Executive Licensing Panel - minutes

Centre 0015 (Sussex Downs Fertility Centre) Renewal Inspection Report

Friday, 20 May 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Howard Ryan Anjeli Kara	Director of Strategy & Corporate Affairs Technical Report Developer Regulatory Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser	Dawn Brathwaite	Mills & Reeve
Observers		

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:

- 8th 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, executive update, correspondence from the centre and licensing minutes for the last three years.

1.2. The panel noted that Sussex Downs Fertility Centre (centre 0015) is located at the BMI Esperance Hospital in Eastbourne. The centre has a satellite treatment agreement with Goring Hall Hospital, Sussex. The centre currently holds a treatment and storage licence and provides a full range of fertility services. In relation to activity levels this is a small centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 1992.

1.4. The panel noted that in the 12 months to 30 November 2015, the centre provided 412 cycles of treatment (excluding partner intrauterine insemination).

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 September 2014 to 31 August 2015 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2014 the centre reported 79 cycles of partner insemination with six pregnancies. This equated to a clinical pregnancy rate of 8%, which was consistent with the national average.

1.7. Between September 2014 and August 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 15%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the renewal inspection on 20 and 21 January 2016, three major and two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has implemented three of the recommendations to address the major areas of non-compliance and has committed to provide the required audits in due course. The PR has committed to ensure compliance with the outstanding recommendations.

1.9. The panel noted that the Executive had concerns regarding the centre's handling of some of their legal parenthood cases and noted their recommendations. The panel noted, however, that the centre subsequently confirmed that all patients where anomalies in their consent to legal parenthood were identified had been contacted and the centre confirmed that they will provide guidance and support to these patients until all outstanding matters are concluded.

1.10. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices.

1.11. The panel noted that the PR is encouraged to continue to use the Quality Management System to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

1.12. The panel noted the inspectorate's recommendations for the renewal of 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 the licensed activities.

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 his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel had regard to its guidance on periods for which new or renewed licences should be granted and agreed to renew the centre's treatment and storage licence for a period of four years without additional conditions. The panel noted that the recommendation of the Executive was for a 3 year licence but felt that 4 years was more appropriate given the updated information it received from the centre regarding legal parenthood.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

3 June 2016

Executive Update for Executive Licensing Panel
20 May 2016

Centre number	0015
Centre name	Sussex Downs Fertility Centre
Person Responsible	Mr David Chui

Background

1. Sussex Downs Fertility Centre is licensed for treatment and storage. The centre's current licence expires on 30 June 2016. A licence renewal inspection was performed on 20 and 21 January 2016, the report of which is set before ELP for consideration at this meeting.

2. As documented in the body of the report, at the time of the inspection there was an on going dialogue with the HFEA regarding issues related to consent to legal parenthood. Whilst the centre's audit of consent to legal parenthood performed in February 2014 identified anomalies, the PR's position at the time of the inspection was that having taken legal advice, he did not intend to inform patients of these anomalies where the couple had completed the centre's internal consent forms as he was of the opinion that valid consent to parenthood was in place.

3. After extensive communication between the centre and the HFEA over a significant period of time the PR informed the HFEA on 29 April 2016 of the following: "despite our view that the risk of the non-birth partner being divested of legal parenthood and/or needing to adopt their child or children is low where our records indicate clear unequivocal consent to being legal parents from the affected patients, we have decided to contact the remaining affected patients in the next few weeks and provide, where required, on-going support and guidance, including appropriate support through any legal process for the non-birth partner".

4. The licence recommendation was for renewal of the centre's licence for a period of three years. The executive also recommended that an interim inspection with a focus on consent to treatment and consent to legal parenthood be conducted within one year of this licence coming into force. Whilst the centre confirmed that it would contact all patients where anomalies in their consent to legal parenthood were identified, to date they had not done so. The executive recommended that the centre informed these affected patients by the 21 May 2016.

5. The inspection report was finalised and sent to the licensing secretary on 10 May 2016 with a copy also sent to the PR. The PR contested the recommendation that a licence be granted for three years (rather than four) and requested that email correspondence sent to the centre's inspector on 6 May 2016 regarding this be included in the inspection papers for ELP consideration.

6. The PR submitted further papers directly to the licensing secretary on 13 May 2016 requesting that they also be set before ELP for consideration; the executive has no comment regarding this submission.

7. In the intervening period, on 11 May 2016, the executive received an email from the centre stating that the two remaining patients highlighted as having anomalies with legal parenthood consent, had been written to on that day to inform them of the issues and offering the full support of the clinic if they wished to use it. A copy of this letter and the questions and answers (Q&A) document is attached for information (annex 1 and annex 2).

