Renewal 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 inspection was scheduled (rather than unannounced) and the report provides information on the Centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. 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: 9 and 10 May 2013
Purpose of inspection: Renewal of a licence to carry out 'Treatment and Storage'

Inspection details:

The report covers the performance of the Centre since the last inspection, findings from the inspection visit and communications received from the Centre up to the submission of the report to the ELP.

Date of Executive Licensing Panel: 19 July 2013

Licence details:

Centre name	Hull IVF Unit
Centre number	0021
Licence number	L/0021/12/c
Centre address	Hull and East Yorkshire Women and Children's Hospital, Hull Royal Infirmary, Anlaby Road, Hull, HU3 2JZ, UK
Person Responsible	Mr Stephen Maguiness
Licence Holder	Dr John Robinson
Date licence issued	1 October 2008
Licence expiry date	30 September 2013
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the Centre and its licensing history:

The Hull IVF Unit has been providing fertility treatment since 1986 and has been licensed by the HFEA since 1992. The Centre is located within the Hull and East Yorkshire (HEY) Women and Children's Hospital and currently offers a full range of fertility treatment to both NHS and private patients.

The Centre provided 376 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2013. In relation to activity levels this is a small Centre.

The Centre's licence was varied in 2010 to add to the licensed premises an andrology laboratory that is used for diagnostic purposes. In 2011, the Centre added two adjacent rooms to its footprint which are used for administration and office space.

The report of the last renewal inspection at the Centre, performed in 2008, noted no non-compliances. This was also the case in the reports of the last two interim inspections performed in March 2010 and August 2011.

Activities of the Centre:

Type of treatment	Treatment cycles performed in the year to 31 March 2013
In vitro fertilisation (IVF)	228
Intracytoplasmic sperm injection (ICSI)	90
Gamete intrafallopian transfer (GIFT)	Not provided
Frozen embryo transfer (FET)	49
Donor insemination (DI)	9
Partner insemination	Not provided

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓

Outcomes*
For IVF and ICSI, HFEA held register data for the period 1 January 2012 – 31 December 2012 show the Centre's clinical pregnancy rates are in line with national averages. Between 1 April 2010 and 31 March 2011, the Centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%: this represented performance that was not statistically likely to be different from the 20% multiple live birth rate target for this period. Between 1 April 2011 and 30 September 2012, the Centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 7%: this represented performance that was likely to be significantly lower than the 15% multiple live birth rate target for this period. The centre is commended by the inspection team for its performance in this regard.

*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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

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), the inspection team considers that it has sufficient information to conclude:

- the Person Responsible (PR) is suitable and has discharged his duty under Section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the Centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the Centre has submitted an application fee to the HFEA in accordance with requirements

The ELP is asked to note that the renewal application form includes in vitro maturation as a new process at the centre. This process has already been approved by the Authority as a method by which the activity of gamete processing can be achieved. The PR has confirmed that before starting to use the new process, it will be validated and staff competence to perform it will be assessed. Gamete processing is also included as an activity on the centre's current licence and is a proposed activity in the licence application.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including no 'critical', one 'major' and three 'other' areas of non-compliance or poor practice, which resulted in the recommendations discussed below.

Since the inspection, the PR has provided evidence that all the report's recommendations have been implemented, these being:

Major areas of non compliance

- Donated sperm samples should only be used when donors have been screened in a manner compliant with SLC T52; notably donors should be tested for both hepatitis B surface antigen (HBsAg) and antibodies against hepatitis B core protein (anti-HBc).

'Other' areas of non-compliance or poor practice that require improvement

- The PR should ensure that the checks that critical work areas are cleared of all tubes and dishes before and after each egg collection, are documented in the patient records.
- The PR should ensure that the information provided to patients and the Centre's website, is reviewed and revised so that its content is compliant with HFEA requirements.
- The PR should check that all third party agreements, including that with SLS Scientific Supplies, contain the full name and address of the service supplier.

Recommendation to the Executive Licensing Panel

The Centre had no recommendations outstanding at the time this report was submitted to the ELP. The Centre's success rates are comparable to national averages and the multiple pregnancy rate indicates the Centre will achieve the target multiple live birth rate of 10%. The inspection team therefore concluded that:

The Centre demonstrates good clinical practice; has suitable premises and equipment for the treatment services offered and has a quality management system (QMS) to continually improve the quality and safety of the service it provides in accordance with good practice. The inspection team is satisfied that the activities carried out at the Centre are necessary or desirable in order to provide licensed treatment services.

