Inspection Report

Date of Inspection: 19 & 20 April 2011
Purpose of inspection: Renewal of Treatment and Storage licence
Length of inspection: 12 hours
Inspectors: Mrs Gill Walsh
Dr Andrew Leonard
Mrs Ellie Suthers

Observing: Dr Vesna Sokol
Dr Vanja Nikolac
Mrs Kristina Stankovic

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 18 July 2009 and 12 August 2011

Date of Executive Licensing Panel: 26 August 2011

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice, to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Human Fertilisation and Embryology Authority's (HFEA) Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Complete Fertility Centre, Southampton
Centre number	0307
Licence number	L0307/1/c
Centre address	Level G Princess Anne Hospital Coxford Road Southampton SO16 5YA
Person Responsible	Professor Nick Macklon
Licence Holder	Dr Michael Marsh
Date licence issued	1 November 2009
Licence expiry date	31 October 2011
Additional conditions applied to this licence	None

Contents

Page

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
Complete Fertility Centre, Southampton is a dedicated unit housed within the Princess Anne Hospital, Southampton University Hospitals NHS Trust. The centre was first licensed on 1 November 2008 for a period of three years with no additional conditions; an interim inspection was conducted on 23 October 2009.

The centre was most recently inspected on 3 November 2010 in response to the centre's application to vary their licence to reflect a change to their premises and licensed activities following Trust approval of the business case to create a refurbished and expanded facility licensed to provide a full IVF / ICSI service. Variation of the licence to reflect the changes to premises and licensed activities was granted by the Executive Licensing Panel (ELP) of the HFEA on 17 December 2010.

Applications to vary the centre's licence to reflect a change of PR to Professor Macklon and to change the centre's name to Complete Fertility Centre, Southampton were granted by the ELP on 10 September 2010.

The inspection team would like to commend this centre on their thorough and thoughtful preparations for this inspection.

Activities of the Centre:

Type of treatment for the period:	Number of treatment cycles
IVF (01/01/11 – 30/04/11)	22
ICSI (01/01/11 – 30/04/11)	15
FET (01/01/11 – 30/04/11)	1
IUI (Partner) (31/03/10 – 01/04/11)	94
IUI (Donor) (31/03/10 – 01/04/11)	22

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

Outcomes*

The centre has only provided 38 cycles of IVF / ICSI and FET (frozen embryo transfer) between January 2011, when their licence was varied to provide these treatments, and the date of inspection. Therefore there is currently insufficient data to provided representative outcome information for IVF and ICSI.

IUI (Donor) outcome data for the period specified demonstrates a live birth rate of 31% averaged over all age ranges treated, which is significantly above the national average. IUI (Partner) outcome data for the period specified demonstrates a live birth rate of 12.5% averaged over all age ranges treated which is consistant with the national average.

*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.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection to conclude that:

- the Person Responsible (PR) is suitable and has discharged their 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 Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including five 'other' areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has provided evidence that the following recommendations have been fully implemented:

Other areas of practice that required improvement:

- witnessing records required review to include the name and signature of the operator and the witness
- one third party agreement required review to reflect all requirements of standard licence condition (SLC) T114.
- the standard operating procedure (SOP) directing the use of embryos in training required review to specifically state the training activities which are authorised.
- the assessment of the competence of staff to maintain patient confidentiality should be documented.
- the SOP for elective single embryo transfer (eSET) required revised to direct that the non compliance log should be updated in the event that two embryos are transferred to a patient who fulfils eSET criteria.

The inspection team considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- 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
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned appropriately

▶ Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

The scientific inspector was able to directly observe witnessing practices on inspection during three procedures, one egg collection and two sperm preparation procedures. From observations made, documentation seen and from discussions with staff, the inspector was able to conclude that all samples and the patients or donors to whom they relate are positively identified against verified photographic ID and primary documentation. Procedures are witnessed contemporaneously by two appropriately trained members of staff at all critical points of the clinical and laboratory process. The date and time each step was witnessed is record alongside the initials of the operator and witness (Standard licence condition (SLC) T71).

The centre's SOP for witnessing was provided prior to inspection (SLC T33(b) and T71). Relevant witnessing steps were also seen to be embedded in SOPs directing activities and processes which require witnessing. Evidence that quality indicators relevant to witnessing procedures have been established and are monitored was provided on inspection (SLC T35). Copies of witnessing procedures and documentation audits conducted in April and October 2010 were provided on inspection. Both audits were seen to contain analysis of the audit findings and recommendations for corrective action where required and scheduled re-audit, to assess the effectiveness of those corrective actions (SLC T36).

Documented competence assessments in witnessing procedures were available to review for all staff conducting witnessing (SLC T 12 and T15(a)). The assessments reviewed were considered by the inspector to be comprehensive, providing detail of discussions assessing underpinning knowledge, observations of practice and overall assessment of competence to witness without supervision. All entries in the assessment process were dated and signed by the assessor.

Following the refurbishment to facilities, the centre is now equipped to conduct radio frequency identification (RFID) witnessing and will be implementing this in the near future following risk assessment, user training and a period of parallel testing and evaluation

against current manual witnessing processes.

What they could do better.
It was noted from practice observed and records seen that only the initials of the person performing the activity and of the person witnessing it are recorded on the witnessing record sheet and not the name and full signature of the participants (Guidance 18.7). It was however also noted that a reference log displaying the name, status, signature and signature initials of all staff authorised to perform witnessed checks was readily available for reference in the laboratory area (Guidance 18.8).