8. The executive has grave concerns regarding the content of the letter. The letter refers to contact being made 'out of the blue'. It is of concern that this letter containing information that could have such a devastating impact on the couples may have been sent without any prior warning. The PR's previous communication to the executive stated the centre would provide, where required, on-going support and guidance, including appropriate support through any legal process for the non-birth partner. The executive is of the opinion that this is not made clear in the letter. In addition, the correspondence appears to focus primarily on adoption as the route to ensuring legal parenthood, rather than seeking a declaration of parenthood through the courts.

Recommendation

9. Given these concerns, in accordance with the HFEA Compliance and Enforcement Policy, a management review meeting was held on 12 May and 13 May 2016 to consider the potential impact of this new information. The executive now considers that the licence recommendation made in the inspection report is one that cannot be supported at this time. The executive intends to fully engage with the centre regarding the actions that they have taken or propose to take to support these couples.

10. It is for the Executive Licensing Panel to determine if it wishes to consider the original application and executive recommendation, together with the submissions made by the licensed centre, regarding the renewal of the centre's licence.

11. If the decision is made to adjourn or refer the application to a Licence Committee for consideration, it should be noted that the centre's licence is due to expire on 30 June 2016. In such circumstances it is recommended that Special Directions are issued to the PR under Section 24 (5A)(b) of the HF&E Act 1990 (as amended) to permit the continuation of licensable activities until 30 September 2016 or until such time as a decision can be made regarding the centre's licence, whichever is sooner.

Janet Kirkland MacHattie.
Inspector

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: 20 -21 January 2016

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.

Inspectors: Janet Kirkland MacHattie, Karen Conyers, Kathryn Mangold.

Date of Executive Licensing Panel: 20 May 2016

Centre name	Sussex Downs Fertility Centre
Centre number	0015
Licence number	L/0015/16/a
Centre address	BMI The Esperance Hospital, Hartington Place, Eastbourne, East Sussex, BN21 3BG, UK
Person Responsible	Mr David Chui
Licence Holder	Sue Mulvey
Date licence issued	01/07/2012
Licence expiry date	30/06/2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report 3

Section 2: Inspection findings 6

1. Protection of the patient and children born following treatment 6
2. The experience of patients 12
3. The protection of gametes and embryos 16
4. Information management 18

Section 3: Monitoring of the centre's performance 19

Areas of practice requiring action 20

Section 1: Summary report

Brief description of the centre and its licensing history:

The Sussex Downs Fertility Centre is located at the BMI Esperance Hospital in Eastbourne and has held a Treatment and Storage licence with the HFEA since 1992. The centre has a satellite treatment agreement with Goring Hall Hospital, Sussex.

The centre provides a full range of fertility services and provided 412 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 2015. In relation to activity levels this is a small centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 September 2014 - 31 August 2015 show the centre's success rates are in line with national averages.

In 2014 the centre reported 79 cycles of partner insemination with six pregnancies. This equates to a clinical pregnancy rate of 8%, which is consistent with the national average.

Multiple births[2]

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

Between September 2014 and August 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

[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), 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 Person Responsible (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 their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

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 three major non compliances and two 'other' areas of concern.

The PR has implemented the following recommendations and has committed to provide the required audits where applicable in due course:

Major areas of non compliance:

- the PR should ensure that witnessing is performed and that witnessing steps are documented at each critical point of the clinical and laboratory process;
- the PR should ensure that patient information accurately reflects regulatory requirements;
- the PR should ensure that patients are provided with the offer of counselling and information regarding their treatment options and legal parenthood, prior to signing consent forms;

The PR has committed to ensure compliance with the following recommendations.

'Other' areas that require improvement:

- the PR should ensure that the content of third party agreements accurately reflects the services provided;
- the PR should ensure that fees are paid to the Authority within the required timescale.

Recommendation to the Executive Licensing Panel:

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

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy rates meet the target. The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

As documented in the body of the report, the inspection findings with regards to the PR's reluctance to inform all affected patients where anomalies in the consent to legal parenthood had been identified were of significant concern – the HFEA's Chief Executive had first asked centres to inform affected patients and partners in September 2014. This duty of candour to patients is a fundamental principle in healthcare. In the time between the inspection and the finalising of this report, the HFEA has been in constant dialogue with the centre and held internal management reviews to discuss progress on five occasions.

