Accredited Providers Service Specification
1st April 2018 – 31st March 2019

for the delivery of

Long-acting Reversible Contraception Services

Service	Long-acting Reversible Contraception Service
Primary Contractor Lead	Rebecca Spencer – General Manager, Integrated Sexual Health Services, Derbyshire Community Health Services NHS Foundation Trust
Subcontractor Lead	GP Practices (Accredited Providers)
Period	1st April 2018 – 31st March 2019
Version	Version 2
Supporting / Additional Documentation	Appendix A Training requirements – Subdermal implants Appendix B Training requirements – Intrauterine techniques Appendix C LARC selection Appendix D Derbyshire pathway Appendix E Prices and payment process Appendix F Agreement to provide LARC service **(to complete and return)** Appendix G. Evidence of competence to deliver service **(to complete and retain at Practice)** Appendix H Glossary of terms and abbreviations Appendix I Data protection protocol Appendix J Information and data provisions

1. Purpose

1.1 Aims and Objectives

This specification for the fitting, monitoring, checking and removal of intrauterine devices (IUDs), intrauterine systems (IUSs) and contraceptive implants collectively known as long acting reversible contraception (LARC) is designed to:

- Ensure good access to and availability of IUDs/IUSs and contraceptive implants through primary care, as part of a range of contraceptive options offered by the practice
- Promote IUDs/IUSs and contraceptive implants as effective methods of long-acting reversible contraception
- Increase uptake and on-going use of IUDs/IUSs and contraceptive implants and thereby contribute to reducing unintended pregnancies and particularly teenage pregnancies
- Ensure the availability of post-coital fitting of copper bearing IUDs for emergency contraception as another means of reducing unwanted pregnancies.

The objectives of this service are to:

- Provide accessible IUD/IUS and contraceptive implant insertion and removal service in general practice as part of a range of contraception choices for women. This specification excludes the use of IUS activity in response to a clinical need to manage heavy menstrual bleeding (HMB) and / or HRT conditions (see Section 4.6 Exclusion Criteria), even if the woman may also receive contraceptive benefit; this group have other clinical needs which might require specialist investigation and input. Provision of injectable contraception is excluded from this specification.
- Raise awareness of the benefits of IUDs, IUSs and contraceptive implants by providing high quality advice, support and information on the full range of contraception methods to all women on or seeking contraception, and particularly to women aged under 25.
- Where appropriate, to promote and facilitate urgent signposting to another GP practice or clinic in the Derbyshire Integrated Sexual Health Services network for accessible and timely post-coital fitting for emergency contraception http://www.yoursexualhealthmatters.org.uk/ or 0800 3283383

1.2 National / Local Context and Evidence Base

The Department of Health's strategy for public health includes the aim of improving access to confidential, non-judgemental sexual health services, including contraception services.

The evidence clearly demonstrates that:

- GP practices are a major source of contraception advice and provision
- Approximately 30% of all pregnancies are unplanned and the majority of teenage pregnancies are unplanned
- Of all teenagers who conceive around 50% lead to terminations. The use of LARC reduces repeat terminations.
- All women seeking contraception should be offered an informed choice and access to LARC methods
- All LARC methods are more reliable than the oral contraceptive pill, where user error often results in unplanned pregnancy. Failure due to inconsistent use of oral contraception and condoms is the main cause of pregnancy among women undergoing termination
- All currently available LARC methods (intrauterine devices [IUDs], the intrauterine system [IUS], injectable contraceptives and implants) are more cost effective than the combined oral contraceptive pill even at 1 year of use. Implants are more cost effective than LARC injectable contraceptives