Patient selection criteria and laboratory tests (Guidance Note 11)

What the centre does well.
Discussions with the PR and other clinical staff and documentation provided by the centre, demonstrated that all patients are selected on the basis of the patient's medical history and therapeutic indications, in accordance with professional body guidelines and locally agreed commissioner treatment criteria The rationale for treatment is also recorded in the patient's medical records (SLC T49).

The laboratory manager was able to provided documented evidence that application for accreditation by Clinical Pathology Accreditation (CPA) UK Ltd has been made for the centre's semenology laboratory. The centre is now awaiting a date for inspection from CPA UK Ltd, who have indicated an inspection will be scheduled some time after October 2011. All other patient / partner and donor diagnostic testing are conducted in the Trust pathology laboratories which were confirmed by the laboratory manager as being CPA UK Ltd accredited (SLC T21).

What they could do better.
Nothing noted on inspection.

Donor recruitment, assessment and screening (Guidance Note 11)
Donor assisted conception (Guidance Note 20)

What the centre does well.

Donor recruitment, assessment and screening
The centre recruits sperm, egg and occasionally embryo donors. The centre has not facilitated egg sharing to date but a SOP was seen to be in place to direct this process when egg sharing commences.

The centre provided SOPs for the recruitment and selection of donors on inspection (SLC T33(b)), which dictate that prospective donors are screened in accordance with professional body guidance (Guidance 11.15) and also identify when additional screening may be required (SLC T52(h)). Four sets of donor records were examined on inspection and all were seen to contain documented evidence of donor screening in accordance with SLC T52(b,e,f,g).
The centre was able to provide documented evidence of their donor selection and recruitment processes having been audited against the SOPs, relevant quality indicators (SLC T35) and the 8th Code of Practice within the last two years (SLC T36). It was also

noted in the audit that no corrective actions were required.

Staff were able to provide documented evidence of training and assessment of their competence in selecting and recruiting donors (SLC T15(a)). Staff involved in the donor recruitment process confirmed that prospective donors are assessed and selected on the basis of age, current health and medical history as determined during interview and from information provided by the donor during the assessment consultation with the respective sperm or egg/embryo donor coordinator (SLC T52(a)). All donor records reviewed on inspection contained a completed health and medical questionnaire and a record of the consultation. Verbal information given to prospective donors is supplemented by written information and counselling had been taken up in all cases.

A paper record of the use of donated gametes and embryos and the treatment outcome is retained in the donor notes, to be made available to the donor for information if requested. (HF&E Act 31 ZD(3)). The donor coordinator stated that the donor is asked if they wish to know the outcome of treatments using their donated gametes or embryos and if a pregnancy is achieved she will inform the donor as agreed.

Donor assisted conception
From discussions with staff and written information provided by the centre, the inspectors conclude that patients receiving treatment with donated gametes are provided with information on the importance of informing any resulting child at an early age, that the child results from the gametes of a person who is not a parent of the child. Evidence of this was seen during review of the centre's patient information (SLC T63(a/b)).

The laboratory manager confirmed that the centre uses donor gametes or embryos created using gametes from identifiable donors when treating new patients. Treatment with gametes from anonymous donors is limited to those seeking to conceive a genetically related sibling for an existing child conceived using the same donor's gametes. The centre's donor bank audit conducted in May 2010 confirmed this (SLC T54).

What they could do better.
Nothing noted on inspection.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)

What the centre does well.

Quality management system
The centre has a quality management system and quality manual in place which encompasses training and reference materials, SOPs, quality indicators and how they are to be monitored, and the audit process and schedule (SLC T32 and T33). The centre provided an index of all quality management system documents prior to inspection and individual documents were viewed in either hard copy or on the centre's computer system on inspection. A list of all current SOPs was provided which appears to encompass all activities carried out in the course of providing licensed activities (SLC T33(b)). Applicable SOPs detail specifications for critical materials used in laboratory procedures (SLC T31)

The centre has processes in place for the review of the performance of the quality management system; a copy of the most recent review conducted on 28 February 2011 was provided on inspection. The review was considered by the inspector to be clear, detailed and comprehensive (Schedule 3A (10) 2006/86/EC, Appendix 1 F).

Traceability
The centre has a SOP in place to direct procedures to ensure traceability (SLC T33b). The laboratory manager was able to demonstrate comprehensive procedures and documentation to ensure the traceability of all gametes and embryos from procurement to treatment or disposal and vice versa (SLC T99). Data relevant to materials and media coming into contact with gametes or embryos is recorded and retained securely, to ensure traceability at each stage of the laboratory process (SLC T102 and T103). Compliance with these standards was confirmed in patient laboratory records seen. All containers and vessels used for the procurement, processing or storage of gametes or embryos seen on inspection securely labelled with the patient's full name (donor samples are given a unique identifying code) plus two other unique identifiers (SLC T101).

Evidence that traceability procedures have been audited against established quality indicators (SLC T35) within the last two years was seen in audit documentation seen on inspection (SLC T36) Staff competence assessment records seen on inspection confirmed that relevant staff have received appropriate training in traceability procedures (SLC T12).