The Executive considered that, as this inspection took place in January 2016 the Compliance and Enforcement Policy and Guidance on Licensing that came in to effect in April 2016 is not applicable. As such the Executive had regard to the HFEA guidance on the period for which licenses could be granted. Taking into account the significant findings of this inspection in relation to patients being asked to sign consent forms prior to their initial consultation, which appears wholly at odds with the general principles of consent the failure of the centres processes for ensuring that effective consent to legal parenthood is in place, and the significant delay in contacting patients where anomalies in the consent to legal parenthood were identified, the Executive recommends renewal of the centre's licence for a period of three years. The Executive also recommend that an interim inspection with a focus on consent to treatment and consent to legal parenthood be conducted within one year of this licence coming into force.

The centre has now confirmed that it will contact all patients where anomalies in the consent to legal parenthood were identified, but to date has not done so. The Executive recommends that the centre informs these affected patients by the 21 May 2016.

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 partially compliant with HFEA requirements.

What the centre could do better
During an audit of six patient records performed on inspection the following non-compliances were observed:

- in one record there was no documentation of the witnessing steps completed at the time of an insemination treatment (verifying the identity of the patient and sample);
- in another record the time that the witnessing steps took place prior to insemination was not recorded;
- the date and time of the witnessing of the discard of gametes and embryos was not documented in two records.

(SLC T71; recommendation 1).

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 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 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)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

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

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 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 to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite 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 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 for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance. It was observed on inspection that the flooring in the theatre area was cracked and in need of repair. The inspection team was informed that following a recent inspection by the Care Quality Commission (CQC), the BMI hospital in which the centre is located is undergoing a refurbishment programme. The flooring in the theatre area used by the centre is scheduled for repair as part of this programme.

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

Pre-operative assessment and the surgical pathway
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 single biggest risk of fertility treatment is a multiple pregnancy. 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.

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 and 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 note15)
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 their storage or use in treatment in a way that does not compromise 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.

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 in place that is 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 are broadly compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has a satellite arrangement with Goring Hall Hospital that is compliant with HFEA requirements. This is important to ensure that activities performed by 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

Third party agreements (Guidance note 24)
The content of a sample of three third party agreements reviewed in the course of the inspection did not meet the requirements of standard licence condition T114 because the agreements were generic and did not relate to the services provided (SLC T114; recommendation 4).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
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/1010/7.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. 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 treatment is provided, the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding
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 does not provide treatment involving preimplantation genetic screening or embryo testing and sex selection and therefore this area of practice is not applicable to this inspection.

What the centre could do better
Not applicable

2. The experience of patients

Patient feedback

What the centre does well

Two patients agreed on the day of the inspection to provide feedback to the inspection team about their experiences at the centre. Their feedback was positive and they referred to the friendly and welcoming staff and felt that they were fully informed about their treatments receiving information both in person and in writing. In addition since the previous inspection 17 patients provided feedback directly to the HFEA. Feedback was primarily positive with 13 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received and two responded that they had complaints.

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;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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.

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 providing relevant consent.

It was noted that current consenting procedures do not make allowance for patients receiving counselling prior to them recording consent to treatment. This non compliant consenting practice is discussed in detail in 'Section 2: The experience of patients: Consent'

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not provide treatment involving egg or sperm sharing, therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
Centre staff informed the inspection team that they had not provided treatment involving a surrogacy arrangement for at least two years. From discussion with the team it was possible to assess that 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; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients are partially compliant with HFEA requirements. It is important 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
The inspection team noted some details in the patient information that could result in misinformation and confusion for patients (recommendation 2). Examples include:

- information about IVF includes a reference to the 'legal' number of embryos to transfer whereas the number of embryos to be transferred is not defined in primary legislation;
- information regarding donor insemination refers to the age limit for sperm donors as being 45, whereas CoP guidance 11.2 states a maximum age of 41;
- embryo freezing information appears to links terms of consent to store with costs of storage stating:
  '…it is the responsibility of the couple to inform the SDFC, in writing, of their wish to extend the storage period. The letter of storage extension has to be signed and dated by both partners. Without written authority and the associated payment from the couple to continue the storage period, the Fertility Centre is obliged by legislation to thaw all unauthorised frozen embryos and allow them to perish.'

The inspectors were concerned that this sentence could be confusing and implied that the payment of fees for storage of gametes and embryos is required under HFEA legislation. This information was considered by the inspectors to be contrary to Guidance note 17.12 and guidance note 5.6, which state: 'Contractual agreements covering payment or funding should be separate to consent'.
See also 'consent' section and recommendation 3.