- Increasing the uptake of LARC methods will reduce the number of unintended pregnancies
- LARC prescribing is increasing locally and nationally and provision via GP practices has significantly contributed to this increased use of LARC
- Contraceptive implants and IUD/IUS provide excellent contraceptive protection over a long period
- Both IUD / IUS and implant provision have relatively high levels of litigation. The most important factor influencing the incidence of problems relating to insertion and removal is the competence of the professional inserting / removing the device
- High quality information and advice influences client satisfaction and continuation rates with long-acting methods of contraception
- The quality of information about contraception choices provided by GP practices is a key determinant of whether young women choose LARC methods
- Public Health England's *Sexual and Reproductive Health Profiles* provide comparative data across a broad range of sexual health indicators. In general, Derbyshire has better sexual health than the population of the country as a whole, but inequalities in sexual health outcomes persist (e.g. high teenage pregnancy rates in some areas of the county), and variation in rates of sexually transmitted infections (STIs) by small area and reflective of the national picture in terms of high risk groups (men who have sex with men, young people, vulnerable young people).

LARC provision across Derbyshire is significantly better than the England average: in 2016 the rate of GP prescribed LARC excluding injections was 42.4 per 1000 females compared to 28.8 per 1000 in England. Delivery of LARC within sexual health clinics in the community shows an increasing trend similar to the England trend; uptake in Derbyshire in 2016 was 19.9 per 1000 compared to the England rate of 17.6 per 1000.

The Department of Health's *Public Health Outcomes Framework* incorporates a key outcome indicator on "under 18 conceptions". The delivery of this service specification is a key intervention to achieve progressing reducing teenage conceptions, and the continuing downward trend both nationally and locally is likely to be directly related to the increasing trend in LARC provision.

The provision of contraception to sexually active women should be in the context of promoting good sexual health, including the prevention of STIs. NICE review of the surveillance published in October 2017 advises healthcare professionals providing contraceptive advice should be able to assess risk for sexually transmitted infections (STIs) and advise testing when appropriate. Healthcare professionals should be able to provide information about local services for STI screening, investigation and treatment. For sexually active women under 25 years of age, any contraception review should include the routine offer of a chlamydia screening test. This will support delivery of the chlamydia diagnosis rate target. In Derbyshire, this could be in the form of signposting to Integrated Sexual Health Services or signposting to the online testing both for all STI tests and Chlamydia tests.

1.3 General Overview

In April 2015 Derbyshire County Council commissioned DCHS to provide an 'Integrated Sexual Health Service' ('Your Sexual Health Matters') to enable more strategic planning of locations and accessibility of services, and to reduce sexual health inequalities by providing an equitable service to Derbyshire residents facilitating prompt access in line with need. Since that date, GP practices have become Accredited Providers of the LARC service via subcontract to DCHS (the Primary Contractor).

The LARC service includes the provision, fitting, checking, monitoring, management and removal of IUDs/IUSs licensed for use in the UK to women for contraception or IUD for emergency contraception as appropriate, and contraceptive implants licensed for use in the UK

(Nexplanon®) to women who choose this method of contraception as the most acceptable to them, provided that it is not contraindicated. The service also includes the on-going management of contraceptive IUD / IUS and implants.

The practice offers and provides IUDs / IUSs and contraceptive implants, as part of a range of contraception choices, to women registered with the practice and where applicable, to women registered with other practices through collaborative agreements.

1.4 Expected Outcomes

It is expected that the enhanced service for IUDs/IUSs and contraceptive implants will contribute to:

- Increased LARC uptake and continued use, particularly in under 25s
- A reduction in the number of unplanned pregnancies
- A reduction in the under 18 conception rate
- A reduction in the number of terminations of unplanned pregnancies and repeat terminations
- Provide or advise on STI testing or signpost to: https://www.yoursexualhealthmatters.org.uk/ for online or face-to-face testing
- Advise under 25s on chlamydia testing via: https://www.yoursexualhealthmatters.org.uk/ this service will also contribute to increasing the chlamydia diagnosis rate.

