<table>
<thead>
<tr>
<th>Particulars</th>
<th>2014/15 NHS STANDARD CONTRACT   IVF Final 24/9/14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract Reference</td>
<td></td>
</tr>
<tr>
<td>DATE OF CONTRACT</td>
<td></td>
</tr>
<tr>
<td>SERVICE COMMENCEMENT DATE</td>
<td></td>
</tr>
<tr>
<td>CONTRACT TERM</td>
<td>[ ] Years/Months [Subject to extension in accordance with Schedule 1 Part C]</td>
</tr>
<tr>
<td>COMMISSIONERS</td>
<td>[ ] CCG (ODS [ ]) [ ] CCG (ODS [ ]) [ ] CCG (ODS [ ]) [NHS England] [Local Authority]</td>
</tr>
<tr>
<td>CO-ORDINATING COMMISSIONER</td>
<td>[ ]</td>
</tr>
<tr>
<td>PROVIDER</td>
<td>[ ] (ODS [ ]) Principal and/or registered office address: [ ] [Company number: [ ] ]</td>
</tr>
</tbody>
</table>
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PAYMENT
QUALITY
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GC12 Assignment and Sub-Contracting
GC13 Variations
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GC15 Governance, Transaction Records and Audit
GC16 Suspension
GC17 Termination
GC18 Consequence of Expiry or Termination
GC19 Provisions Surviving Termination
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GC24 Change in Control
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CONTRACT

This Contract records the agreement between the Commissioners and the Provider and comprises

1. the Particulars;

2. the Service Conditions;

3. the General Conditions,

as completed and agreed by the Parties and as varied from time to time in accordance with General Condition 13 (Variations).

IN WITNESS OF WHICH the Parties have signed this Contract on the date(s) shown below

SIGNED by .................................................................

Signature

[INSERT AUTHORISED SIGNATORY’S NAME] for
and on behalf of ..........................................................
[INSERT COMMISSIONER NAME] Date

[INSERT AS ABOVE FOR EACH COMMISSIONER]

SIGNED by .................................................................

Signature

[INSERT AUTHORISED SIGNATORY’S NAME] for
and on behalf of ..........................................................
[INSERT PROVIDER NAME] Date
<table>
<thead>
<tr>
<th>SERVICE COMMENCEMENT AND CONTRACT TERM</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date</td>
<td></td>
</tr>
<tr>
<td>Expected Service Commencement Date</td>
<td></td>
</tr>
<tr>
<td>Longstop Date</td>
<td></td>
</tr>
<tr>
<td>Commissioner Documents</td>
<td>Set out in Schedule 1 Part B or None</td>
</tr>
<tr>
<td>Service Commencement Date</td>
<td></td>
</tr>
</tbody>
</table>
| Contract Term                          | [__] Years/Months  
[Subject to extension in accordance with Schedule 1 Part C] |
| Option to extend Contract Term         | YES/NO  
By [__] months/years |
| Expiry Date                            | [__]  
[Subject to extension in accordance with Schedule 1 Part C] |
## SERVICES

<table>
<thead>
<tr>
<th>Service Categories</th>
<th>Tick all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accident and Emergency (A+E)</td>
<td></td>
</tr>
<tr>
<td>Acute Services (A)</td>
<td></td>
</tr>
<tr>
<td>Ambulance Services (AM)</td>
<td></td>
</tr>
<tr>
<td>Cancer Services (CR)</td>
<td></td>
</tr>
<tr>
<td>Care Home Services (CH)</td>
<td></td>
</tr>
<tr>
<td>Community Pharmaceutical Services (Ph)</td>
<td></td>
</tr>
<tr>
<td>Community Services (CS)</td>
<td></td>
</tr>
<tr>
<td>Diagnostic, Screening and/or Pathology Services (D)</td>
<td></td>
</tr>
<tr>
<td>Hospice Services (H)</td>
<td></td>
</tr>
<tr>
<td>Mental Health and Learning Disability Services (MH)</td>
<td></td>
</tr>
<tr>
<td>Mental Health Secure Services (MHSS)</td>
<td></td>
</tr>
<tr>
<td>Patient Transport Services (PT)</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy Services (R)</td>
<td></td>
</tr>
<tr>
<td>Substance Misuse Services (SM)</td>
<td></td>
</tr>
<tr>
<td>Surgical Services in a Community Setting (S)</td>
<td></td>
</tr>
<tr>
<td>Urgent Care/Walk-in Centre Services/Minor Injuries Unit (U)</td>
<td></td>
</tr>
</tbody>
</table>

### Service Requirements

<table>
<thead>
<tr>
<th>Service Specifications</th>
<th>Set out in Schedule 2 Part A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicative Activity Plan</td>
<td>Set out in Schedule 2 Part B or Not applicable</td>
</tr>
<tr>
<td>Activity Planning Assumptions</td>
<td>Set out in Schedule 2 Part C or Not applicable</td>
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<tr>
<td>Essential Services (NHS Trusts only)</td>
<td>Set out in Schedule 2 Part D or Not applicable</td>
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<tr>
<td>Services to which 18 Weeks applies</td>
<td>YES/NO</td>
</tr>
</tbody>
</table>
## PAYMENT

<table>
<thead>
<tr>
<th>Particulars</th>
<th>YES/NO</th>
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</thead>
<tbody>
<tr>
<td>National Prices</td>
<td>YES [List Services, by Specification No. if desired] or Not applicable</td>
</tr>
<tr>
<td>Local Prices</td>
<td>Set out in Schedule 3 Part A or Not applicable</td>
</tr>
<tr>
<td>Local Variations</td>
<td>Set out in Schedule 3 Part B or Not applicable</td>
</tr>
<tr>
<td>Local Variations</td>
<td>Set out in Schedule 3 Part C or Not applicable</td>
</tr>
<tr>
<td>Local Modifications</td>
<td>Set out in Schedule 3 Part C or Not applicable</td>
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<tr>
<td>Small Provider</td>
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<tr>
<td>Expected Annual Contract Value</td>
<td>YES/NO</td>
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<tr>
<td>Any Services not included in Expected Annual Contract Value</td>
<td>YES/NO</td>
</tr>
<tr>
<td>First/Last Contract Year less than 12 months</td>
<td>YES/NO</td>
</tr>
<tr>
<td>Notice given to aggregate payments</td>
<td>YES/NO</td>
</tr>
<tr>
<td>Notice given to disaggregate payments</td>
<td>YES/NO</td>
</tr>
<tr>
<td>QUALITY</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Sanction Variations</td>
<td>YES/NO</td>
</tr>
<tr>
<td>CQUIN Scheme(s)</td>
<td>YES/NO</td>
</tr>
<tr>
<td>CQUIN Variations</td>
<td>YES/NO</td>
</tr>
<tr>
<td>CQUIN Payments on Account Made</td>
<td>Monthly/Other (Specify)</td>
</tr>
<tr>
<td>Local Incentive Scheme</td>
<td>YES/NO</td>
</tr>
<tr>
<td>Provider type</td>
<td>NHS Foundation Trust/NHS Trust Other</td>
</tr>
<tr>
<td>Clostridium Difficile Baseline Threshold</td>
<td>[    ] or Nil or Not applicable</td>
</tr>
</tbody>
</table>
## GOVERNANCE AND REGULATORY

<table>
<thead>
<tr>
<th><strong>Documents Relied On</strong></th>
<th>Set out in Schedule 5 Part A or Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mandatory Material Sub-Contractors</strong></td>
<td>Set out in Schedule 5 Part B1 or Not applicable</td>
</tr>
<tr>
<td><strong>Permitted Material Sub-Contractors</strong></td>
<td>Set out in Schedule 5 Part B2 or Not applicable</td>
</tr>
<tr>
<td><strong>IPR</strong></td>
<td>Set out in Schedule 5 Part C or Not applicable</td>
</tr>
<tr>
<td><strong>Commissioner Roles and Responsibilities</strong></td>
<td>Set out in Schedule 5 Part D</td>
</tr>
<tr>
<td><strong>Nominated Mediation Body</strong></td>
<td>CEDR/Other – [ ]</td>
</tr>
<tr>
<td><strong>Provider’s Information Governance Lead</strong></td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>Provider’s Caldicott Guardian</strong></td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>Provider’s Senior Information Risk Owner</strong></td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>Provider’s Accountable Emergency Officer</strong></td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>Provider’s Safeguarding and Prevent Lead</strong></td>
<td>[ ]</td>
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</tbody>
</table>
**CONTRACT MANAGEMENT**