The inspection team notes the treatment success rates are similar to national averages. The PR should continue to ensure that the QMS is used to best effect to monitor and improve the Centre's success rates and, in doing so, further improve the quality of the service offered to patients.

The inspection team recommends the renewal of the Centre's Treatment and Storage licence for a period of four years without additional conditions, subject to compliance with the outstanding recommendation made in this report being implemented within the prescribed timescale.

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 (Guidance note 18)

What the Centre does well.

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 with one exception, discussed below. This ensures that patients receive treatment using the correct gametes or embryos.

What the Centre could do better.

Eggs are collected in the procedure room into tubes which are not labelled and no witnessing is performed of the transfer of eggs from these tubes into a dish for microscopic examination in the laboratory (SLC T71; T101). At this point the eggs are then transferred into an appropriately labelled egg culture dish which has been witnessed. Witnessing and labelling practices at egg collection have been risk assessed by centre staff and found to be safe. The risk assessment and witnessing practices at egg collection were reviewed by the inspection team, who considered that practices appeared safe and to prevent mis-identification of gametes. It was also noted that the completion of two key risk control measures, involving checks by two staff members that the critical work areas are clear of tubes and dishes before and after egg collection, are not documented in the patient records.

Patient and Donor selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for Donors (Guidance note 13)
- Donor assisted conception (Guidance note 20)

What the Centre does well.

Screening of patients and / or donors

The Centre's procedures for screening patients and / or egg and sperm donors are broadly 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.

Payments for donors
Payments to donors are fully in line with the requirements of the HFEA. 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
People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The Centre is fully compliant with the requirements of the HFEA to ensure the donor-conceived will be able to receive this information.

What the Centre could do better.

Screening of patients and / or donors
Sperm donors have not been screened appropriately for hepatitis B in some cases (SLC T52b). The Centre has requested hepatitis B screening for all donor blood samples from a local CPA-accredited laboratory, using tests for HBsAg and anti-HBc. For some donors the anti-HBc testing was not performed. The checklist used for releasing donated sperm samples lists only 'hepatitis B' and this has been ticked for all donors, even though anti-HBc testing data is absent for some. Thus inappropriately screened donors have been released and used in the treatment of recipient couples. It is noted that an audit of records showed that patients are, in contrast to donors, screened for hepatitis B in a compliant manner, probably because the patient test request sheet and checklist used to check screening results include testing for both anti-HBc and HBsAg.

Good clinical practice

What the Centre does well.

Multiple births (Guidance note 7)
The single biggest risk of fertility treatment is a multiple pregnancy.

The Centre's progress in reducing the clinical multiple pregnancy rates from 16% (1 April 2010 – 31 March 2011) to 7% (1 April 2011 - 30 September 2012), suggests that the Centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target. The Centre is commended by the inspection team for its performance in this regard.

Process Validation(Guidance note 15)
The Centre has fully validated all critical processing procedures to ensure that these procedures are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Traceability (Guidance note 19)
The Centre's procedures are broadly compliant with HFEA requirements, with one exception discussed below, ensuring it has the ability -
(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
(b) identify the donor and recipient of particular gametes or embryos,
(c) to identify any person who has carried out any activity in relation to particular gametes

or embryos, and
(d) 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 (Guidance note 23)
The Centre has an ISO 9001:2008 certified (inspected February 2013) QMS that is compliant with HFEA requirements. The Centre uses its QMS to ensure optimum outcomes and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)
The Centre has compliant agreements in place, except for one minor exception discussed below, which cover the:
(a) procurement, testing or processing of gametes or embryos on behalf of the licensed Centre, and/or
(b) supply of any goods or services (including distribution services) to the licensed Centre which may affect the quality or safety of gametes or embryos.

Equipment and materials (Guidance note 26)
All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately monitored and maintained in order to minimise any hazard to patients and/or staff.

Premises (Guidance note 25)
The Centre conducts all of the licensed activities in an appropriate environment, in line with good clinical practice. All diagnostic testing is carried out in suitable accredited laboratories.

During the inspection, the PR showed the inspection team two rooms on the Centre's perimeter which he wishes to include in its licensed premises. Site plans including the rooms were provided. These rooms are to be used for consultations and administrative functions, rather than for licensed activity per se, and were considered by the inspection team to be appropriately secure.