The scientific inspector considered that the mechanism for recording traceability data relating to materials and consumables was effective given the current activity of the centre, but may require modification as activity increases to ensure the efficient capture of all information. The inspector also noted however that the centre's monitoring of quality indicators for traceability and audit of the process will indicate if changes become

necessary.

Validation
All critical processes and equipment used in the centre's activities have been appropriately validated, as evidenced in validation documents completed in November 2010 prior to the centre varying their licence to provide a full IVF / ICSI service (Act Schedule 3a (11) 2006/86/EC and SLC T24 and T72). Revalidation of equipment following repair was demonstrated by validation of performance by the biomedical engineering service and critical parameter monitoring (SLC T25).

Equipment and materials
The laboratory manager provided evidence that all equipment and materials used in the procurement and processing of gametes and embryos can be traced (SLC T22). All media batch numbers used are recorded and the records retained in the laboratory as seen on inspection. Service schedules and evidence of servicing were seen in the equipment records held (SLC T23). The centre has documented SOPs in place for the operation of all critical equipment, which includes information to direct actions in the event of failure or malfunction (SLC T27). Instruction manuals were also seen to be readily available to staff.

The scientific inspector observed that key equipment critical to the processing or storage parameters of gametes and embryos is subject to appropriate monitoring and alarms via a digital environmental monitoring system (EMS). The EMS constantly monitors key equipment parameters against defined tolerance limits. The system has an automated 'dial out' facility to alert appointed staff if the parameters fall outside the tolerance limits and is regularly tested for efficacy (SLC T24). Equipment that provides a critical measuring function was seen to be subject to scheduled maintenance which included re-calibration and functional testing against validated standards specified in service records.

Centre staff provided a documented log recording regular cleaning and decontamination of equipment in the laboratory and clinical areas (SLC T26).

Equipment and medical devices seen to be in use on the day of inspection was CE marked and evidence had previously been provided that such equipment has been validated for use (SLC T28). Staff confirmed that only CE marked goods and equipment are in use and are periodically subject to sperm survival testing (SLC T30).

Premises
A tour of the premises confirmed that all licensable activities are carried out on the premises to which the licence relates and are within the same building. The premises were considered suitable for the activities for which the centre is licensed (Act S.12 (1) Act Schedule 2 S. 4 and SLC T1). A copy of the centre's current licence was seen to be displayed in the patient waiting area (SLC T5). Documented logs recording regular cleaning of the premises and facilities were seen on inspection (SLC T26).

Documented evidence was provided on the day of inspection that processing of gametes and embryos takes place in an environment currently of grade A air quality in the critical work areas and grade C or above in the background environment, compliant with SLC T20). Evidence was also provided that the air quality monitoring methods and frequency of monitoring has been validated (SLC T24 and T72).

The Authority was appropriately advised of proposed changes to the centre premises prior to refurbishment and expansion of the centre in the autumn 2010 (SLC T18). Application to vary the centre's licence to reflect these changes was granted in December 2010 following an onsite HFEA inspection of the premises and facilities in November 2010.

Adverse incidents
The centre is governed by the Trust incident and adverse event reporting policy to which the HFEA requirements for incident reporting have been embedded locally. Historically the centre has a good record of reporting and communicating with the HFEA regarding incidents or adverse events. A review of the centre's incident log confirmed that incidents reportable to the HFEA recorded at the centre correspond to those reported to the Authority (SLC T118).

Third party agreements
The centre was able to demonstrate that there are third party agreements in place for all goods and services that influence the quality and safety of gametes and embryos. A complete list of agreements held and the agreements themselves were available to review on inspection (SLC T111 and T115). Documented evidence of review and evaluation of the third parties ability to meet the requirements of standard licence conditions and HFEA code of practice guidance was also seen on inspection (SLC T12).

A random audit of five third party agreements was conducted on inspection. This audit confirmed that all agreements reviewed were compliant with SLC T112, T113 and T116 and all elements of SLC T114 with one exception detailed below.

What they could do better.

Third party agreements
The audit of five third party agreements in place revealed that element SLC T114(f) was absent from the agreement with an external laboratory which requires the third party to (f) describe how any test/diagnostic results are to be relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.

Multiple Births (Guidance Note 7)

Treatment using IVF or ICSI commenced in January 2011 following variation of the centre's licence. There is currently insufficient data available to assess the efficacy of the centre's multiple birth minimisation strategy.

What the centre does well.
The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions 0003 in that:

- they were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff at the centre will audit their strategy and protocols as part of the quality management audit programme;
- the centre maintains a log which indicates the reasons for variation from the single embryo transfer policy and outcomes, which are also recorded in the patients records.

Patients and their partners are provided with written and verbal information about elective single embryo transfer (eSET) and the risks of multiple births. Written patient information was

available for review on inspection; that it was fully discussed with patients was seen to be recorded in the patient records seen on inspection.

Centre staff were able to demonstrate that, to the date of inspection, no patients eligible for eSET had elected to have more than one embryo transferred. The centre's SOP to guide the eSET process directs that in the event that a woman eligible to have eSET elects to have two embryos replaced, her decision is recorded in her medical records, along with a clear explanation of the reasons for transferring more than one embryo and that the patient has been fully informed of the risks of multiple pregnancy and has had the opportunity to discuss this fully.

The centre has made a local policy decision that they will only replace up to two embryos in any woman treated.

What they could do better.