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 partially 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

Consent (Guidance note 5;6)
The centre's practice is to send a basic information pack to patients prior to their first consultation. The information pack includes consent forms for treatment and legal parenthood. An accompanying letter asks the patients to complete the forms prior to their first consultation. Information regarding treatment options and the implications of each consent are then discussed with patients at their first consultation and counselling is offered. This practice leads to patients completing their consent forms, as requested by the centre in the letter accompanying the basic information pack, prior to the first consultation when they have not yet received all relevant information and an offer of counselling (HF&E Act 1990 (as amended) schedule 3 (1); CH14(01); recommendation 3).
The centre changed their consenting procedure immediately after the inspection visit and patients are now asked to read the consent forms in the basic information pack but not to complete or sign them until they have seen their consultant and received the relevant information and offer of counselling.

Legal parenthood (Guidance note 6)
The partners of women treated with donated gametes, where the couple are not married or in a civil partnership, must give written consent in order 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's audit noted the following issues:

- in four cases patients had not completed the HFEA consent to legal parenthood but had completed the centre's own internal consent forms confirming that they would be the legal parents of any resulting child;
- in four cases there was either no formal indication from the non-birth partner of their consent to legal parenthood or the non birth partner had not completed any forms.

Following further evaluation into these anomalies, the PR has provided assurance that of the eight cases identified in their original audit, four were discounted on the basis that the couples were married or in a civil partnership at the time the treatment took place, and in one case it was appropriate that consent to legal parenthood was absent (on the basis that the partner did not seek legal parenthood), Therefore, there are three instances where there is concern as to the validity of the consents to legal parenthood in relation to the couples concerned.

Where anomalies were identified in audits, centres were encouraged by the HFEA to seek legal advice and to inform the affected patients.

In October 2015 the HFEA Chief Inspector wrote to all licensed centres further to the judgment handed down in September 2015 by the President of the Family Division of the High Court with respect to seven cases where a declaration of parenthood was sought. The purpose of the letter was to seek evidence from centres that where anomalies to legal parenthood existed legal advice had been sought; patients and partners involved informed; and that procedures for taking consent to parenthood were robust. The letter was followed up by a telephone interview between the PR and the executive. The PR provided assurance that the centre's team had reflected on the reasons why the appropriate consent to parenthood consent forms had not been completed. The PR also confirmed that all staff had been given feedback on the audit results and the recommendations from the HFEA. He also confirmed that staff had been made aware of subsequent changes of the centre's policy on legal parenthood.

The PR did seek legal advice and, on the basis of this advice, informed the HFEA that in cases where the HFEA parenthood consent forms were absent or contained anomalies, patients would be contacted and actions taken to correct the situation if required. One couple was contacted on this basis – and the centre has yet to receive contact from the couple. Attempts to make contact are ongoing.

In early January 2016 the PR informed the HFEA that if the patients had completed 'in house' forms documenting consent to parenthood they would not be contacted. The HFEA responded encouraging the PR to review his position and to contact all affected patients. The PR informed the HFEA that he had indeed reviewed his position and did not intend to contact all affected patients. Following further dialogue and engagement with the HFEA, the PR confirmed on 29 March 2016 that he is committed to act in accordance with HFEA guidance and is contacting the affected couples and has committed to providing necessary support. The HFEA will continue to liaise with the PR in following up on these actions.

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 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
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

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)

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. 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** (Guidance note 22)
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
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 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 ; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are 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

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
In the previous nine months, the centre has taken an average of 47 days to pay fees to the HFEA, rather than the required 28 days (SLC T9d; recommendation 5).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014 recommendations for improvement were made in relation to one area of major non-compliance and four 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented.

On-going monitoring of centre success rates

In 2015, the centre did not receive any requests to review procedures for the provision of treatment.