<table>
<thead>
<tr>
<th>Addresses for service of Notices</th>
<th>Co-ordinating Commissioner: [ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: [ ]</td>
<td></td>
</tr>
<tr>
<td>Email: [ ]</td>
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<tr>
<td>Commissioner: [ ]</td>
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<td>Address: [ ]</td>
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<td>Email: [ ]</td>
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<tr>
<td>Provider: [ ]</td>
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</tr>
<tr>
<td>Address: [ ]</td>
<td></td>
</tr>
<tr>
<td>Email: [ ]</td>
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</tr>
</tbody>
</table>

| Frequency of Review Meetings     | Ad hoc/Monthly/Quarterly/Six Monthly |

<table>
<thead>
<tr>
<th>Commissioner Representative(s)</th>
<th>[ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: [ ]</td>
<td></td>
</tr>
<tr>
<td>Email: [ ]</td>
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</tr>
<tr>
<td>Tel: [ ]</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Provider Representative</th>
<th>[ ]</th>
</tr>
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<tbody>
<tr>
<td>Address: [ ]</td>
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</tr>
<tr>
<td>Email: [ ]</td>
<td></td>
</tr>
<tr>
<td>Tel: [ ]</td>
<td></td>
</tr>
<tr>
<td>PENSIONS</td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>---</td>
</tr>
<tr>
<td>New Fair Deal applies</td>
<td>YES/NO</td>
</tr>
</tbody>
</table>
SCHEDULE 1 – SERVICE COMMENCEMENT
AND CONTRACT TERM

A. Conditions Precedent

The Provider must provide the Co-ordinating Commissioner with the following documents:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Evidence of appropriate Indemnity Arrangements</td>
</tr>
<tr>
<td>2.</td>
<td>Evidence of CQC registration in respect of Provider and Material Sub-Contractors (where required)</td>
</tr>
<tr>
<td>3.</td>
<td>Evidence of Monitor’s Licence in respect of Provider and Material Sub-Contractors (where required)</td>
</tr>
<tr>
<td>4.</td>
<td>[Copies of all Mandatory Material Sub-Contracts, signed and dated and in a form approved by the Co-ordinating Commissioner]</td>
</tr>
<tr>
<td>5.</td>
<td>[Copies of all Permitted Material Sub-Contracts, signed and dated and in a form approved by the Co-ordinating Commissioner]</td>
</tr>
<tr>
<td>6.</td>
<td>[A copy of the/each Direction Letter]</td>
</tr>
<tr>
<td>7.</td>
<td>[Insert text locally as required]</td>
</tr>
</tbody>
</table>

The Provider must complete the following actions:

[Insert text locally as required]
B. Commissioner Documents

<table>
<thead>
<tr>
<th>Date</th>
<th>Document</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insert text locally or state Not Applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
C. Extension of Contract Term

1. As advertised to all prospective providers during the competitive tendering exercise leading to the award of this Contract, the Commissioners may opt to extend the Contract Term by [      ] months/year(s).

2. If the Commissioners wish to exercise the option to extend the Contract Term, the Co-ordinating Commissioner must give written notice to that effect to the Provider no later than 6 months before the original Expiry Date.

3. The option to extend the Contract Term may be exercised:
   
   3.1 only once, and only on or before the date referred to in paragraph 2 above;
   
   3.2 only by all Commissioners; and
   
   3.3 only in respect of all Services

4. If the Co-ordinating Commissioner gives notice to extend the Contract Term in accordance with paragraph 2 above, the Contract Term will be extended by the period specified in that notice and the Expiry Date will be deemed to be the date of expiry of that period.

Or

NOT USED
SCHEDULE 2 – THE SERVICES

A. Service Specifications

Mandatory headings 1 – 4: mandatory but detail for local determination and agreement
Optional headings 5-7: optional to use, detail for local determination and agreement.

All subheadings for local determination and agreement

<table>
<thead>
<tr>
<th>Service Specification No.</th>
<th>Service</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assisted Conception Service</td>
</tr>
<tr>
<td>Commissioner Lead</td>
<td>TBC</td>
</tr>
<tr>
<td>Provider Lead</td>
<td>TBC</td>
</tr>
<tr>
<td>Period</td>
<td>April 15-Mar 16</td>
</tr>
<tr>
<td>Date of Review</td>
<td>TBC</td>
</tr>
</tbody>
</table>

1. Population Needs

The purpose of the Assisted Conception Service is to provide a range of appropriate assisted conception services for couples who meet the eligibility criteria.

This service specification is an agreement between Merton CCG who have commissioned the service and the tertiary providers of assisted conception services.

The service aims to treat subfertility. The objective of treatment for subfertility is to achieve a successful pregnancy quickly and safely with the least intervention required and the delivery of a healthy child.

The criteria set out in this policy apply irrespective of where the residents of Merton CCG have their treatment. A Merton CCG patient is defined as someone registered with a Merton GP practice.

This policy has drawn on guidance issued by the Department of Health, Infertility Network UK and the revised NICE guidance (CG 156) published in February 2013.


http://www.infertilitynetworkuk.com/uploadedFiles/Standardising%20Access%20Criteria%20to%20NHS%20Fertility%20Treatment%202009%202006%202009.doc

http://guidance.nice.org.uk/CG156 (summary guidance)

Merton CCG will fund assisted conception as set out in the Merton CCG Assisted Conception and Pre implantation Genetic Diagnosis Policy 2014/15.

This policy describes circumstances in which Merton CCG will fund treatment for assisted conception.

Currently the service will provide 1 cycle of IVF with a view that further increases in the number of cycles may be offered in the future dependent upon local governance decisions and available funding.

1.2 Evidence base

This specification is designed to sit alongside the legislative provisions of Infertility treatment and the Care Standards Act, and is not designed to replicate these provisions, or to duplicate, replicate or supersede the following policies and guidelines, which may change over time:

- The Human Fertilisation and Embryology Act; 1990
- The East of England Fertility Services Commissioning Guidelines; 2013
- National Minimum Standards for Independent Healthcare; 2000
- Any Quality standard as determined by the Care Quality Commission
- Any Quality standard required under the terms of the Care Standards Act; 2000
- Ethnicity
- Disability Discrimination Act; 2005
- Equality Act 2010

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

<table>
<thead>
<tr>
<th>Domain 1</th>
<th>Preventing people from dying prematurely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domain 2</td>
<td>Enhancing quality of life for people with long-term conditions</td>
</tr>
<tr>
<td>Domain 3</td>
<td>Helping people to recover from episodes of ill-health or following injury X</td>
</tr>
<tr>
<td>Domain 4</td>
<td>Ensuring people have a positive experience of care X</td>
</tr>
<tr>
<td>Domain 5</td>
<td>Treating and caring for people in safe environment and protecting them from avoidable harm X</td>
</tr>
</tbody>
</table>

3. Scope

3.1 Aims of the service

- To help couples suffering from subfertility to achieve a successful pregnancy
- To offer assessment and treatment for patients suffering from subfertility.
• To provide a quality, safe, cost effective Assisted Conception service ensuring that the risk of infection and other complications to service users is minimised.
• To provide a personal service sensitive to the physical, psychological and emotional needs of service users.
• To ensure effective communications between service users and the service providers.
• To ensure effective communication between commissioners and the service providers.
• To develop and implement a data collection and monitoring processes which provides fertility services intelligence to support the future commissioning of fertility services

3.2 Objectives

• To offer Assisted Conception Services which are safe, effective, appropriate, accessible and acceptable to Service users, and represent good value for money
• To offer Service users consistent, appropriate and suitable information in a format that they can understand.
• To offer Assisted Conception treatment in line with the care pathway agreed by the Clinical Commissioning Group, see policy documents

3.3 Service description/care pathway

Please refer to the latest Merton CCG Assisted Conception and Pre implantation Genetic Diagnosis Policy 2014/15 for further details.

3.31 Principles of care

The Assisted Conception offered will be safe, effective, appropriate, accessible and acceptable to Service users and represent good value for money.