The scientific inspector noted that the centre's SOPs to guide the implementation of the centre's multiple birth minimisation strategy do not currently include a prompt for the embryologist to update the eSET non compliance log if a patient who is eligible for eSET elects to have more than one embryo replaced against advice.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

Person Responsible

The PR has held that role since September 2010. He is registered with the General Medical Council (GMC) and has been on the GMC specialist register for Obstetrics and Gynaecology since February 1997. Professor Macklon is also Chair of Obstetrics and Gynaecology at the University of Southampton and a Consultant Gynaecologist with Southampton University Hospitals Trust. The PR has successfully completed the HFEA PR entry programme and is considered by the inspection team to have discharged his duties and responsibilities as PR effectively. The PR is also the nominated medical practitioner who oversees all medical activities at the centre (SLC T16).

Staff

The PR was able to confirm that staff working under the auspices of the licence are qualified and suitable persons to participate in the activities authorised by the licence (HF&E Act (1990) as amended, Schedule 17 (1) (a)). The PR explained that for all relevant staff, prior to their appointment, professional body registration and Criminal Records Bureau (CRB) checks are performed and references are obtained, as per the Trust human resources policies. The PR confirmed that continued professional body registration is periodically checked and that all staff members participate in professional development, performance appraisals, mentorship and assessment of their competence to fulfil assigned tasks and procedures. This is done by a process of discussion and assessment of relevant underpinning knowledge, observation and supervision of practice, before being 'signed off' as competent by the assessor (SLC T12 and T14).

The PR confirmed that workforce requirements have been reviewed within the last six months against the centre's current and projected future activity, as specified within the

business expansion plan. The centre will review activity and resources on a rolling programme as the centre increases activity. The PR stated that the centre is appropriately staffed and resourced to meet the current and short to mid-term future activity requirements but that this is monitored on a monthly basis as part of the centre's operational meetings. The PR was able to provide a comprehensive documented contingency plan for use in the event of the significant absence of key personnel. Formal contingency arrangements have also been established with another licensed centre for the continuation of patient care in the event of significant service disruption.

The laboratory manager and other members of the laboratory team are registered with the Health Professionals Council (SLC T14).

From documents seen on inspection, centre staff across all disciplines were able to demonstrate documented evidence of the assessment of their competence to perform their designated tasks (SLC T12 and T15a), with one minor exception referred to in the section 'Disclosure of Information' in this report.

What they could do better.
Nothing noted on inspection.

Welfare of the Child (Guidance Note 8)
Counselling (Guidance Note 3)

What the centre does well.

Welfare of the child
From discussions with staff and the review of documents and records provided by them, the inspectors conclude that before any woman is provided with treatment services, proper account is taken of the welfare of the child who may be born as a result of treatment and of any other child who may be affected by the birth (SLC T56). The PR and other clinical staff were able to appropriately describe the process for conducting a welfare of the child assessment and their actions in the event that matters of concern arise. Staff also stated that the centre has access to the Trust ethics committee for the consideration of matters relating to welfare of the child, should they arise (SLC T56).

An audit of ten sets of patient records demonstrated completed and signed welfare of the child assessment forms were present in all records. The SOP for welfare of the child assessment was also provided and was considered by the inspection team to be comprehensive and clear (SLC T33(b)).

The centre has agreed the quality objective that all patients and partners should undergo an appropriate welfare of the child assessment which is recorded in the patient / partner's medical record. The completion of welfare of the child assessments is monitored by retrospective audit in patient records as a quality indicator (SLC T35), to measure compliance with the quality objective.

The senior nurse reported that she is currently extending the scope of the welfare of the child audit, to provided more information about the welfare of the child process. An audit of patient records has demonstrated the presence and completeness of welfare of the child records in patient notes audited. (Schedule 3A (10) 2006/86/EC, Appendix 1 F and SLC

T36)

Counselling
Discussions with one of the centre's two counsellors and a review of relevant documents presented by the centre, allowed the lead inspector to conclude that professional independent counselling regarding the implications of providing consent to treatment or donation, is offered and readily accessible to patients, their partners and donors; the offer and provision of counselling is provided well before consent to treatment or donation (HF&E Act (1990) as amended, Schedule 3, S.13 (6), S.3 (1a) and SLC T60) or to agreed fatherhood or legal parenthood (Act schedule 3ZA part 2) is sought by the centre.

The centre has a comprehensive SOP to guide the counselling process (SLC T33 (b)). Quality objectives and indicators have also been established which are monitored and feed into the audit of counselling services provided on inspection (SLC T35, HF&E Act (1990) as amended, Schedule 3A (10) 2006/86/EC, Appendix 1 F and SLC T36).

The counsellor interviewed provided evidence of the professional assessment of her competence to counsel patients considering treatment or donation, this being in the form of documentation associated with her working towards full accreditation with the British Infertility Counselling Association (BICA). The centre's senior counsellor is fully accredited with BICA. The centre emphasises a holistic approach to preparing patients for assisted reproductive therapies, including lifestyle coaching, general health and wellbeing coaching. Both counsellors actively contribute to this ethos and provide information and support to the programme. The counsellors also support the professional development of other centre staff, by providing workshops for them about listening and supporting skills and communicating bad news.

The counsellors can refer patients and their partners for more specialist counselling (e.g. specific counselling for oncology patients considering storing gametes for the preservation of fertility and for adolescent patients) or for more complex therapeutic counselling.