Adverse incidents (Guidance note 27)
The Centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The Centre investigates all adverse incidents and shares the lessons learned in order to continuously improve the services it offers.

What the Centre could do better.

Traceability (Guidance note 19)
Eggs are collected in the procedure room into tubes which are not labelled and no witnessing is performed of the transfer of eggs from these tubes into a dish for microscopic examination in the laboratory (SLC T71; T101). This non-compliance is discussed in detail in 'Witnessing and assuring patient identification' above.

Third party agreements (Guidance note 24)
The content of one of the five third party agreements audited against CoP requirements did not contain a full address for the service supplier (SLC T114a).

Staff engaged in licensed activity

What the Centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

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 (T/1015/7).

Staff (Guidance Note 2)
The Centre has suitably qualified and competent staff to carry out all of the licensed activities and associated services.

What the Centre could do better.

No issues were identified on this inspection

Welfare of the Child (Guidance note 8)

What the Centre does well.

The Centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. The Centre takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the Centre, and of any other child who may be affected by that birth.

What the Centre could do better.

No issues were identified on this inspection

Embryo Testing

- Preimplantation genetic screening (Guidance note 9)
- Embryo testing and sex selection (Guidance note 10)

What the Centre does well.

The Centre does not perform embryo biopsy or provide genetic screening services

What the Centre could do better.

No issues were identified on this inspection

2. The experience of patients

Patient feedback

What the Centre does well.

During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences. A further 14 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was fairly positive with eleven of the individuals providing feedback to the HFEA commenting that they have compliments about the care that they received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the Centre could do better.

No issues were identified on this inspection

Treating patients fairly

What the Centre does well.

Counselling (Guidance note 3)
The Centre's counselling staff and procedures are compliant with HFEA requirements, ensuring that counselling support is available to patients before and during the consenting process and treatment.

Egg sharing arrangements (Guidance note 12)
The Centre's procedures for egg sharing arrangements are compliant with HFEA requirements to ensure that:
(a) care is taken when selecting egg and sperm providers donating for benefits in kind
(b) egg and sperm providers are fully assessed and medically suitable, and
(c) the benefit offered is the most suitable for the egg or sperm provider and recipients (where relevant).

Surrogacy (Guidance note 14)
The Centre has only performed one cycle of surrogacy treatment in the last three years. The Centre's procedures for treatments involving surrogacy are however compliant with HFEA requirements to ensure that the arrangement is legal and protects the rights of the surrogate and the commissioning couple. Patients providing gametes in surrogacy arrangements are screened as donors in order to safeguard the health of the surrogate.

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

Treating patients fairly (Guidance note 29)
The Centre treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

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 well being of prospective and current patients and donors. The Centre's information security system is certified to the ISO 27001:2005 standard.

What the Centre could do better.

No issues were identified on this inspection

Information

What the Centre does well.

The Centre's procedures for providing information to patients and / or donors are broadly 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.

Provision of a costed treatment plan (Guidance note 4)
The Centre provides an individual costed treatment plan to all of its patients who are self-funding. This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed or not.

What the Centre could do better.

Some non-compliance with HFEA guidance concerning information provided to patients was observed during the audit of patient information and the Centre's website:

- Written patient information regarding legal parenthood was considered inaccurate in that it stated that unmarried heterosexual couples undergoing treatment need not complete legal parenthood forms. It was noted in the patient records audit that unmarried heterosexual couples had completed legal parenthood consent forms, suggesting that the Centre's practices are compliant but the written information is not accurate or proper (HF&E Act 1990 (as amended), Section 13 (6)).
- Audit of the Centre's website indicated it was non-compliant with Chair's Letter (11)02 in that:
    i. there was confusion regarding the time periods for which success rates are quoted
    ii. the reference to national success rates for comparison was unclear
    iii. success rate data are not age stratified

  The Quality Manager reported that the website was in the process of being upgraded and provided evidence of this to the inspection team.

Consent

What the Centre does well.

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.

Disclosure of information, held on the HFEA Register, for use in research
The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), treatment outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The Centre's procedures for doing this ensure that the HFEA holds an accurate record of patient consent for disclosure, so that it only releases patient identifying information to researchers when the patient's consent to do so is in place.

What the Centre could do better.

No issues were identified on 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). This ensures that the Centre has respect for the special status of the embryo when conducting licensed activities.