Clinical management of eligible couples should be in line with the agreed local care pathway. This is based on the NICE clinical practice algorithm as modified by individual CCG policies. This local pathway identifies the tests and treatments to be undertaken within Primary (level 1), Secondary (level 2) and Tertiary care (level 3). Within the pathway test results should be passed on and not duplicated.

Where clinically appropriate, waiting times should conform to the 18-week pathway, which begins when a patient is referred from a specialist service to tertiary, and is considered eligible based on the relevant criteria. Service users should be seen in the chronological order of admission on waiting lists and informed of their acceptance on the waiting list.

The Provider will co-ordinate inpatient, day care and outpatient services to ensure continuity of care.

Couples should be seen together because both partners are affected by decisions about investigations and treatment and to allow them to participate in planning their care. They should be seen in a comfortable environment ensuring privacy and
Couples should be treated by a specialist team to improve the effectiveness and efficiency of treatment and outcomes. Service arrangements with Tertiary Specialist Providers will be via a specific contract.

Couples should be provided with consistent, appropriate and suitable information in a format that they can understand. This information will be provided by the specialist centre.

The Provider will ensure that the Service user is afforded the right to be fully informed of their condition, if they so wish, and to ensure information is communicated in an understandable and sympathetic manner.

Couples should be offered counselling prior to, during and after assessment or treatment irrespective of the outcome of that treatment, from someone independent of the treatment team, the cost for which will be met by the Tertiary Provider.

Couples should be informed that they may find it helpful to contact a fertility support group and information.

### 3.32 Service requirements

The Provider will ensure that the Fertility services, where appropriate are shaped around the preferences of service users, their families and their carers.

Service users will be treated with respect and their dignity to be safeguarded regardless of age, sex, ethnicity, religion, culture and sexuality.

Services provided should be culturally sensitive.

Where appropriate, the Provider will work in partnership with other organisations to promote the delivery of a seamless service.

All staff will respect the confidentiality of the service user as required by the NHS document: The Care Record Guarantee (Department of Health, 2007). The Provider will be responsible for asking the patient to sign a confidentiality release clause to share treatment data to the funding authority.

The Provider will offer the service user an appropriate and timely first Outpatient Appointment from the initial referral from the secondary provider.

Hospitalisation will normally be dealt with on a day case basis. If, however, this requires to be extended for clinical requirements, for a maximum of 24 hours, no further charge will be raised.

Should emergency re-admission be required within 30 days, as a result of complications arising as a direct result of the initial clinical operative procedure, this will be absorbed as part of the initial episode of care to a maximum of five days.

The Provider will offer a 5 day normal working hours service, with the ability if necessary, to provide services up to seven days, in addition to an out of hours
emergency contact details.

Service users will be offered counselling with an Assisted Conception Counsellor in line with the HFEA Code of Practice.

Information sheets in non-technical language should be available to explain the proposed investigations and treatment, including detailed information on drugs (and any possible side effects) prescribed by the centre. Information should be tested out with couples to ensure it is user-friendly and available in a range of languages.

Information relating to outcomes should be available for couples on request.

The Tertiary Provider will confirm the removal from the list by written communication to the named Fertility Services Contracts Manager at Merton CCG with a copy sent to the service user, the service user’s GP and referring consultant from the secondary provider.

It is the responsibility of the Provider to bear the cost of all ultrasound scans and any additional outpatient appointments, which may include other tests or observations, until the woman is referred by her GP to the maternity services.

Response Times

If a received referral is rejected as it falls outside of the Acceptance Criteria, or meets the Exclusion Criteria of this specification then this should be communicated to the referring clinician within 2 working days.

If, following triage by the Consultant leading the service, a received referral is deemed inappropriate to be seen in the service, this should be communicated to the referring clinician within 5 working days of receipt of referral and no less than 5 working days prior to any appointment already booked for that patient. This communication will include:

The reason that the referral is not appropriate

A suggested alternative management plan

Any follow-up procedure, investigation or appointment which forms part of the management plan agreed with the patient should be scheduled with the patient as part of the consultation, or immediately following it. This should be communicated to the referring clinician at the same time.

Failure to Attend (DNAs)

If a patient does not attend (DNAs) their appointment the service will communicate directly with the patient and the GP, allowing the patient a 3 week window to rearrange their appointment by phone. If the patient fails to rearrange the appointment within this time, or also DNAs the rearranged appointment, then the patient will be discharged. When a patient is discharged under these circumstances this will be communicated, in writing, to the patient and their GP.

Every effort should be made to ensure DNA rates are as low as possible. This will
include:
the use of technology (e.g. text messaging) where possible/appropriate to ensure
that patients are reminded of appointments in a timely fashion
engaging with patients following a DNA to ascertain the reason and, where possible,
address this to ensure that any subsequent appointment is kept.

Communications

All communications to Primary Care clinicians referred to in this document will be
made electronically using nhs.net, or an approved system integrating securely with
all Merton GP systems.

After each attendance there will be written communication, to both the patient and
referring clinician, of the assessment findings and the subsequent management
plan. This communication will be as timely as possible, and must be received within
5 working days of the attendance.

Dedicated phone numbers will be available for:
Appointments/booking/cancellation etc. (available to GP Practices and to patients)
Primary Care clinicians to contact each service directly

Additional Requirements

The mean clinic waiting time for the service must be less than 15 minutes.

In line with GMC Guidance, it is the responsibility of the Consultant leading the
service to ensure that any investigations requested by the service are followed-up
and dealt with by the service, including contacting the patient directly regarding
results.

Where clinically appropriate, patients will be given the option of follow-up
consultation, or discussion of the results of investigations, by phone rather than in
person.

The Provider is expected to be aware of local lifestyle services and voluntary sector
agencies and, where appropriate, signpost patients to these. (Information regarding
such services and agencies will be made available to the Provider by the Merton
CCG and the London Borough of Merton Public Health.)

The Provider must have a Business Continuity Plan in place to ensure that all
services are available at their stated times, including adequate cover for planned
and unplanned leave. In the event of a service being unavailable/inaccessible, the
service must have documented contingency plans to ensure that patients are
provided with (and advised of) alternative services

3.33 Treatment details

For continuity of care delivery, the service user will have a named Lead Clinician,
who will take responsibility for the service user during this pathway of care.

Referral criteria and sources are listed in section 4.4 of this document. It is the
responsibility of the commissioned provider to ensure all criteria are met, all relevant
investigations are completed, and the specific number of fresh cycles and embryo transfers allowed to be funded by the referring CCG, has been applied.

Please refer to policy documents for further details.

Embryo transfer strategies:

• For women less than 37 years of age only one embryo or blastocyst to be transferred in the first cycle of IVF and for subsequent cycles only one embryo/blasto cyst to be transferred unless no top quality embryo/blasto cyst available then no more than 2 embryos to be transferred
• For women age 37-39 years only one embryo/blasto cyst to be transferred unless no top quality embryo/blasto cyst available then no more than 2 embryos to be transferred.
• For women 40-42 years, double embryo transfer may be considered.

For couples where the woman is under 38 years of age, there should be a six month period between completion of the pregnancy test post embryo transfer and commencement of drugs for the next fresh cycle.

Should an attempted fresh cycle be abandoned the reason must be recorded in the context of:

• Poor/over ovarian response
• Poor fertilisation
• Poor embryo quality
• Poor Service user compliance

If any fertility treatment results in a live birth, then the couple will no longer be considered childless and will not be eligible for further NHS funded fertility treatments, including the implantation of any stored embryos. Any costs relating to the continued storage of the embryos beyond the first calendar year of the retrieval date, are the responsibility of the couple.

**Treatment will include:**

Initial consultation, follow up consultation, and counselling sessions.

All ultrasound scans and hormone assessments during the treatment cycle.

Oocyte recovery - by vaginal ultrasound guided by aspiration under sedation or local anaesthesia or laparoscopy as appropriate. General anaesthesia will be provided when necessary.

Embryo, or blastocyst transfer, into uterine cavity.

All embryology including sperm preparation and sperm retrieval where indicated.

Embryo/blasto cyst freezing and storage will be commissioned as part of the service requirement, and will be funded for up to 12 months following completion of NHS Treatment, when further discussions with the couple will need to take place.
A pregnancy test and a maximum of two scans to establish the viability of the pregnancy.