What they could do better.
Nothing noted on inspection.

Embryo Testing – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening)*

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

What the centre does well.
This centre does not conduct preimplantation genetic screening or embryo testing.

What they could do better.
Not applicable

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of a costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the centre does well.

Treating patients fairly

The PR provided evidence that an effective Trust Equal Opportunities Policy is in place. From discussions staff and documentation reviewed, the inspection team could conclude that patients are selected on the basis of their medical history and therapeutic indications in accordance with professional body guidelines and locally agreed treatment criteria and the equal opportunities policy. The rationale for treatment decisions are recorded in the patient's medical record (SLC T49). The PR stated that careful consideration is given during the decision making process as to how the centre will endeavour to meet the individual needs and circumstances of the patient.

Confidentiality and privacy

A tour of the centre confirmed that all confidential patient information is stored securely with access restricted to authorised personnel only (SLC T45). Areas where confidential consultations and conversations occur were seen to be private and the opportunities to be overheard reduced to a minimum (CoP Guidance 25.7). The centre also monitors service user satisfaction with their privacy during treatment, as part of the patient feedback questionnaire.

All staff are asked to sign an enhanced confidentiality agreement (SLC T43) and all non patient / partner / donor visitors are asked to sign a visitor confidentiality agreement prior to entering the centre. Maintaining confidentiality forms part of the Trust mandatory training, records of which were seen on inspection (SLC T15(a)). The PR provided a copy of the SOP for the control of access to health data and records which encompasses the Trust and HFEA enhanced confidentiality requirements (SLC T44).

Access to registers and data is restricted to persons authorised by the PR. This was demonstrated by the centre's swipe card access system which restricts access to the

centre to authorised staff, and access to areas within the centre to those staff whose roles require it (HF&E Act (1990) as amended, S.33A (1) and SLC T45). Access to certain rooms is also restricted with key pad combination locks.

Complaints
The centre's complaints process is governed by the Trust complaints policy which incorporates the National Health Service (Complaints) Regulations 2004. Information on how service users may make a complaint was seen to be displayed in patient areas (CoP Guidance 28.5). The centre's complaints register was reviewed on inspection and provided evidence of discussion at the team meeting, evaluation of the complaint and resolution / actions (CoP Guidance 28.7 and 28.8).

Provision of costed treatment plan
Self funding patients and their partners are provided with clear written information regarding the anticipated cost of treatment prior to initial consultation and when the treatment pathway is decided (CoP Guidance 4.3). This information is also discussed at consultation prior to treatment commencing to provide the opportunity for questions (CoP Guidance 4.3). The information provided to patients regarding treatment costs is also available on the centre's website. Information reviewed by the inspector is considered to be clear and easily understood.

Egg sharing arrangements
The centre has not facilitated egg sharing to date but the donor coordinator was able to demonstrate that procedures and patient information to guide the patient who is considering egg sharing are in place.

Surrogacy
The centre does not currently facilitate surrogacy.

What they could do better.
Nothing noted on inspection.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytroplasmic sperm injection (Guidance Note 21)
- Information about preimplantation genetic testing (Guidance Notes 9 & 10) – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening*
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Information to be provided prior to consent
From information provided and discussions with staff on the day of inspection, the inspectors conclude that proper information is provided to patients, their partners and donors prior to them providing consent to treatment or donation (HF&E Act (1990) as amended, Schedule 3 (1) (b)).

Staff who are involved in the information giving process confirmed that prospective

patients are provided with written information specific to their particular treatment pathway or donation. The information is provided with sufficient time for consideration and discussion prior to any consent decision being required. The centre provides treatment information evenings at which representatives from each discipline within the centre team are available, including the independent counsellor, to provide information and stimulate discussion with prospective patients in an open forum. Prior to treatment, centre staff formally review the information provided with the patient, using a documented 'check list' as an aide memoire. The patient is asked to sign the check list to confirm that they have been provide with and understood the information listed. Staff were able to provide documented evidence of the assessment of their competence to provide appropriate information to patients, their partners and donors (SLC T12 and T15a).

The centre has a SOP which details the process to be followed when providing information prior to consent for treatment, donation or for use of gametes / embryos in training (SLC T33(b)). The centre does not currently participate in research regulated by the HFEA.

A quality objective that 100% of patients will receive the relevant information to the satisfaction of the recipient has been established (SLC T35). Compliance with this quality objective is monitored via patient feedback and by the annual audit of the signed patient information check lists retained in patient records, evidence of which was provided on inspection (SLC T36).

An audit of 10 patient records for evidence of the provision of information, showed that all relevant information had been confirmed by staff and recipient as provided and understood on the checklists held within each record.

.

Information about storage of embryos (cooling off period)

From discussions with the PR and staff and from written information seen on inspection, the centre demonstrated that patients and their partners are provided with information regarding the individual gamete provider's right to withdraw their consent to continued storage of the embryos created with their gametes. The PR described established processes for use in the event of a dispute between gamete providers regarding the continued storage of embryos and the instigation of the 12 month 'cooling off' period. The cooling off period will commence from the point at which the centre is notified in writing of a gamete provider's withdrawal of consent to continue storage of the embryos. The PR stated that all reasonable attempts to resolve the dispute will be made during the cooling off period. In the event that the dispute cannot be resolved and a mutual decision agreed, the processes in place directs that the embryo(s) will be allowed to perish one year from the date of written notification of consent withdrawal by one gamete provider, unless the end of the statutory storage period is reached before this date (HF&E Act (1990) as amended, Schedule 3 4A and CoP Guidance 5H).