- 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.
- 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.

No issues were identified on this inspection

Storage of gametes and embryos

What the Centre does well.

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.

The Centre's procedures for storing gametes and embryos are 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.

What the Centre could do better.

No issues were identified on this inspection

Distribution and / or receipt of gametes and embryos

What the Centre does well.

The Centre's procedures for distributing and / or receiving gametes and embryos are compliant with HFEA requirements. This ensures that all gametes / embryos sent to other licensed Centres within or outside the UK are appropriately labelled and relevant information is sent to the other Centre to ensure the continued quality and safety of the gametes and embryos. The Centre only accepts gametes and embryos from other centres

if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in a way that does not comprise their quality and safety.

What the Centre could do better.

No issues were identified on this inspection

Use of embryos for training staff (Guidance note 22)

What the Centre does well.

The Centre does not currently use embryos in training embryology staff however it does have procedures in place to allow this when needed and staff are trained in the application of those procedures. The procedures for using embryos in training are compliant with HFEA requirements and ensure that embryos are only used for the purpose of training staff in activities expressly authorised by the Authority, for example:

- Cryopreservation and thawing techniques
- Vitrification
- Embryo handling and manipulation
- Assessment of embryos

What the Centre could do better.

No issues were identified on this inspection

4. Information management

Record keeping and submitting information to the HFEA

What the Centre does well.

Record keeping and document control (Guidance note 31)
The Centre's procedures for keeping records are 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.

Obligations and reporting requirements (Guidance note 32)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this Register, Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The Centre's procedures for submitting information, about licensed activities, to the Authority are compliant with HFEA requirements and ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

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.

No issues were identified on this inspection

Section 3: Monitoring of the Centre's performance

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in 2011, no recommendations for improvement were made and the Centre was considered compliant with all HFEA requirements reviewed on an interim inspection. This was also the case at the previous interim inspection in March 2010. The Centre was also considered compliant with all HFEA requirements at the last renewal inspection in 2008.

On-going monitoring of success rates

In the last year, the Centre has received no alerts from the HFEA Risk Tool regarding its treatment success rates and the Executive has no concerns regarding the Centre's performance.

Areas of practice requiring action

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

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several 'other' areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Sperm donors are in some cases not screened appropriately for hepatitis B (SLC T52b): all have been screened for HBsAg while only some of them have been tested for anti-HBc. Thus inappropriately screened donors have been released and used in treatment.	Donated sperm samples should only be used when donors have been screened in a manner compliant with SLC T52. Regarding sperm donors already used, the PR should ensure that their stored blood samples are tested for anti-HBc. The results should be reviewed, with expert advice if necessary, to identify any risks to patients already treated. If risks are identified, the PR should develop a plan by 10 August 2012 to inform the patients at risk regarding those risks and to consider the future assessment and treatment of those patients.	2 donors have been recruited since the requirement for HepB cAb screening was introduced. Both had serum samples stored which have retrospectively been screened negative for HepB c Ab. Although not a requirement, we have in addition begun to retrospectively screen all our other donors. Two results are awaited and they have been put on hold. The other 9 are negative for Hep B cAb. The Donor check list has been amended to specify viral screen requirements (attached).	24 June 2013: The inspection team consider the Centre has provided evidence that appropriate actions have been taken to correct this non-compliance. The Centre's inspector will follow up with the PR regarding the anti-HBc test results for the remaining two donors, as part of the on-going monitoring process. No other actions are necessary

‘Other’ areas of practice that requires 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Eggs are collected into tubes which are not labelled and no witnessing is performed of the transfer of eggs from these tubes into a dish for microscopic examination (SLC T71; T101). Witnessing and labelling practices at egg collection have been risk assessed. The inspection team noted that practices appeared safe but also that the checks by two staff members that the critical work areas are clear of tubes and dishes before and after egg collection are not documented in the patient records.	The inspection team considered the risk assessment to be detailed and appropriate, and to provide good evidence that witnessing practices at egg collection are safe. To increase the robustness of the risk control measures however the inspection team recommends that checks that critical work areas are cleared of all tubes and dishes before and after each egg collection are, when completed, documented in the records. This action should be implemented by 10 August 2013. An audit of the completion and documentation of the checks should be performed for a sample of records in the three months after implementation. A report of the audit should be provided	The laboratory procedure record sheet has been amended to ensure a written record evidences that current good practice is documented (amended document attached).	24 June 2013: The Centre provided evidence that appropriate actions have been taken to correct this non-compliance. No other actions are necessary