The service will no longer provide assisted conception when...

- A live baby has been born
- The couple choose not to proceed
- There is clinical evidence to show that a successful outcome will not be possible

3.34 Prescribing

The commissioned provider of the IVF service under this contract will prescribe and supply the necessary drugs.

Providers must refrain from asking patients to request prescriptions for medication that is part of the IVF treatment pathway from their GPs.

Accurate and detailed information of the drug, the dosage and the frequency and possible side effects will be given to the service user including:

- Possible drug interactions
- The risk of Ovarian Hyper Stimulation Syndrome (OHSS)
- The risks associated with multiple pregnancies
- Follow-up and monitoring arrangements, and how the consultant will monitor the woman’s progress
- The circumstances under which treatment should be stopped or re-referral made to the secondary provider consultant
- The Tertiary Provider consultant will retain overall clinical responsibility

In accordance with HFEA guidelines, the provider will seek the consent of the service user to relevant information being shared with the registered GP.

Subject to the above recommendations being followed, the cost of this prescribing will be part of the contract.

In line with NHS regulations, prescribing costs for residents receiving IVF on a private basis will not be funded under the NHS.

3.35 Service users Reports

The tertiary provider will provide a formal written report to be sent to the referrer from the secondary provider, with a copy to the Service user and their GP within 5 working days of the first consultation, out-lining clinical findings, plan of care and waiting list status.

Following the service user’s first outpatient consultation, a written report will be sent to the service user’s referring consultant, copied to the service user and their GP.

Robust records of treatment given and treatment outcomes and pregnancy outcomes must be recorded against the woman’s NHS number.

3.36 Information & Data Requirements
In order to achieve accurate forecasting, activity monitoring and prompt and accurate payment, there needs to be timely regular exchange of detailed and accurate information. The Provider will provide the information as requested, in the format requested and to the agreed timescales. The Provider, in addition to the Information requirements set out below, will also provide upon request any additional information that the Commissioner may request.

### 3.37 Standard minimum dataset information

The Provider will be required to submit standard minimum datasets via SUS which comply with guidance relating to clinical coding published by the NHS Classifications Service and with the definitions of activity maintained under the NHS Data Model and Dictionary. Timescales for provision of this data will comply with those specified by SUS and the Standard NHS Contract for Acute Services.

### 3.4 Outcomes

- Achieve a 40% or higher live birth rate for women aged up to 37 years
- Achieve a 20% or higher live birth rate for women aged between 38 years and 40 years
- Achieve a 15% or higher live birth rate for women aged between 40 years and 42 years
- Annual multiple-birth rate to 10% or below
- Reduction in the onward transmission of chronic viral infections such as Hep B, Hep C and HIV from 13/14 levels.

### 3.41 Service user Satisfaction

Using the HFEA Service user questionnaire, the Provider will give regular feedback to Merton CCG, on the recommendations and action plans of these audits.

The referral letter from the Secondary Provider to the Tertiary Provider must be responded to within 5 working days with

- An acknowledgement to the GP
- A first outpatient appointment (OPD) sent to the service user

Treatment will commence as soon as possible, determined by the woman's menstrual cycle.

### 3.5 Population covered

The provider will provide the service to the adult population that is registered with a Merton GP.

Services provided to population groups not registered with a Merton GP are outside the scope of this service specification. However, the provider will be responsible for any negative impact on service provision in Merton.

### 3.6 Any acceptance and exclusion criteria and thresholds
The Provider will ensure that its services are accessible regardless of age, disability, race, culture, religious belief, sexual orientation or income levels. The Provider will deal sensitively with all service users, potential service users and their family/friends and advocates.

This service agreement does not cover:

The referral of couples by the Secondary Provider to the Tertiary Providers, who have not had the prerequisite investigations or treatments required, at either the primary level or secondary level. The agreed pro-forma to be used will need to be completed, and will need to include information such as any investigations, information on patients and clearly state whether the patient is eligible for specialist treatment.

Referrals for infertility treatment must be from the following pathways;

• Referral from GP (Primary Care) following primary investigations to secondary provider services.

• Referral from the Secondary Provider service named Gynaecologist or GPSI, following on from a diagnosis of infertility. Secondary investigations and/or treatments to have been undertaken (see Criterion number 14 – minimum investigations)

Self-referrals or from any other source than those detailed above will not be accepted and the Service user should be directed back to their GP.

Couples will be assessed for referral using the following referral criteria as per the CCG Assisted Conception and Pre implantation Genetic Diagnosis Policy 2014/15.

3.7 Interdependence with other services/providers

The Tertiary Service Provider will work directly with the following professionals to ensure a seamless service and the continuity of holistic care:

• General Practitioners
• General Practitioners with Special Interest
• Referring Secondary Provider Clinical Leads and Fertility Nurses
• Clinical Commissioning Group Exceptionality Clinical Review Boards
• NHS Genetic Services

3.8 Activity and financial monitoring information

The Provider will produce activity and financial summaries on a monthly basis which will give an overview of the performance of the contract for that particular month and for the year-to-date.

3.9 Monitoring of performance targets and other outcome measures

The Provider will provide regular monitoring information on a range of performance and outcome measures to be agreed with provider.
The Provider will also provide regular status reports on each couple referred for treatment, which will include details of the treatments-to-date.

4. Information Governance

The provider shall conform to the Data Protection Act, (Department of Health, 2006)

4.1 Quality of Information

The Provider will ensure that all data provided is complete, accurate and timely. The Provider will ensure that it’s staff do not adopt, desist from any current clinical protocol, practice or procedure, or any administrative (or coding) practice or procedure, which will either intentionally or inadvertently, maximise income to the Provider, rather than to reflect the actual necessary treatment received by a Service user, or a group of Service users.

4.2 Performance Targets

The Provider will comply with current performance targets as laid down by the Department of Health and any local additional performance targets defined by Merton CCG.

18 week pathway for Fertility services (\

• It will be the responsibility of the Provider to identify, in a timely fashion in advance of the occurrence, any service user where the performance targets and maximum waiting times as identified within the this document cannot be met by the Provider.

The provider will then agree with the Lead Commissioner from Merton CCG, the necessary actions to remedy these breaches of the service management.

• All tertiary providers will have an elective Single Embryo Transfer (eSET) Strategy, inclusive of selection criteria, for implementation from April 2009 as per HFEA requirements, to reduce multiple births to 10% by 2011.
  • A 40% or higher live birth rate for women aged up to 37 years
  • A 20% or higher live birth rate for women aged between 38 years and 40yrs
  • A 10% or higher live birth rate for women 40 years to 42 years

4.3 Complaints

The Provider must establish a written complaints procedure. The procedure must incorporate the following:

• A nominated person within the organisation to be responsible for handling complaints;
• Complaints must be acknowledged within 2 working days;
• A full response or holding letter, signed by the Chief Executive or equivalent, to be sent within 20 working days;
• Merton CCG may wish to conduct an Independent Review Panel Investigation if they are dissatisfied with the Provider’s response.
4.4 Waiting times for Tertiary Service Provision

There will be no user waiting over 18 weeks from referral to the commencement of treatment unless there are mitigating medical circumstances.

4.5 Clock Stops as per the Department of Health 2008 18 week pathway for fertility services i.e. when the procedure starts

- Gonadotrophin stimulation of hypogonadal men
- Treatment for pituitary tumours and other medical conditions discovered
- For IUI, IVF, ICSI, PGD as above if cycle control issues take time or if the Service user is not ready the clock can be stopped. The clock stop is the first day of the menstrual cycle in which the assisted conception is to start.
- Service users waiting for egg/sperm donation: the clock stops once they are put on the waiting list (as per transplant lists)
- Post surgery in the event of a miscarriage/ectopic pregnancy
- Ovarian Hyperstimulation Syndrome (OHSS)
- Active monitoring will begin once the Service user is on a recognised local protocol.

4.6 Outcome Data

Information on the Provider’s activities will be provided on a quarterly basis, submitted by week 5 of the quarterly end, as follows:

**Basic outcome data**
- Number of couples seen
- Number of couples treated
- Live birth rates per embryo transfer treatment cycle
- Clinical pregnancy rate – singleton and multiple
- Clinical pregnancy rate – per embryo transfer

The commissioner reserves the right to audit 5% of clinical notes at anytime to ensure appropriate referrals only are being processed by provider.