Information about ICSI

As part of the treatment information provided in writing and given verbally during consultation, patients and their partners identified as likely to benefit from having ICSI, are given specific information regarding this procedure and any associated risks. This was confirmed in discussions with staff and by review of written information and information check lists seen in patient notes on inspection (HF&E Act (1990) as amended, Schedule 3 S.3 (1) (b)).

Information about legal parenthood
From discussions with staff, documentation seen and an audit of patient records for couples affected by legal parenthood legislation, the inspection team consider that proper written and verbal information is given to a woman and the prospective second parent of children to be born as a result of treatment with donor gametes or embryos (SLC T33(b)). Legal parenthood is discussed (including the opportunity to vary or withdraw consent to legal parenthood), with those affected by this legislation at initial consultation and is reiterated prior to treatment commencing (SLC T60).

The centre's SOPs 'withdrawal of consent' and 'legal parenthood' were reviewed on inspection and were seen to document procedures to be followed: To ensure that a woman is not provided with treatment when a person consenting to be the second parent has withdrawn consent to parenthood before the woman being treated is notified of the change (SLC T64 (b)); and to ensure that if a woman to be treated withdraws her consent to the nominated second parent being the legal parent or varies that consent to another individual, the original nominated second parent is informed in writing of this (SLC T65).

What they could do better.
Nothing noted on inspection.

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the centre does well.
Consent to treatment, storage, donation, training and disclosure of information
Discussions with staff and a review of documents seen on inspection including a SOP, patient checklists and consents in patient records, confirmed to the inspectors that valid consent is obtained before gametes or embryos are used in the provision of treatment services (SLC T33(b) and T57). The actions to be taken in the event of withdrawal of consent to treatment and / or storage and the initiation of a 'cooling off' period was seen to be embedded into the centre's 'withdrawal of consent' SOP. Evidence was also provided on inspection confirming that quality indicators relevant to consent processes and documentation, have been established and are monitored quarterly (SLC T35). An audit of consent processes and documentation is conducted annually (HF&E Act (1990) as amended, Schedule 3A (10) 2006/86/EC, Appendix 1 F, SLC T36).

Documented competence assessment records were seen on inspection for laboratory and clinical staff who are authorised to seek consent. Assessment records seen were considered to be clear and comprehensive (SLC T15(a)). The identity of the person giving consent is verified when consent is provided against a copy of the patient / partner / donor ID retained in the patient / donor's medical record and again when procedures are carried out, evidence of which was seen in patient record consent check lists.

Consent to legal parenthood
Centre staff were able to demonstrate that effective consent is obtained to legal parenthood, where applicable, prior to treatment commencing in accordance with the centre's SOP (SLC T33(b)). Staff were able demonstrate the documented assessment of their competence to provide information regarding legal parenthood, to seek valid consent

to legal parenthood, and to follow the necessary process in the event of withdrawal or variation of consent to parenthood (SLCs T12 and T15(a)). An audit of 5 patient records affected by legal parenthood legislation was conducted on inspection. It demonstrated that all women being treated and their nominated second parent had completed all appropriate consents in each record seen. Treatment and information checklists retained in the patient records indicated the requirements of the relevant consent forms in each case.
What they could do better. Nothing noted on inspection.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- 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 where created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

Following a tour of the licensed premises, review of documentation provided by the centre and discussions with staff, the inspection team consider that they have sufficient information to determine that all activities for which the centre is licensed are conducted within the precincts of the building to which that licence applies. All staff at the centre conduct their assigned activities with appropriate respect for the special status of the embryo. Embryos are created, stored and used in treatment where permitted in law.

The inspection team consider that following discussion and review of documentation and records provided by the centre on inspection, no money or benefit is given or received for the supply of gametes or embryos except where authorised by the Authority. Donor compensation records indicated that compensation paid to donors is within the prescribed limits of General Direction 0001.

What they could do better.

Nothing noted on inspection.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well.

All gametes and embryos in storage at the centre are stored in accordance with the gamete provider's consent and in circumstances permitted in accordance with the HF&E Act 1990 (as amended), as confirmed in discussions with staff and by a review of storage records.

The centre has a SOP to be followed when storing gametes and embryos and the documented validation of the storage procedures was considered to comprehensive (SLC T33(b) and T72). A number of quality indicators relevant to the storage of gametes and embryos have been established and performance against these indicators is monitored and feeds into the centre's storage audits. Comprehensive audits conducted throughout 2010 and 2011, relating to all aspects of gamete and embryo storage, were seen on inspection and were considered to be detailed and comprehensive. Audits seen demonstrated analysis of the audit findings and corrective actions where non-conformities were found (HF&E Act (1990) as amended (SLC T35 and T36). A review of the centre's storage records confirmed that all material currently in storage has been appropriately screened and is stored within the relevant statutory storage periods and with the valid consent of the gamete providers (HF&E Act (1990) as amended, S.14 (1) (c)). Laboratory staff demonstrated the operation of a compliant 'bring-forward' system, established to ensure sufficient advance notice of the end of a sample's statutory storage period, or earlier consented period if so specified by the gamete provider (CoP Guidance 17.17).

