made in relation to three areas of critical non compliance (storage consent; legal parenthood consent; treatment data submission to the HFEA register), one area of major non compliance (medicines management) and four 'other' areas of non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the timescales required. Implementation of the actions was verified during the visits to the centre between December 2019 and March 2020.

On-going monitoring of centre success rates

In 2020, the centre was not asked to review procedures for the provision of any treatment.

Areas of practice requiring action

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

Critical 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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

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
None			

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 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.

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Medicines management (Controlled Drugs) The controlled drugs register contained entries which were not in line with the centre's SOP, relevant medicines legislation or best practice guidelines. Some staff had not undertaken training or competence assessment in medicines management practices in the last two years.	The PR should ensure that controlled drugs are recorded in the record book in the manner required by the centre's SOP, drug legislation and best practice guidelines. Staff training and competence assessment to manage medicines should be undertaken at an appropriate frequency. This recommendation should be implemented and the centre's inspector	A meeting was held between the ACU matron, the ACU QM and Medicines Management Matron for GSTT on the 12th May. At this meeting, it was agreed that a training session for all clinical staff would be held on 10th June 2021. This would cover drug legislation updates, safety checkpoints and general medicine management. Focus would also be given to the appropriate management of the CDs used in the ACU theatre and also the best practice management of the CD book. Since the ACU is a unique setting within the hospital, this training will be	12 May 2021: The centre provided revised training and competence assessment frameworks for relevant staff which will ensure that medicines management update training is undertaken at least every two years. The PR should ensure that they are implemented. Evidence that these frameworks have been applied to all relevant staff needs to be provided to the centre's inspector. 24 May 2021: The inspection team acknowledges the PR's response and planned

SLCs T2, T12 and T15.	advised of the actions taken by 15 August 2021.	accompanied with a virtual module that will specifically cover the CD and Medicines Management required in the ACU. Both elements of this training will be mandatory for the ACU nursing team and required annually. We have also invited the ODPs who work in the ACU theatre to attend. 2 Medicines Link Nurses have also been nominated to attend the GSTT Medicines Management Nurses Forum with a view to disseminating all learning to the wider ACU team on a quarterly basis. Further discussions will be held with the anaesthetics service regarding the appropriate use of the CD book. There has been extended dialogue with the lead anaesthetist who has assured us that our concerns have been addressed with the relevant staff. To ensure compliance, the CD book will be audited on monthly basis. The audit will then be processed through the audit module of Q-Pulse to ensure that there is formalised, accurate and timely follow up of any non-conformances.	actions which, if fully implemented, will address this non compliance. The inspection team looks forward to receiving evidence of implementation by 15 August 2021. The centre should also audit these areas of practice to ensure actions taken have been effective. Reports of the audits should be provided to the centre's inspector by 15 November 2021. Further actions are required.

		All actions and evidence will be made available as requested to the HFEA on August 15th 2021.	
2. QMS The QMS is well developed however several non compliances detract from its robustness, as detailed in the main body of the inspection report, related to: audit scope and methodology, recording and implementing corrective actions; document review; and reviewing third party agreements and auditing associated third party services. SLC T32, T34 and T36.	The PR should ensure that the QMS is consistently robust, including the audit scope and methodology, recording and implementing corrective actions, document review; and reviewing third party agreements and auditing associated third party services. An action plan to implement this recommendation should be provided to the HFEA by 15 August 2021, with an expected completion date of 15 November 2021.	The effectiveness of the QMS, is reliant on the engagement of the entire team and with this in mind a series of information sessions have been planned during the weekly Thursday Morning ACU Teaching Sessions. These sessions will cover the ACU's regulatory and legal responsibilities with regards to all elements of the QMS and offer an opportunity for more team members to become actively involved in the systems ongoing improvements and development. The audit schedule is in the process of being audited. Those areas that require additional focus are now being added to the audit schedule. The QM is now ensuring that the audits are logged through Q-Pulse, such that appropriate reoccurrence scheduling is immediately evident. Audit responsibilities are now being allocated to an increased number of staff. Audits of systems, processes, SOPS and KPIs can then be audited both internally and by colleagues from other disciplines. This process will encourage improvement, widen scope and also	12 May 2021: The centre has provided some revised audits which address concerns regarding the methodology and scope, e.g. for multiple births; donor screening. 24 May 2021: The inspection team acknowledges the PR's response and planned actions and also notes that some actions discussed in response to recommendation 3 are also relevant to this recommendation. If fully implemented, the planned actions will address this non compliance. The inspection team looks forward to receiving the specifics of the action plan by 15 August 2021, and evidence of implementation by 15 November 2021. Further actions are required.