**Implantation rates and live birth rates by:**
- Diagnostic group
- GP and Patient Postcode

**Complications**
- Twin clinical pregnancy rate.
- Twin births per treatment cycle.
- Ectopic pregnancies per treatment cycle.
- Rate of Ovarian Hyper-stimulation Syndrome (OHSS) – severity and duration of hospitalisation
- Other adverse outcomes needing inpatient management

4.7 Facilities and Equipment

The provider will be required to show evidence that all equipment used is regularly
maintained to a standard commensurate with the needs of the service.

4.8 Service Agreement Management

The provider and the lead commissioner will nominate a contract manager who will be responsible for the operation of the service agreement. This contract manager is to be available to the lead commissioner, or the provider, during normal working hours.

Where due to sickness, absences or annual leave the contract manager is unavailable, then the lead commissioner and the provider will identify a suitable replacement officer who will be able to provide assistance to the other party in any enquiry regarding this service agreement, or its operations.

4.9 Care Pathways

The Care pathway route is detailed in Appendix 2. Referrals that do not adhere to this pathway should not be accepted and returned to the originating referrer.

5. Discharge

Discharge from the Tertiary Provider service will occur before the completion of a maximum of 2 embryo transfers or a maximum of 1 fresh cycles when either:

• A live baby has been born
• The couple choose not to proceed
• There is clinical evidence to show that a successful outcome will not be possible

Written confirmation will be sent to the referring consultant and/or GP with a copy to the Service user detailing the reasons for the above action.

Should there be an unsuccessful treatment outcome; Assisted Conception counselling will be offered at the expense of the Tertiary Provider.

Should the couple have a viable pregnancy and are requiring access to maternity services the following should occur:

• A letter confirming the pregnancy and the need for an antenatal referral will be given to the patient and sent to the GP when a viable clinical pregnancy is confirmed and the patient instructed to make an appointment with their GP to arrange antenatal referral
• The GP will refer the pregnant woman to the maternity services at or around 8 weeks of pregnancy
• The woman should access the midwifery services between 8-10 weeks

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

• National Institute for Health and Care Excellence (NICE)
• Standards for Better Health Framework
• National Service Frameworks (NSFs)

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

The Provider will follow the following guidance:
• Royal College of Surgeons
• British Association of Urological Surgeons
• Care Quality Commission Provider Registration
• Care Quality Commission Essential Standards of Quality and Safety

4.3 Local networks

All Providers must be licensed by the Human Fertilisation and Embryology Authority (HFEA). Core skills and competencies of Staff are set by the HFEA as the regulatory authority for tertiary fertility services.

In addition Providers are expected to comply with relevant legislation, including Health and Safety requirements, and to follow best practice guidelines.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4 Parts [A-D])

Merton CCG has a robust governance process in place which includes a decision making process via the EMT, CRG and CQC which meets on a regular basis and can mitigate any identified risks.

5.2 Applicable CQUIN goals (See Schedule 4 Part [E])

6. Location of Provider Premises

The Provider’s Premises are located at:

7. Individual Service User Placement
B. Indicative Activity Plan
C. Activity Planning Assumptions

Responsibility for Managing Activity
The Commissioner is responsible for managing external demand for services, e.g. through GP referrals. The Provider is responsible for managing their internal activity once a referral has been accepted. The thresholds for activity are set out in the table below. The threshold is not for numbers or volumes of patients to be treated, but the point at which the Provider is expected to notify the Commissioner of the breach. This includes local quality requirements as detailed in the particulars schedule C, which are included below for completeness. Activity thresholds will be applied at the following levels depending on how they are recorded:

- Treatment Function Code (TFC)
- Point of Delivery (POD)
- Service Line Reporting

Definition of Breach
A breach in activity thresholds will have taken place when activity at POD, TFC and/or specialty level has been exceeded materially contract-wide.

Reasons for Breaching Activity Thresholds
If thresholds are exceeded, the Provider is expected to notify Merton CCG and provide an explanation as to the cause. Examples of threshold breaches might include, but are not restricted to:

- increased referrals
- counting/recording changes
- shifts in case mix
- changes in clinical practice
- changes in capacity
- natural fluctuation

Responsibility to Notify
The Provider is required to manage internal demand and co-operate with Commissioners in ensuring that activity planning assumptions are not breached. This includes managing waiting lists in order to maintain the 18 week standard and ensure patients are treated according to clinical priority and in turn.

The Provider is required to notify Commissioners of any threshold breaches without delay.

Managing the Breach – Initial Resolution
In order to keep the process simple and reduce the need for unnecessary reporting, the Commissioner and Provider will agree the over-performance indicators to be included in the monthly activity and finance reports sent to commissioners for contract management.

Both parties will endeavour to resolve over-performance breaches through routine contract monitoring and the Contract Management Meetings. Where one or more breach requires further investigation and analysis, the parties will agree the priority, timescales and actions required.

Not all over-performance breaches will be of sufficient materiality to warrant detailed investigation. The Commissioner will confirm to the Provider those breaches that do require further investigation and those that do not. This decision will be made either via email or at the Contract Management Meetings.

Changes to counting and recording
All changes to counting and recording will be agreed with the Commissioner being being implemented following an agreed process. Where there is an un-agreed change in data
recording, coding or counting, the Provider will be expected to provide analysis to explain the reason for the over-performance.
D. Essential Services

N/A
E. Essential Services Continuity Plan

N/A
F. Clinical Networks

Where a clinical network exists, the service provider will be expected to demonstrate its participation in the development of protocols, audits and educational activities and comply with all clinical standards where these are established. In addition, the provider will actively participate in any relevant clinical networks that are constituted during the duration of this contract.

Where relevant, appropriate clinical networks for each service will be identified in the relevant *Individual Service Specification*.
### G. Other Local Agreements, Policies and Procedures

<table>
<thead>
<tr>
<th>Policy</th>
<th>Date</th>
<th>Weblink</th>
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<tbody>
<tr>
<td>To be agreed between Merton CCG and the Provider prior to commencement of the service.</td>
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<tr>
<td>SWL ECI Policy 2013/14</td>
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<td><a href="http://www.swlmcg.nhs.uk">www.swlmcg.nhs.uk</a></td>
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<tr>
<td>SWL Interface Prescribing Policy 2014/15</td>
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<td><a href="http://www.swlmcg.nhs.uk">www.swlmcg.nhs.uk</a></td>
</tr>
<tr>
<td>SWL Interface Prescribing Policy Appendix 1: Hospital / Specialist Only Drug List 2014/15</td>
<td>2014 15 SWL Interface Prescribing</td>
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<tr>
<td>SWL Interface Prescribing Policy Appendix 2B: SWL Shared Care Prescribing Agreements in place 2014/15</td>
<td>2014 15 SWL Interface Prescribing</td>
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<tr>
<td>SWL Commissioning Principles for PbR Excluded Drugs / Devices 2014/15</td>
<td>2014 15 SWL Commissioning Princip</td>
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<tr>
<td>SWL CCG Commissioned PbR excluded drug list 2014/15</td>
<td>2014 15 SWL Commissioning Princip</td>
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## H. Transition Arrangements

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<tr>
<th>To be agreed between the Provider and Merton CCG prior to commencement of contract</th>
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</table>
I. Exit Arrangements

To be agreed between the Provider and Merton CCG prior to commencement of contract

On termination or expiry of this Contract or any Service the Provider must, acting in accordance with the instructions of the Responsible Commissioner, promptly transfer, or deliver a copy of, any Service User Health Record held by the Provider to the Responsible Commissioner or to a third party nominated by that Commissioner.
J. Social Care Provisions

N/A
K. Transfer of and Discharge from Care Protocols

**Discharge Planning (Outpatient Procedures and Day Case Admissions)**

Patients without suitable discharge care should not undergo any procedure. Patients should be assessed, and a discharge plan established, prior to booking an appointment for a procedure. Patients should be reassessed on the day of attendance, prior to any procedure taking place, to ensure that the discharge plan is still appropriate.

On discharge patients should be provided with a summary of any procedure undertaken and details of future follow-up arrangements. They should also be provided with any newly prescribed medication and instructions for on-going care. Details of the same will be provided to the referring clinician by electronic means on the day of the procedure.