Staff provided comprehensive documented evidence of the assessment of their competence to perform all procedures relating to the storage of gametes and embryos (SLC T15a).

What they could do better.
Nothing noted on inspection.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*
- Export of gametes and embryos (Guidance Note 16) – *only applicable for centres that has exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*
- Import of gametes and embryos (Guidance Note 16) – *only applicable for centres that has imported gametes and / or embryos*

What the centre does well.
From discussions with staff and a review of documents on inspection, the inspection team conclude that the centre has processes and procedures in place to ensure that gametes and embryos are only sent to other licensed centres in conditions that protect their quality and safety (SLC T105).

A comprehensive SOP (SLC T33 (b)) directs the details, circumstances, responsibilities and procedures for the release of stored material prior to distribution and also defines the critical transport conditions to ensure that the required tissue and cell properties and viability is maintained (SLC T105). The centre's SOP also details the responsibilities and procedures to be employed in the event that gametes or embryos need to be recalled and how the returned material is to be handled (HF&E Act (1990) as amended, Schedule 3A (11) 2006/86/EC). Discussion with the laboratory manager and review of SOPs indicated that before any transport the primary container is placed within an appropriately labelled shipping container (HF&E Act (1990) as amended, Schedule 3 (11) 2006/86/EC and SLC

T107) which is confirmed as fit for purpose and has been validated (HF&E Act (1990) as amended, Schedule 3A (11) 2006/86/EC and SLC T105 and T108).

The centre's record of gamete / embryo movements was reviewed on inspection. These records were seen to correlate with gamete / embryo movement data submitted to the HFEA and was considered compliant with General Direction 0005.

What they could do better.
Nothing noted on inspection.

Use of embryos for training staff (Guidance Note 22) – *only applicable for centres which use embryos to train staff*

What the centre does well.
Following discussions with staff and a review of documents seen on inspection, the inspection team conclude that the centre only uses embryos with the written consent of the gamete providers to train laboratory staff in embryological techniques. All training procedures for which the embryos are used are those approved by the Authority. The centre has a SOP in place to direct the use of embryos in training, defines that clinical and training roles are separate and that the number used is kept to a minimum (SLCs T92, T93, T95 and T96)

A log, for which each entry is signed by the relevant staff member, is maintained recording embryos used in training. Embryos designated for training are separated from embryos for use in treatment.

The centre has established quality indicators relevant to the use of embryos for training (SLC T35). There is insufficient training data since January 2011 to perform an audit but the centre confirmed that this will be conducted within the next year (Schedule 3A (10) 2006/86/EC, Appendix 1 F and SLC T36)

What they could do better.
It was noted that the centre's SOP specifies that embryos may only be used for training purposes expressly authorised by the Authority, but does not specify what those purposes are..

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

All patient / partner and donor records seen at the time of inspection were considered to be legible and well organised. Each record reviewed was seen to include appropriate demographics for the person(s) to whom the record related and details of how the patient / partner / donor may be positively identified using photographic ID copied into the record. Each record also provided detail of the person's medical history and indications for treatment, welfare of the child documentation, clinical and laboratory test results and relevant documented consents (SLC T46). The staff member responsible for the management of medical records confirmed that the records are protected from unauthorised amendment and are retained securely but accessible for a minimum of 30 years (or longer if specified by Directions) (SLC T47 and T48).

The centre has a SOP in place to direct the process to be followed when submitting data to the HFEA which was seen to be compliant with Directions 0005 (SLC T33(b)). The centre has established quality indicators relevant to the submission of data to the HFEA and a quality objective that all treatment records are submitted within the prescribed timeframe accurately (SLC T35). The centre has a good history of timely and accurate data submission to the HFEA, as reported by the HFEA registry team, and have audited their practice In this area (HF&E Act (1990) as amended, Schedule 3A (10) 2006/86/EC, Appendix 1 F and SLC T36).

The centre has a document control procedure in place that records the history of document reviews and ensures that only current versions of documents are available for use. All documents reviewed on inspection were seen to be appropriately authorised, version controlled and within review date (SLC T34).

What they could do better.

Nothing noted on inspection.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well.

The PR provided all information required by the application process prior to inspection. All members of staff cooperated fully with the inspection and information requested at the time of inspection was provided in an efficient manner.

The PR responded positively to the small number of recommendations from the previous inspections with no outstanding issues noted.

Licensed treatment reporting

An operational audit was not conducted on this occasion as it was considered that the centre has insufficient data to provide a representative data sample since the variation of the license in December 2010.

What they could do better.

Nothing noted on inspection.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclose of information, held on the HFEA Register, for use in research

What the centre does well.

Confidentiality and privacy

From discussions with staff, a tour of the centre premises and facilities, and from documentation seen, the inspection team consider that the centre staff ensure that information about people receiving or who have received treatment, or who have donated gametes and embryos, and children born as a result of assisted conception, is not disclosed unless authorised to do so. The privacy and dignity of those being treated or donating gametes is protected at all times (SLC T43 and T33(b)).

Disclosure of information held by the HFEA Register for use in research

Patients are informed about the disclosure of information held on the HFEA register for use in research as part of the overall consent process. Staff asked demonstrated a good understanding of the circumstances under which patients would be eligible to consent to disclosure of such information and of the process to be followed.

Three patient files were reviewed to determine consent to disclosure of information held by the HFEA to researchers against records of consent notified to the HFEA. Consent details seen in records on inspection correlated with information held by the HFEA in each case.