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, General Direction 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 identified			

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
1. During an audit of six patient records four did not have complete documentation of all witnessing steps (SLC T71).	The PR should ensure that all witnessing steps are documented at each critical point of the clinical and laboratory process. The centre's inspector should be advised of the measures taken to ensure that this happens when responding to this report. The PR should review the centre's witnessing procedures and relevant documentation to ensure that all witnessing procedures are compliant with regulatory requirements and guidance and are documented clearly. A summary of the findings of the review including	The witnessing procedure was reviewed immediately by the PR and three laboratory record forms were amended to ensure the appropriate witnessing steps are documented according to regulatory requirements and guidance. Please see attachments in 'other comments' (SDFC279, SDFC34, SDFC35). A copy of the written review will be provided to the authority by 21st April 2016. A witnessing audit was conducted for 2015 and report attached. In addition to this a copy of Unit meeting minutes (11.02.16) are attached which	The inspector acknowledges the PR's response in addition to a witnessing audit report dated 21 April 2016. A further audit of witnessing practice and a summary report of the findings of the audit should be provided to the centre's inspector by 21 July 2016.

	corrective actions and the timescales for implementation should be provided to the centre's inspector by 21 April 2016. Within three months of the implementation of revised witnessing procedures, the centre should conduct an audit of witnessing practice and a summary report of the findings of the audit should be provided to the centre's inspector by 21 July 2016.	provides evidence of the PR confirming staff responsibilities with regards to witnessing. A repeat audit will be completed at the end of May/beginning of June to ensure compliance and a copy of this report will be submitted to the authority by 21st July 2016.	
2. The inspection team noted some details in the patient information that could result in misinformation and confusion for patients as described in the body of the report (HF&E Act 1990 (as amended) Schedule 3 3 (1) b, Guidance note 5.6 and 17.12).	The PR should ensure that patient information is reviewed so that it accurately reflects regulatory requirements and guidance. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 21 April 2016.	All patient information is reviewed annually and reissued as required as part of the routine management of the QMS. A full review of all patient information will be conducted and a report sent to the authority by 21st April 2016. The areas specifically identified in the body of this report were amended immediately. Copies of these (SDFC105 IVF information, SDFC99 Donor information & SDFC100 Embryo Freezing information) are attached in the 'other comments' section.	The inspector acknowledges the PR's response and has received the amended patient information relevant to the areas of concern identified in the report. The inspector has also received an information review report dated 19.4.2016. The report does not include any corrective actions however it states that all patient information is reviewed annually and reissued as required as part of the routine

			management of the QMS. No further action.
3. Prior to the inspection, the centre's practice was to send forms to record treatment and legal parenthood consent, to patients prior to their first scheduled appointment with instructions that they should complete the forms prior to their visit, before they had received all relevant information and an offer of counselling (HF&E Act 1990 Schedule 3 1 (a,b); CH14(01).	The centre team changed this practice immediately following the inspection and patients' are now asked to bring their consent forms with them to their scheduled appointment. No further action.	The policy has been amended and already forwarded to the authority.	This area of concern was addressed immediately following the inspection. The inspector has received the amended policy. The PR should monitor compliance with this change in centre policy to ensure that all patients have the opportunity to receive relevant information and an offer of counselling prior to completing consent forms. Compliance with this recommendation will be reviewed at a focused interim inspection within one year of the new licence coming in to force.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. The content of a sample of third-party agreements reviewed in the course of the inspection did not meet the requirements of standard licence condition T114 because the agreements were, in some instances, generic and did not relate to the services provided (SLC T114).	The PR should review all TPAs to ensure compliance with T114 and that they accurately reflect the services provided. The PR should provide the centre's inspector with a copy of the review together with an action plan of how they intend to address corrective actions by 21 April 2016.	BMI Group Fertility Lead is currently reviewing Third Party Agreements for BMI Fertility Centres to ensure that they accurately reflect the services provided. A report will be submitted to the authority from the Group Fertility Lead by 21st April 2016.	The Inspector acknowledges the PR's response. The inspector awaits the report of the review of the third party agreements. This will be followed up with the PR. Further action required.
5. In the previous nine months, the centre has taken an average of 47 days to pay fees due to the HFEA, rather than the required 28 days (SLC T9d).	The PR should ensure that fees are paid to the Authority within the timescale specified in Directions. The PR should review the processes for payment of fees, to identify where there are barriers to timely payment. The outcome of this review and actions taken should be provided to the centre's inspector when responding to this report.	All HFEA invoices are submitted monthly to BMI Central Finance Team for processing. The PR has written and reminded this team of the importance of prompt payment and to inform him in a timely fashion when there are barriers to creating a delay in payment.	The inspector acknowledges the PR' response. Payment of fees within the timescale specified in Directions will continue to be monitored.

Reponses from the Person Responsible to this inspection report
Documents attached within email: - SDFC279 Oocyte recovery sheet - SDFC34 IUI husband - SDFC35 IUI donor - Witnessing audit report Jan 2016 - Unit meeting minutes 11.02.16 - SDFC105 IVF patient info - SDFC99 Donor Insemination patient information - SDFC100 Embryo/blastocyst freezing information