2. Scope

2.1 Service Description

This service specification covers the following:

2.1.1. Fitting, monitoring, checking and removal of IUDs/IUS and contraceptive implants in line with current guidelines on best practice (e.g. NICE guidance on LARC, Faculty of Sexual and Reproductive Healthcare). All IUCDs/IUS and implants must be licensed for use in the UK i.e. Nexplanon®. Fitting, monitoring and removal should be in line with the most uptodate Faculty of Reproductive and Sexual Health guidelines and Summary of Product Characteristics guidelines

2.1.2 Fitting of copper bearing IUDs for emergency contraception, within 5 days (120 hours) from the first unprotected sexual intercourse at any time in the cycle or up to 5 days after the expected date of ovulation in a regular cycle, provided that it is not contraindicated. If the patient is not having a copper coil for emergency contraception, and has OEC with Levonelle, consider quick starting contraception with implant as a LARC as per the faculty guidance.

2.1.3 Maintenance of an up-to-date practice contraception register including all patients fitted with either an IUD/IUS or a contraceptive implant. This will include sufficient data to be able to report against the KPIs specified in Section 7, including the type of device fitted, the batch number and expiry date, the name and designation of the person completing the procedure, along with the fields in the table below This is to be used for audit purposes and to enable the Public Health team to target these patients for healthcare checks.

Field	Categories
Age	• Under 16 • 16-17 • 18-24

	• 25-44 • 45-54 • 55+
Partial postcode (minus last 2 digits)	• Free text (in postcode format) • Postcode unknown / not given
Activity provided by GP / nurse	• Inserts implant and manages pathway • Inserts IUD and manages pathway • Inserts IUS and manages pathway • Removes implant/IUD/IUS
	•
Which type of IUD/IUS device was inserted?	• Name of the device / batch number / expiry date
If the patient has an implant / IUD / IUS removed, how long was this in-situ for?	• Less than 3 months • 3 months or more
Was this information "patient reported" or obtained from GP records?	• Patient reported • GP records
GP Practice Name	
GP Practice Address where the service was provided	
Date procedure took place	
GMC / NMC number of the clinician who carried out the procedure	
GP / nurse has current LOC SDI and intrauterine technique	

2.1.4 Sexual history taking. Assessment in terms of suitability and specifically patients to be excluded from the service, to ensure that either the IUD/IUS or the contraceptive implant is the most appropriate method of contraception based on medical evidence, clinical guidelines (http://www.nice.org.uk/CG30), sexual history and practice.

2.1.5 Risk assessment. Based on sexual history to assess the need for testing for STIs, including HIV, prior to recommending either the IUD/IUS or the contraceptive implant. This should ideally include an offer of chlamydia screening to 15 to 24 year olds as part of the National Chlamydia Screening Programme.

STI testing for contraception patient should be offered (STI tests can be requested by patient online via http://www.yoursexualhealthmatters.org.uk) and signposting to Sexual Health services.

2.1.6 C-Card. C-Card scheme is a community-based condom distribution scheme, which provides confidential access to free condoms, lube and dams, as well as sexual health advice and support to young people aged 13-24. Promotion and/or provision of condoms to prevent infection, and public health information on safer sex including signposting to the Derbyshire C-Card scheme for 13 - 24 year olds: http://www.yoursexualhealthmatters.org.uk or 0800 3283383

2.1.7 Patient information. Patient information leaflets should be provided at the time of counselling and reinforced after fitting with information about signs and symptoms that require urgent assessment, non-contraceptive benefits, procedures for initiation and discontinuation. Women should be given verbal and written details about the lifespan of the IUD/IUS or the implant, side-effects and effectiveness in a format appropriate to their needs. The patient's understanding of either the IUD/IUS or the contraceptive implant should be checked prior to fitting; consider use of interpreter services as required (see Section 2.2).

2.1.8 Consent. The clinician will ensure the process for obtaining informed patient consent is in line with Department of Health guidance:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf

2.1.9 Assessment and follow up

IUD/IUS: A routine follow up is not required except for IUDs fitted for emergency contraception to check for pregnancy. The need for additional protection at the time of starting LARC should be addressed and at the time of fit, thread check should be explained and demonstrated. Signs and symptoms requiring attention to be explained. Routine annual checks are not required. Arrangements should be in place to review clients experiencing problems in a timely fashion and to provide information and treatment to manage common side effects and problems, in line with NICE guidelines and current best practice. Arrangements should be in place to ensure timely access for women requesting removal of the device for any reason including problems or at expiry of the device. The IUD should be removed or replaced after between five and ten years, depending on the device, age of the patient and reason for fitting/removal. Any copper containing IUD fitted over the age of 40 can stay in until menopause. IUDs fitted for emergency contraception can be removed at/after the next normal period if the woman does not wish to consider long term use and options for future contraception should be discussed.

