

**Annex A**

**REPORT TO LICENCE COMMITTEE OF INSPECTION VISIT**  
**DATED .....**

**CENTRE DETAILS**                      *Centre name, number & address*

**PERSON RESPONSIBLE**

**NOMINAL LICENSEE**

**ACTIVITIES OF CENTRE**              *Current licenced activities only / new treatments applied for*

**LICENCE EXPIRY DATE**

**INSPECTION TEAM**                      *Senior Regulatory Manager*  
*Clinical Inspector*  
*Scientific Inspector*  
*Social & Ethical Inspector*  
*Regulatory Officer*

**REASON FOR INSPECTION**          *renewal etc*

**FOCUS – description here**

**Section 1 – Profile of Centre**

**Number of cycles (over last twelve months)**

**Breakdown of treatments**

<b>Fresh IVF</b>	<input type="text"/>	<b>Frozen Embryo Transfer</b>	<input type="text"/>
<b>Fresh ICSI</b>	<input type="text"/>	<b>Donor Insemination</b>	<input type="text"/>

**Patient demographic:-**

**Patient Involvement:-**

**Private/NHS:-**

**Section 2 – Staff Details**

<u>NAME</u>	<u>POSITION</u>	<u>CV</u>	<u>COMMENTS</u>
	<i>Person Responsible</i>		<ul style="list-style-type: none"> <li>▪ <i>This section will list the length of service in the post for each of the positions and other related details, i.e. training to be an ICSI practitioner</i></li> <li>▪</li> </ul>
	<i>Nominal Licensee</i>		<ul style="list-style-type: none"> <li>▪</li> </ul>
	<i>Accredited Consultant</i>		<ul style="list-style-type: none"> <li>▪ <i>NHS Accredited</i></li> </ul>
	<i>Senior Embryologist (ICSI)</i>		<ul style="list-style-type: none"> <li>▪</li> </ul>
	<i>Embryologist (ICSI)</i>		<ul style="list-style-type: none"> <li>▪</li> </ul>
	<i>Counsellor</i>		<ul style="list-style-type: none"> <li>▪</li> </ul>
	<i>Nurse Co-ordinator</i>		<ul style="list-style-type: none"> <li>▪</li> </ul>
	<i>ALL STAFF</i>		<ul style="list-style-type: none"> <li>▪</li> </ul>

CV – CV submitted



HFEA (18/02/04) 136

Total number of centre staff

Number of new staff employed in last year

Is there a CPD programme (Yes/No)

Number of staff who have left in the last year

**Section 3 – Review of patient records**

Treatment	No. Audited	Anomalies	Issues	Reference
DI	10	4	2 x missing consent to disclosure 1 x missing consent to treatment 1 x missing WOC	CoP 3.2
IVF				
ICSI				
Egg Sharing				
Other				
TOTAL				

**Findings of Audit Team**

*Summary description to go here*

**Findings of Laboratory Audit Trail**

*Description to go here*

Percentage of above audited patient records out of all patients receiving treatment over past year: 0.00%

Number of 1 embryo transfers from audit:  
 Number of 2 embryo transfers from audit:  
 Number of 3 embryo transfers from audit:

**Section 4 – Licensed treatments reviewed against patient information (PI), clinical protocols (CP), laboratory protocols (LP) and social & ethical protocols (SE)**

<u>LICENCED TREATMENTS</u>	<u>PI</u>	<u>CP</u>	<u>LP</u>	<u>SE</u>	<u>COMMENTS</u>	<u>REFERENCE</u>
DI	✓	✓	✓	✓	▪	
IVF	✓	✓	✗	✓	▪ <i>Witnessing procedures should be fully documented.</i>	<i>CH(02)01 08/02 CoP</i>
IVF with Donor sperm/eggs	✓	✓	✓	✓	▪	
Egg sharing - recipient	✗	✓	✓	✓	▪ <i>“That if less than 9 eggs are found treatment may be halted” is incorrect and should be changed to state that the clinic offers that donors may continue as a normal IVF cycle.</i>	<i>HFE Act sec12.14</i>
Egg sharing - donor					▪	
ICSI	✓	✓	✓	✓	▪	
Egg Donation	✓	✓	✓	✓	▪	
Storage (eggs)	✓	✓	✓	✓	▪	

Storage (Sperm – patient)					▪	
Storage (Sperm – donor)					▪	
PGD	✓	✓	✓	✓	▪ <i>Expecting 15 cases per year. Presently had 2.</i>	
PGS					▪	

**New Treatments applied for (if applicable)**

<u>TREATMENT APPLIED FOR</u>	<u>PI</u>	<u>CP</u>	<u>LP</u>	<u>SE</u>	<u>COMMENTS</u>	<u>REFERENCE</u>
e.g. assisted hatching (chemical)					▪	

**Research (if applicable)**

<u>RESEARCH PROJECT NUMBER</u>	<u>PI</u>	<u>CP</u>	<u>LP</u>	<u>SE</u>	<u>COMMENTS</u>	<u>REFERENCE</u>
e.g. R0141					▪	

PI – Patient Information    CP – Clinical Protocol    LP- Laboratory Protocol    SE – Social & Ethical

**Satellite/Transport Links**

<u>Satellite</u>		<u>Transport</u>	
<b>Name</b>	<b>Protocols &amp; PI</b>	<b>Name</b>	<b>Protocols &amp; PI</b>

**Section 5 - Areas for follow up highlighted from Inspectors' protocols**

<b>Protocol</b>	<b>Comment</b>	<b>Reference</b>
<i>Clinical</i>	▪	
<i>IVF Laboratory</i>	▪	
<i>Audit</i>	▪	
<i>Andrology Laboratory</i>	▪	
<i>Storage Centre</i>	▪	
<i>Counselling</i>	▪ <i>Counsellor's audit has not been received by the HFEA.</i>	
<i>Welfare of the Child</i>	▪	
<i>Egg-Sharing</i>	▪	
<i>Patient Information</i>	▪	
<i>Premises</i>	▪ <i>The hospital wing is expected to move to a new location some time in the next year. The centre stated that arrangements would be forwarded to the HFEA in due time.</i>	
<i>Research</i>	▪	
<i>Other Issues</i>	▪	

**COMMENDATIONS**

- *The clinic's laboratory procedures were of a high standard.*

<b>SIGNED</b> _____ Chair of inspection team	<b>DATE</b> _____
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### Annex A – Last three years licensing history

	Number complied with	Number outstanding
Number of current conditions		
Number of previous conditions		
Number of current recommendations		
Number of previous recommendations		

No. resolved

Number of patient complaints received by the HFEA



Number of patient complaints received by the Centre



Number of adverse incidents reported to the HFEA



Yes

No

Current HFEA Licence/s on display



Complaints procedure on display



Annual Audit conducted

**Annex B**

Conditions, Recommendations and Commendations of the last 3 years.