What they could do better.

It was noted that the assessment of the competence of staff to implement procedures and processes to maintain patient confidentiality has not been documented (SLC T15(b)).

5. Changes / improvements since the previous inspection on 3 November 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Gamete and embryo transport dewars had not been validated.	The transport dewars should be validated for suitability for purpose.	Evidence was provided by the centre that this had been completed. No further action required.
The witnessing record template did not include the time at which patients are positively identified at egg collection.	The witnessing procedure and template documentation should be reviewed to include this.	Evidence was provided by the centre that the witnessing records sheet has been updated to reflect this. No further action required.

Areas of practice that require the attention of the Person Responsible

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

Area of practice and reference	Action required	PR Response	Executive Review
None noted			

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	PR Response	Executive Review
None noted			

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	PR Response	Executive Review
Witness / operative signature on records. Only the initials of the person performing the activity and of the person witnessing it are recorded on the witnessing record sheet and not the name and signature of the participants. This is potentially non-compliant with CoP Guidance 18.7.	The PR should consider revising this practice to reflect guidance. Action should be taken by 12 August 2011	Practice has been revised to ensure that both the name and signature of both the person performing the activity and the person witnessing it are recorded.	No further action required.
Third party agreements The audit of five third party agreements in place revealed that element SLC T114(f) was absent from the agreement with an external laboratory. SLC T114 (f) requires the third party agreement to describe how any test/diagnostic results are to be relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.	The third party agreement with this service provider should be reviewed to reflect all required elements of SLC T114. Action should be taken by 12 August 2011	This third party agreement in being reviewed to ensure that the requirements of T114(f) are included in the agreement.	The centre has provided a copy of the reviewed agreement. No further action required.

The use of embryos in training It was noted that the centre's SOP specifies that embryos may only be used for training purposes expressly authorised by the Authority, but does not specify what those purposes are. This leaves the centre at risk of non-compliance with SLC T93	The PR should consider revising the SOP to specify the specific training activities, authorised by the Authority, which can be undertaken. Action should be taken by 12 August 2011	This SOP has been revised to include detail of the specific training activities authorised by the Authority.	The centre has provided a copy of the revised SOP. No further action required.
Documentation of competence assessment The assessment of staff competence in procedures to ensure the maintenance of patient confidentiality was not documented, contrary to SLC T15(b)	Assessments of competence should be documented and demonstrable. Action should be taken by 12 August 2011	Competence assessments conducted will be fully documented.	No further action required.
Multiple birth eSET non compliance log The scientific inspector noted that the centre's SOPs to guide the implementation of the centre's multiple birth minimisation strategy do not currently include a prompt for the embryologist to update the eSET non compliance log if a patient who is eligible for eSET elects to have more than one embryo replaced against advice. This leaves the centre at risk of non-compliance with General Direction 0003.	The PR should consider revising the SOP to direct that the eSET non compliance log where a patient declines eSET. Action should be taken by 12 August 2011	The SOP will be reviewed and revised to ensure the eSET non compliance log is competed in the event that a woman eligible for elective single embryo transfer elects to have more than one embryo replaced.	The centre have provided a copy of the revised SOP for review. No further action required.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

26 August 2011

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

Minutes – Item 2

Centre 0307 (Complete Fertility Centre Southampton) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Ian Peacock, Analyst Programmer	Lauren Crawford

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 the centre is within the Princess Anne Hospital, Southampton University Hospitals NHS Trust.

2. The Panel noted that the centre was first licensed in November 2008 and had been licensed, in December 2010, to provide a full IVF/ ICSI service.

3. The panel noted that, at the time of the inspection report, the centre's treatment cycle figures were quite low, and that this was considered to be due to it being a relatively new centre expanding its level of activities.

4. The panel noted that the centre had, in September 2010, been approved to vary its licence to change the name of the centre and appoint a new PR.

5. The Panel noted that, at the time of the inspection, there were a number of areas of practice that required improvement, none were major, but there were five other areas of non-compliance or poor practice.

6. The Panel noted that, since the previous inspection on 3 November 2010, the Person Responsible (PR) has provided evidence that two areas for improvement have been fully implemented.

7. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a four year period with no additional conditions.

8. The Panel confined its consideration to the evidence before it.

The Panel's Decision

9. The Panel referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and contained the supporting information required by General Direction 0008.

10. The Panel was satisfied that the qualifications and character of the PR is such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the HF&E Act 1990 (as amended).

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

12. The Panel was satisfied that the centre's use of embryo's for training purposes was necessary.

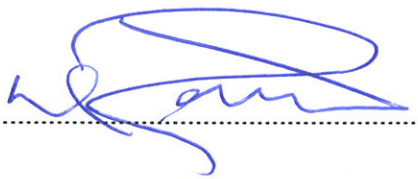
13. The Panel was satisfied that premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report.

14. The Panel referred to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Executive Licensing Panel] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

15. The Panel considered it had no concerns in the matters specified as the centre and PR had either already addressed or committed to resolve the areas identified in the report, none of which were critical or major.

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

17. The Panel urged the PR to complete the small number of outstanding recommendations, within the agreed timeframes and to also keep a close eye on the outcomes of the centre's treatment cycles as the centre increases activity.

Signed  Date 6 Sept 2017

Mark Bennett (Chair)