**Discharge from a Service**

A patient cannot be formally discharged from a service until all results from investigations are available and can be communicated to the patient and the referring clinician.

On discharge from a service there will be written communication, to both the patient and the referring clinician, of the assessment findings and the subsequent management plan. This communication will be as timely as possible, and must be received within 5 working days of the final attendance. There may then need to be a further final communication once any outstanding results are available, to inform the patient and the referring clinician of the results and any changes to the management plan.

The discharge communication must include:

- The diagnosis (or differential diagnosis).
- Summary of relevant patient history, the findings of any examination(s) and the results of investigations.
- A clear management plan, including details of any medication stopped, changed or started, and action to be taken in the event of deterioration.

If the service recommends, or has started the patient on, a new medication then he or she must be discharged with either a full course of this medication or, for long-term medication, one month’s supply.

**Emergency Transfer**

The service provider must ensure that the unit and clinical staff are competent to manage patients in the event of cardiac arrest, respiratory arrest, or anaphylaxis, or any other condition that requires emergency transfer to an Emergency Department.

In the event of complications or a medical emergency the service provider must demonstrate that robust processes are in place for the rapid transfer of care to other specialities or providers where the patient’s condition warrants this transfer.

**Patients with suspected Cancer**

Following investigation or procedure any patient with suspected cancer should immediately be referred onwards by the Provider via the appropriate 2 Week Wait Pathway. The Provider must ensure robust pathways are in place between themselves, the GP and secondary care to facilitate and communicate this.
L. Safeguarding Policies

**Adult Safeguarding Policy**
Merton CCG and LB Merton are signed up to the London wide adult safeguarding policy and procedures – “Protecting adults at risk: London multi-agency policy and procedures to safeguard adults from abuse”.

The policy will be reviewed by NHS England however this will occur once the Care and Support Act has been passed by Parliament. Therefore it is likely that the full review will be finalised in the Autumn.

Please note that the document refers to CCGs and the SHA rather than the new system. If it is unclear how responsibilities have passed from the old to the new system please refer to the Director of Quality, Merton Clinical Commissioning Group. Please refer to the below link:


**Safeguarding Children through Commissioning Policy**

Merton Clinical Commissioning Group is under a duty to have robust arrangements in place that ensure that good quality services are commissioned on behalf of its children (0 – 18 years) and vulnerable adults who are parents/carers.

The Provider is required to demonstrate strong commitment to safeguarding children within all the services they provide and to comply with Merton CCG Safeguarding Children Through Commissioning Policy, Standards and Quality Indicators – Please refer to the below link:

A. Local Prices

Enter text below which, for each separately priced Service:

- identifies the Service;
- describes any agreement to depart from an applicable national currency (in respect of which the appropriate summary template (available at: http://www.monitor.gov.uk/locallydeterminedprices) should be copied or attached);
- describes any currencies (including national currencies) to be used to measure activity;
- describes the basis on which payment is to be made (that is, whether dependent on activity, quality or outcomes (and if so how), a block payment, or made on any other basis);
- sets out any agreed regime for adjustment of prices for the second and any subsequent Contract Year(s).

<table>
<thead>
<tr>
<th>ASSISTED CONCEPTION</th>
<th>Tariff</th>
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<tbody>
<tr>
<td>ICSI - With drugs</td>
<td>£3,380</td>
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<tr>
<td>IUI Cycle in addition to IVF/ICSI</td>
<td>£621</td>
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<tr>
<td>IVF - With drugs</td>
<td>£3,057</td>
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<tr>
<td>Embryo Freezing additional</td>
<td>£382</td>
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<tr>
<td>Full Embryo Transfer (FET) additional</td>
<td>£812</td>
</tr>
<tr>
<td>Sperm aspiration additional</td>
<td>£2,388</td>
</tr>
<tr>
<td>Donor Sperm additional</td>
<td>£2,312</td>
</tr>
</tbody>
</table>
B. Local Variations

For each Local Variation which has been agreed for this Contract, copy or attach the completed publication template required by Monitor (available at: http://www.monitor.gov.uk/locallydeterminedprices) – or state Not Applicable. Additional locally-agreed detail may be included as necessary by attaching further documents or spreadsheets.

N/A
C. Local Modifications

For each Local Modification Agreement (as defined in the National Tariff) which applies to this Contract, copy or attach the completed submission template required by Monitor (available at: http://www.monitor.gov.uk/locallydeterminedprices). For each Local Modification application granted by Monitor, copy or attach the decision notice published by Monitor. Additional locally-agreed detail may be included as necessary by attaching further documents or spreadsheets.
Or state Not Applicable

N/A
D. Marginal Rate Emergency Rule: Agreed Baseline Value

N/A
E. Emergency Re-admissions Within 30 Days: Agreed Threshold

N/A
## F. Expected Annual Contract Values

<table>
<thead>
<tr>
<th>Commissioner</th>
<th>Expected Annual Contract Value</th>
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<tbody>
<tr>
<td></td>
<td><em>(Where applicable, specify Expected Annual Contract Value including and excluding anticipated values of any high cost drugs, devices and procedures (as listed in the National Tariff) expected to be used in connection with the relevant Services)</em></td>
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Insert text and/or attach spreadsheets or documents locally

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**Total**

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</table>
G. Notices to Aggregate / Disaggregate Payments

N/A
H. Timing and Amounts of Payments in First and/or Final Contract Year

Payments will be made quarterly upon receipt of confirmed invoices from the provider.
SCHEDULE 4 – QUALITY REQUIREMENTS

A. Operational Standards

<table>
<thead>
<tr>
<th>Service user Experience</th>
<th>HFEA Service user questionnaire</th>
<th>Greater 80% completed surveys</th>
<th>Performance Management report</th>
<th>As per agreed Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service users Experience Improvement Plan</td>
<td>Local Action Plan to be agreed</td>
<td>100%</td>
<td>Performance Management report</td>
<td>As per agreed Schedule</td>
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<tr>
<td>Outcomes</td>
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<td>100%</td>
<td>Performance Management report</td>
<td>As per agreed Schedule</td>
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<tr>
<td></td>
<td>20% or higher live birth rate for women aged between 38 and 40 years</td>
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<td>Performance Management report</td>
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<td>100%</td>
<td>Performance Management report</td>
<td>As per agreed Schedule</td>
</tr>
</tbody>
</table>
### Elective Single Embryo Transfer (eSET) Strategy
Reduce total number of multiple births to 10% in line with HFEA requirements
- **Percentage**: 100%
- **Report**:
  - Performance Management report
- **Schedule**: As per agreed Schedule

### Service user Information
All Service user information to be referenced by the User's NHS number and GP
- **Percentage**: 100%
- **Report**:
  - Performance Management report
- **Schedule**: As per agreed Schedule

### Performance & Productivity

<table>
<thead>
<tr>
<th>Access</th>
<th>Local Plan to ensure equality of access to Service Provider's services.</th>
<th>Decided locally</th>
<th>Performance Management report</th>
<th>As per agreed Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complaints</td>
<td>Complaints to be acknowledged within 2 working days of complaint receipt</td>
<td>100%</td>
<td>Performance Management report</td>
<td>As per agreed Schedule</td>
</tr>
<tr>
<td></td>
<td>A full response or holding letter, signed by the Chief Executive of the Provider to be sent within 20 working days</td>
<td>100%</td>
<td>Performance Management report</td>
<td>As per agreed Schedule</td>
</tr>
<tr>
<td>Waiting Times</td>
<td>No Service user will wait over 18 weeks from referral to commencement of treatment unless there are mitigating medical circumstances</td>
<td>100%</td>
<td>Performance Management report</td>
<td>As per agreed Schedule</td>
</tr>
</tbody>
</table>
| Service user Information | A formal report to be sent to the referring Clinical load from the Secondary Provider, with a copy to the Service user and their GP within 5 working days of the First consultation outlining:
  - Clinical findings
  - Plan of Care
  - Waiting List status | 100% | Performance Management report | As per agreed Schedule |
| Counselling | All Service users will be offered access to a Specialist Counsellor in line with HFEA Code of Practice | 100% | Performance Management report | As per agreed Schedule |
B. Never Events
E. Commissioning for Quality and Innovation (CQUIN)