	to the Lead Inspector by 10 November 2013.		
The content of one of the five third-party agreements audited against CoP requirements (that with SLS Scientific Supplies) did not contain a full address for the service supplier (SLC T114a).	The PR should check that all third party agreements contain the full name and address of the service supplier. All actions taken should be advised to the Lead Inspector by 10 August 2013.	SLS have a number of separate premises. We have re-sent the third party agreement to one of these for re-signing and including an agreement as to which address they wish us to use.	24 June 2013: The Centre has taken appropriate actions to correct this non-compliance, and await the response from the third party concerned. This will be followed up with the PR through the on-going monitoring system. 4 July 2013: The laboratory manager emailed to confirm that the third party agreement with SLS Scientific Supplies is now in place. No further actions are needed.
Information provided to patients was considered non-compliant with HFEA guidance in that: • Written patient information regarding legal parenthood stated that unmarried heterosexual couples undergoing treatment need not complete legal parenthood forms. It was noted in the patient records audit that unmarried heterosexual couples had in fact completed legal parenthood consent	The PR should ensure that the written information provided to patients, including that regarding legal parenthood, and the Centre's website, are reviewed and revised so that they are compliant with HFEA requirements. The PR should provide a summary report of the actions taken to implement this recommendation by 10 August 2013.	Patient info: Amended wording attached. Website: As discussed at the inspection, your information was obtained some time prior to the inspection, and had been updated by the time of the inspection. As discussed we had difficulties changing our website information, as we were relying on a third party to do so. You have seen evidence that we are	24 June 2013: The inspection team acknowledge that plans to upgrade the Centre's website to bring it under the Centre's control were being implemented at the time of the inspection. The Centre has subsequently provided additional evidence to show appropriate actions to correct this non-compliance have been implemented. No other actions are necessary.

forms, suggesting that the Centre's practices are compliant but the written information is not accurate or proper(HF&E Act 1990 (as amended), Section 13 (6)). • Audit of the Centre's website indicated it was non-compliant with Chair's Letter (11)02 in that: i. there was confusion regarding the time periods for which success rates are quoted ii. the reference to comparative national success rates was unclear iii. success rate data are not age stratified		currently re-developing the website to comply with your requirements, and will be able to amend in-house.	

Reponse from the Person Responsible to this inspection report
The inspection was extremely valuable to our unit. We felt that the process was a dialogue which provided positive feedback on our current good practice as well as constructive suggestions for areas to improve all of which have been addressed.

HFEA Executive Licensing Panel Meeting

19 July 2013

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

Minutes – Item 3

Centre 0021 – (Hull IVF Unit) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair) Matthew Watts – Regulatory Policy Manager Joanne Anton – Policy Manager	Rebecca Loveys

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this is a small centre which has held a licence with the HFEA since 1992.

2. The Panel noted that the centre provides a full range of fertility treatments.

3. The Panel noted that the centre is on a five-year licence due to expire September 2013, and that the inspection took place on 9 and 10 May 2013.

4. The Panel noted that in the 12 months to 31 March 2013, the centre provided 376 cycles of treatment (excluding IUI), and that for IVF and ICSI for the 12 months to 31 December 2012, the centre's clinical pregnancy rates were in line with the national averages.

5. The Panel noted that for the time period 1 April 2011 to 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%, and that this represents performance that is likely to be significantly lower than the 15% multiple live birth rate target for this period.

6. The Panel noted that, at the time of inspection, one major and three other areas of non-compliance were identified by the Inspectorate.

7. The Panel noted that, since the time of inspection, all four areas of non-compliance have been addressed, and that no areas of non-compliance were identified during the centre's two most recent interim inspections.

8. The Panel commended the centre for being highly compliant and for its low multiple births rate.

9. The Panel noted that the application form does not state the use of embryos for training but that procedures for it are in place at the centre.

Decision

10. 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.

11. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities.

12. The Panel was satisfied that the licence renewal application concerns treatment or non-medical fertility services which relate to gametes intended for human application.

13. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence provided within the report.

14. The Panel agreed with the Inspectorate's recommendations made in the report and endorsed the recommendations. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed: 
Juliet Tizzard (Chair)

Date: 26 July 2013