		provide an unbiased assessment of staff performance. Since all audits are now being processed 'through' Q-Pulse, rather than being 'added to' Q-Pulse, the process of the accurate logging of non-conformances and the subsequent CAPA is formalised and all required actions followed up and 'prompted' electronically. As previously described, a satellite audit is underway and moves have been made to remove the responsibility for TPAs away from the commercial department and into the control of the departmental heads and QM.	This area will be an area of focus at the centre's next on site inspection, which will be held in February or March 2022 to meet the requirement for on site inspection every two years.
3. Record keeping and document control Patient records were not stored in a robust manner: • Relationship status was imprecisely characterised and recorded in the patient records; • Patient information transferred from the hospital records system to the centre's	The PR should ensure that information about patients in the centre's records system is accurate. Relationship status should be consistently reviewed and recorded using legally defined terms. Staff verifying relationship status, entering data into the records system, and	Following concerns raised by the HFEA during the DBA, a number of meetings have taken place with the administration team and the developers of BBS to ensure that relationship status is more accurately represented in the newest version of BBS which is due to be installed prior to integration with PRISM. As requested SOP A-CLA-I7, has been further amended and all staff made aware of the updates.	12 May 2021: The centre provided a documented procedure to ensure the accuracy of records imported to the centre's records system. This procedure needs to be revised to ensure additional focus on the verification of relationship status by centre staff and also on the recording of the name of the staff member who checks the accuracy of the

records system was not consistently verified for accuracy in a robust manner nor was the staff member entering and/or verifying data recorded. The inspection team was concerned because these problems have the potential to impact on patient care and the parenthood of children conceived through licensed activity. SLCs T37 and T46 CoP Guidance 5.13 and 5.15. The centre's procedures for document control were not robust because numerous documents were beyond their review dates. It is recognised that these documents were described as predominantly being not in use. The documents are however classified as active in the centre's	ensuring its accuracy, should be identifiable. The PR should ensure that the document control procedures are robust. Active documents should be reviewed annually and more frequently if necessary. Documents which are no longer relevant should be archived. This recommendation should be implemented and the centre's inspector advised of the actions taken by 15 August 2021.	As described above, a number of teaching sessions relating to quality management have been scheduled. The first took place on Thursday 20th May 2021, where the QM presented the legal and licensing obligations of the team in relation to Guidance Note 31 and its relevant license conditions. This was following by a refresher training session on how to use Q-Pulse most effectively to review documents and issue document 'change requests'.	database. The centre has committed to do this. 24 May 2021: The inspection team acknowledges the PR's response and actions, some already delivered and some planned, which, if fully implemented, will address this non compliance. The inspection team looks forward to receiving evidence of implementation by 15 August 2021. The centre should also audit these areas of practice to ensure actions taken have been effective. Reports of the audits should be provided to the centre's inspector by 15 November 2021. Further actions are required.

document management system so must be controlled and reviewed, or archived. SLCs T34, CoP Guidance 31.9.			

Other areas of practice that require improvement

'Other' areas of practice that require improvement are any areas of practice which cannot be classified as either a critical or major area of non compliance, 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
4. Donor screening The egg donor and sperm donor recruitment protocols discuss HTLV 1 and 2 screening in donors in an 'at risk' population, whereas revised professional body guidelines released in late 2019 recommend all donors are screened for HTLV 1 and 2. Professional body guidelines should be adhered to (CoP Guidance 11.24). This non compliance has been assessed as an 'other' non compliance because the centre's screening protocols meet licence condition requirements and because of the actions already taken to correct screening practices.	The PR should ensure that the donor recruitment protocols describe donor screening practices which are compliant with the current professional body guidelines, including the screening of all donors for HTLV 1 and 2. The PR should also assess the risks to the recipients of gametes procured from donors recruited at the centre since 1 January 2020, who were not screened in line with professional body guidelines. If risks are identified, appropriate actions should be taken to control those risks and to inform recipients of those risks.	As requested, audits relating to the screening undertaken for donors registered at centre #0102 is underway. This audit together with a risk assessment of recipients treated since 1 January 2020 will now be scheduled and made available to the HFEA by 15 August 2021	12 May 2021: The PR provided evidence that: the donor recruitment protocols have been revised in a suitable manner to include screening all donors for HTLV1 and 2. The audit of donors recruited in 2020 and the assessment of risks is being undertaken. The PR should provide the audit report and risk assessment to the HFEA by 15 August 2021. 24 May 2021: The inspection team acknowledges the PR's response and actions, some already delivered and some planned, which, if fully implemented, will address this non compliance. The inspection team looks forward to receiving the audit and risk