CQUIN Table 1: CQUIN Schemes

<table>
<thead>
<tr>
<th>Commissioner</th>
<th>Payment</th>
<th>Frequency/Timing</th>
<th>Agreed provisions for adjustment of CQUIN Payments on Account based on performance</th>
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<tbody>
<tr>
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</table>

CQUIN Table 2: CQUIN Payments on Account

<table>
<thead>
<tr>
<th>Commissioner</th>
<th>Payment</th>
<th>Frequency/Timing</th>
<th>Agreed provisions for adjustment of CQUIN Payments on Account based on performance</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

N/A
F. Local Incentive Scheme

N/A
G. Clostridium difficile

Clostridium difficile adjustment: NHS Foundation Trust/NHS Trust

The financial adjustment (£) is the sum which is the greater of Y and Z, where:

\[
Y = 0
\]

\[
Z = ((A - B) \times 10,000) \times C
\]

where:

\[
A = \text{the actual number of cases of Clostridium difficile in respect of all NHS patients treated by the Provider in the Contract Year}
\]

\[
B = \text{the Baseline Threshold (the figure as notified to the Provider and recorded in the Particulars, being the Provider's threshold for the number of cases of Clostridium difficile for the Contract Year, in accordance with Guidance)}
\]

\[
C = \frac{\text{no. of inpatient bed days in respect of Service Users in the Contract Year}}{\text{no. of inpatient bed days in respect of all NHS patients treated by the Provider in the Contract Year}}
\]

The financial adjustment is calculated on the basis of annual performance. For the purposes of Service Condition 36.47 (Operational Standards, National Quality Requirements and Local Quality Requirements), any repayment or withholding in respect of Clostridium difficile performance will be made in respect of the final quarter of the Contract Year.

Clostridium difficile adjustment: Other Providers

The financial adjustment (£) is the sum equal to A x 10,000, where:

\[
A = \text{the actual number of cases of Clostridium difficile in respect of Service Users in the Contract Year}
\]

The financial adjustment is calculated on the basis of annual performance. For the purposes of Service Condition 36.47 (Operational Standards, National Quality Requirements and Local Quality Requirements), any repayment or withholding in respect of Clostridium difficile performance will be made in respect of the final quarter of the Contract Year.
H. Sanction Variations

N/A
I. CQUIN Variations

N/A
SCHEDULE 5 - GOVERNANCE

A. Documents Relied On

Documents supplied by Provider

<table>
<thead>
<tr>
<th>Date</th>
<th>Document</th>
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</tbody>
</table>

Documents supplied by Commissioners

<table>
<thead>
<tr>
<th>Date</th>
<th>Document</th>
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<tbody>
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Insert text locally or state Not Applicable
### B1. Provider’s Mandatory Material Sub-Contractors

<table>
<thead>
<tr>
<th>Mandatory Material Sub-Contractor [Name] [Registered Office] [Company number]</th>
<th>Service Description</th>
<th>Start date/expiry date</th>
<th>Processing data – Yes/No</th>
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<tbody>
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### B2. Provider’s Permitted Material Sub-Contractors

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<tr>
<th>Permitted Material Sub-Contractor [Name] [Registered Office] [Company number]</th>
<th>Service Description</th>
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<th>Processing data – Yes/No</th>
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</tbody>
</table>
### C. IPR

#### Commissioner IPR

<table>
<thead>
<tr>
<th>Commissioner</th>
<th>Document/Data/Process</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

#### Provider IPR

<table>
<thead>
<tr>
<th>Provider/Sub-Contractor</th>
<th>Document/Data/Process</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Insert text locally or state Not Applicable</strong></td>
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</tbody>
</table>
## D. Commissioner Roles and Responsibilities

<table>
<thead>
<tr>
<th>Co-ordinating Commissioner</th>
<th>Role/Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
E. Partnership Agreements

To which the Provider is a party:

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<thead>
<tr>
<th>Date</th>
<th>Parties</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
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</table>

To which a Commissioner is a party:

<table>
<thead>
<tr>
<th>Date</th>
<th>Parties</th>
<th>Description</th>
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</thead>
<tbody>
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</tbody>
</table>
SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

A. Recorded Variations
B. Reporting Requirements

Excel spreadsheet to be supplied separately. To be completed and submitted quarterly. No more than 5 working days from the start of the new quarter.

C. Data Quality Improvement Plan

<table>
<thead>
<tr>
<th>Data Quality Indicator</th>
<th>Data Quality Threshold</th>
<th>Method of Measurement</th>
<th>Milestone Date</th>
<th>Consequence</th>
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</thead>
<tbody>
<tr>
<td>Insert text locally</td>
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</tbody>
</table>
D. Incidents Requiring Reporting Procedure

<table>
<thead>
<tr>
<th>Procedure(s) for reporting, investigating, and implementing and sharing lessons learned from:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Serious Incidents</td>
</tr>
<tr>
<td>(2) Reportable Patient Safety Incidents</td>
</tr>
<tr>
<td>(3) Other Patient Safety Incidents</td>
</tr>
</tbody>
</table>
### E. Service Development and Improvement Plan

<table>
<thead>
<tr>
<th>Milestones</th>
<th>Timescales</th>
<th>Expected Benefit</th>
<th>Consequence of Achievement/Breach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insert text locally</td>
<td></td>
<td></td>
<td>[Subject to General Condition 9 (Contract Management)] or [locally agreed]</td>
</tr>
<tr>
<td>Type of Survey</td>
<td>Frequency</td>
<td>Method of Reporting</td>
<td>Method of Publication</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>----------------------------------------</td>
<td>----------------------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Friends and Family Test</td>
<td>As required by FFT Guidance</td>
<td>As required by FFT Guidance</td>
<td>As required by FFT Guidance</td>
</tr>
<tr>
<td>(where required in accordance with FFT Guidance)</td>
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<td></td>
</tr>
<tr>
<td>Service User Survey</td>
<td></td>
<td></td>
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<tr>
<td>Insert further description locally</td>
<td></td>
<td></td>
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<tr>
<td>Staff Surveys</td>
<td>NHS Staff Survey: where required by Guidance</td>
<td>NHS Staff Survey: where required by Guidance</td>
<td>NHS Staff Survey: where required by Guidance</td>
</tr>
<tr>
<td>Insert further description locally</td>
<td>Other</td>
<td>Other</td>
<td>Other</td>
</tr>
<tr>
<td>Carer Survey</td>
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<td></td>
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</tr>
<tr>
<td>Insert further description locally</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other insert locally</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 1: Merton CCG Criteria for Access to Intrauterine Insemination (IUI), In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI)

Refer to CCG Assisted Conception and Pre implantation Genetic Diagnosis Policy 2014/15

Appendix 2: Glossary of Terms

Assisted conception
The name for treatments that enable people to conceive by means other than sexual intercourse. Assisted reproduction techniques include intra-uterine insemination (IUI), in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI), donor insemination and egg donation.

Azoospermia
When a man has no sperm in his semen.
**Chromosome**
A structure found in cells that contains a person’s genetic information in the form of genes.

**Cryopreservation**
The freezing of eggs, sperm and/or embryos that may be thawed for use in future IVF treatment cycles.

**Cryostorage**
The storage of frozen eggs, sperm and/or embryos that may be thawed for use in future IVF treatment cycles.

**Donor insemination**
The placing of donor sperm into a woman’s womb.

**Egg**
The female reproductive sperm. A woman usually produces one egg in a normal monthly cycle.

**Egg collection**
A procedure by which a woman’s eggs are collected from her ovaries, usually using a needle guided by ultrasound. Also known as egg retrieval.

**Egg donation**
The process by which a fertile woman donates her eggs for use in the treatment of other women or for use in research.

**Embryo transfer**
Transfer of one or two embryos into the womb as part of IVF.

**Endometriosis**
A condition where cells like those in the lining of the womb are found in other areas of a woman’s pelvis, usually causing pain and damage.

**Epididymis**
A structure within the scrotum that is attached to the back side of the testis. The epididymis is a coiled segment of the spermatic ducts that stores spermatozoa while they mature and then transports the spermatozoa between the testis and the tube connecting the testes with the urethra (vas deferens).

**Fertilisation**
When a sperm penetrates an egg and forms an embryo. Natural fertilisation takes place in a woman’s fallopian tubes, but fertilisation can also be done in the laboratory for IVF.

**Follicle-stimulating hormone (FSH)**
A hormone produced by the pituitary gland which stimulates the ovaries to produce follicles. It can be used as part of ovulation induction therapy.

**Implantation**
The process by which an embryo attaches to the lining of the womb.

**In vitro fertilisation (IVF)**
A technique by which eggs are collected from a woman and fertilised with a man’s sperm outside the body. Usually one or two resulting embryos are then transferred to the womb. If one of them attaches successfully, it results in a pregnancy.

**Insemination**
A technique to place sperm into a woman’s vagina or womb.

**Intracytoplasmic sperm injection (ICSI)**
A variation of IVF in which a single sperm is injected into an egg.

**Intra-uterine insemination (IUI)**
A technique to place sperm into a woman's womb through the cervix.

**Ovaries**
A pair of organs in women which produce follicles and eggs

**Ovulation**
The process by which the ovaries produce eggs. If you have periods every 28 days you should be ovulating around day 14 or 2 weeks after the first day of your period.

**Ovulation induction**
A course of fertility drugs used to control and/or stimulate a woman's ovulation.

**Rhesus isoimmunisation**
This occurs when there is an incompatibility between an infant's blood type and that of its mother, resulting in destruction of the infant's red blood cells (hemolytic anemia) during pregnancy and after birth by antibodies from its mother's blood.
(Source: http://www.moondragon.org/obgyn/pregnancy/rhisoimmune.html)

**Semen**
The fluid containing sperm and secretions that is expelled in an ejaculation.

**Sperm**
The male reproductive cell produced by men, usually through ejaculation, which fertilises a woman's eggs. Men usually have millions of sperm in their semen.

**Sperm recovery**
A surgical procedure to obtain sperm from the testicles in men who cannot ejaculate or have a blockage in the flow of sperm from their testicles.

**Stimulated cycle**
A round of treatment in which drugs are used to make the woman's ovaries produce more eggs than usual in a monthly cycle.

**Teratogenic**
Causing harm or disturbing the development of the embryo or foetus

**Unexplained fertility problems**
Problems for which no reason can be found.

**Unstimulated cycle**
A woman's natural cycle. A cycle where no drugs are used to stimulate egg production.

---

**Appendix 3**

**Action in the event of an IVF/ICSI treatment cycle not reaching embryo transfer**
A “non-abandoned” cycle of IVF/ICSI is one where one or more embryos resulting from treatment are transferred to the uterus. An “abandoned” cycle is one which does not reach the stage of embryo transfer.
If a cycle is abandoned further action should depend on the clinical circumstances and the reason for abandoning the cycle. If the cycle was abandoned due to predictable, non-correctable factor, further treatment should NOT be offered as it has a low likelihood of success. Where there is a non-predictable or correctable cause, further attempts should be made to achieve a completed cycle of treatment.

1. Cycle cancelled owing to poor ovarian response on maximal gonadotrophin stimulation (ie 450 iu FSH daily): No further treatment, as high likelihood of failure in subsequent cycles.

2. Cycle cancelled due to poor ovarian response on less than maximal gonadotrophin stimulation: Further attempts using maximal stimulation, provided repeat Day 2 FSH is within the criteria (<8.9 iu/l)

3. Cycle cancelled due to excessive ovarian response and no eggs retrieved: Further attempts with lower dose of gonadotrophin


5. Cycle cancelled due to failure of fertilisation at standard IVF: Further attempts using ICSI


7. Cycle cancelled due to incident clinical factor coming to light during treatment (e.g. hydrosalpinx or endometrioma): Further attempts after correcting the abnormality.

8. “Exceptional” reasons (e.g. death in family): individualise on a case by case basis.

**Categories of abandoned cycles:** Abandoned cycles fall into three categories.
1. Abandoned cycles before attempted egg retrieval:
2. Abandoned cycles after unsuccessful egg retrieval attempt:
3. Abandoned cycles after successful egg retrieval (+/-embryo creation)

---

Appendix4
REFERRAL PATHWAY FOR SPECIALIST FERTILITY TREATMENT

Level 1 Care
Attend GP with a fertility problem

Level 2 Care
Referred by GP to Consultant led fertility clinic

Level 3 Care
Referred by consultant from secondary provider to centre for assisted conception

Initial investigation & management by primary care team
- Confirm the couple’s health status is appropriate for conception
  - Confirm ovulation
  - Semen analysis
  - Lifestyle support & advice

Further investigation & management by specialist & secondary provider unit
- Tubal patency
- Ovulation induction with clomiphene
- Surgical treatments
- Semen analysis

Tertiary referral centre commissioned by EOESCG
- Assisted conception techniques IVF/ICCSI/IUI
- Donor insemination
- TESE, MESA, PESA
- Egg, sperm, embryo & gonadal cryostorage & replacement techniques
- Egg donation where no other treatment is available

Appendix 5
### Activity Performance indicators (98% completion expected)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Month actuals</th>
<th>Month actuals</th>
<th>Month actuals</th>
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</thead>
<tbody>
<tr>
<td>Number of service users treated in the 18 week pathway</td>
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<td></td>
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</tr>
<tr>
<td>Number of service users treated outside 18 week pathway</td>
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</tr>
<tr>
<td>Number of weeks service user waited for first outpatient attendance</td>
<td></td>
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<tr>
<td>Number of service users seen for first outpatient attendance within 6 weeks.</td>
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<tr>
<td>Number of service users who have commenced first cycle treatment within 6 weeks of first outpatient appointment</td>
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<tr>
<td>Total number of couples referred</td>
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<tr>
<td>Total numbers of couples seen</td>
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<tr>
<td>Total number of couples treated</td>
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<tr>
<td>Live birth rate per embryo transfer treatment cycle</td>
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<tr>
<td>Twin clinical pregnancy rate</td>
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<tr>
<td>Total number of readmissions within 30 days of initial clinical operative procedure as a result of other adverse outcomes</td>
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<tr>
<td>Ectopic pregnancies per treatment</td>
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<tr>
<td>Clinical pregnancy rate per embryo transfer</td>
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### Number of procedures

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<td>ICSI - With drugs</td>
<td>23-24</td>
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<tr>
<td>IUI Cycle in addition to IVF/ICSI</td>
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<td>25-29</td>
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</tr>
<tr>
<td>IVF - With drugs</td>
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<td>30-35...</td>
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<tr>
<td>Embryo Freezing additional</td>
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<tr>
<td>Full Embryo Transfer (FET) additional</td>
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<tr>
<td>Sperm aspiration additional</td>
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<tr>
<td>Donor Sperm additional</td>
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### Referrals and live birth rates

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<tr>
<th>Referral rates per GP</th>
<th>Month actuals</th>
<th>Month actuals</th>
<th>Month actuals</th>
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<td>Alexandra Road</td>
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<td>Cannon Hill Lane</td>
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<td>Church Lane Practice</td>
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<tr>
<td>Colliers Wood Surgery</td>
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<tr>
<td>Cricket Green Medical Practice</td>
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<tr>
<td>Francis Grove Surgery</td>
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<tr>
<td>Freeman &amp; Partners</td>
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<td></td>
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<tr>
<td>Graham Road Surgery</td>
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<tr>
<td>Grand Drive Surgery</td>
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<td></td>
<td></td>
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<tr>
<td>Merton Medical Practice</td>
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<td>Mitcham Medical Centre</td>
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<td>Morden Hall Medical Centre</td>
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<tr>
<td>Pepys Road Surgery</td>
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<tr>
<td>Princes Road Surgery</td>
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<td></td>
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<tr>
<td>Riverhouse Medical Practice</td>
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<tr>
<td>Rowans Surgery</td>
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<tr>
<td>Tamworth House Medical Centre</td>
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<td>Wideway Medical Centre</td>
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### 2014/15 NHS STANDARD CONTRACT PARTICULARS

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<th>Month</th>
<th>Month</th>
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<tbody>
<tr>
<td>Patient 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality requirements</th>
<th>Target</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>HFEA service user questionnaire completed</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>40% or higher live birth rate for women aged up to 37%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>20% or higher live birth rate for women aged between 38 and 40 years</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>10% or higher live birth rate for women aged between 40 and 42 years</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Reduce total number of multiple births to 10%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>All service user information to be referenced by the users nhs number and GP</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>