	This recommendation should be implemented by 15 August 2021 and the centre's inspector advised of the actions taken.		assessments by 15 August 2021. To ensure the actions taken have been effective, the centre should audit screening in all donors used in treatment from 1 May 2021 onwards. A report of the audit should be provided to the centre's inspector by 15 November 2021. Further actions are required.
5. Payments to donors Donor compensation reports in line with GD 0001, paragraph 13, have not been provided to the centre for some imported donors. For such donors, evidence for compensation compliant with GD0001, paragraph 12, is based only on the relevant third party agreements and an assumption that the donor banks concerned have adhered to their terms. This is not robust or in line with the requirements of GD0001, paragraph 13.	The PR should ensure that the donor compensation reports required by General Direction 0001 paragraph 13, are provided to the centre for all donors whose gametes have been imported since 1 January 2020, as well as for all future imports. The PR should audit the compensation provided to all donors whose gametes have been imported since 1 January 2020 and should report to the HFEA where it does not comply with the	As previously described, an audit of all imported donors since January 1st 2020 is underway to identify any potential discrepancies related to compensation paid to donors. During this audit the TPAs are also being interrogated to ensure they are robust and reflective of current legislation and compliant with General Direction 0001. The TPA is also being audited against 'actual' practise to ensure it is being followed both by the	12 May 2021: The centre advised the inspector that an audit of donor compensation was being undertaken. 24 May 2021: The inspection team acknowledges the PR's response and planned actions which, if fully implemented, will address this non compliance. The inspection team looks forward to receiving the evidence of implementation by 15 August 2021. To ensure the actions taken have been effective, the

General Direction 0001, paragraphs 12 and 13.	requirements of General Direction 0001, paragraph 12. This recommendation should be implemented and the HFEA informed of the actions taken by 15 August 2021.	donor sperm supplier and by us at Guys ACU. Any improvements required will be presented to the ACU Governance meeting and then the completed (and closed) audit and actions will be supplied to the HFEA by 15 August 2021.	centre should audit the records of compensation provided to all imported donors used in treatment from 1 May 2021 onwards. A report of the audit should be provided to the centre's inspector by 15 November 2021. Further actions are required.
6. Satellite services IVF Ipswich provides satellite services to the centre but the centre has not notified the HFEA of this satellite relationship or provided a compliant satellite agreement. The PR informed the inspection team after the inspection that IVF Ipswich provided only scanning services to patients having treatment at the centre but also that this arrangement had been cancelled on 30 April 2021. General Direction 0010.	It is noted that the satellite relationship with IVF Ipswich ceased on 30 April 2021, therefore no further actions regarding this satellite arrangement are necessary. The PR should however take actions so that in future the centre formally notifies the HFEA regarding any new satellite services which are developed and provides a suitable satellite agreement for each satellite service, compliant with the terms of GD0010. The PR should advise the HFEA of the actions taken to implement this	A new SOP has been introduced to the QMS, focusing on the requirements of reporting satellite changes to the HFEA. This SOP is also mentioned as part of the satellite audit schedule.	24 May 2021: The inspection team acknowledges the PR's actions which should address this non compliance. No further actions are required.

	recommendation by 15 August 2021.		

Responses from the Person Responsible to this inspection report
We want to thank the HFEA inspectors for their diligence. The inspection process was conducted thoroughly and has benefited the clinic in highlighting what is done well and areas where the clinic could do better. The report is comprehensive and the clinic is fully engaged to ensure all areas for improvement are addressed within the required timeframe as stipulated by the inspectors.