Implant: The need for additional protection at the time of starting LARC should be addressed. Routine annual checks are not required; however arrangements should be in place to review clients experiencing problems in a timely fashion and to provide information and treatment to manage common side effects and problems, in line with NICE guidelines and current best practice. Arrangements should be in place to ensure timely access for women requesting removal of the implant for any reason including problems or at expiry of device. The implant should be removed or replaced within three years.

2.1.10 Record keeping. Production of an appropriate clinical record, either via paper based or electronic clinical systems using appropriate Read codes where these exist. Adequate recording should be made, to include the data fields in the table in section 2.1.3 to ensure reporting at patient level and compliance with the KPIs, along with the following:

- the patient's name/NHS number/date of birth/sex
- the patient's clinical, reproductive and sexual history
- the counselling process and documentation of consent (written/verbal)
- the results of any STI testing
- any contraindications
- the site of insertion for implant
- reason for fitting IUD/IUS
- problems with insertion/removal
- the type and batch number of the IUD/IUS or implant
- expiry date of the device and follow-up arrangements
- any adverse reactions
- name and designation of person(s) completing the procedure
- referring practice if applicable

As Accredited Providers, practices are required to submit patient level anonymised data to DCHS for the purposes of monitoring, audit and payment claims. This data needs to be submitted monthly via the online Accredited Providers Activity and Payment System (see Section 9). Payment can only be made by DCHS upon receipt of this data which is a requirement specified by DCC (the Commissioner) in the overarching contract with DCHS.

If the patient is not registered with the Accredited Provider, the practice must ensure that the patient's registered practice is given all appropriate clinical details for inclusion into the patient's notes, unless the patient withholds consent to inform her GP.

Full records of all procedures should be maintained in such a way that aggregated data and

details of individual patients are readily accessible if requested by the Commissioner.

2.1.11 Provision of adequate equipment. Certain special equipment is required for both IUD/IUS and implant fitting and removal. This includes an appropriate room fitted with an examination couch and with adequate space and equipment for resuscitation.

For IUD/IUS a variety of vaginal specula, cervical dilators, allis and vulsellum forceps and equipment for cervical anaesthesia also need to be available. An appropriately trained assistant also needs to be present to support the patient and assist the clinician during the procedure.

For implant a variety of artery/vasectomy forceps and facility for local anaesthesia provision also need to be available.

2.1.12 Sterilisation and infection prevention and control. Although LARC minor surgery has a low incidence of complications, it is important that practices providing the procedures listed in this specification operate to the highest possible standards. Practices must use one of the following arrangements for sterilisation:

- disposable sterile instruments
- sterile packs from a local central sterile supply department
- approved sterilisation procedures that comply with national guidelines (e.g. Medical Devices Directive MDD/93/42/EEC), which will include, at a minimum, validated and automated cleaning and sterilisation and traceability.

Where local reprocessing of instruments is undertaken, GPs are responsible for the effective operation and maintenance of sterilising equipment in their practices. Bench top sterilisers and washer disinfectors must comply with Medicines and Healthcare products Regulatory Agency (MRHA) publications, and be appropriately validated / maintained by staff trained in their usage.

Practices must have infection control policies that are compliant with national guidelines including the handling of used instruments, aseptic technique and the disposal of clinical waste.

2.1.13 Clinical skills and competencies. As Accredited Providers, practices providing services under this specification will be expected to ensure that all clinicians (partners, employees, sub-contractors) carrying out the fitting and removal of IUDs, IUSs and implants are appropriately trained and qualified to do so (see Section 5 Workforce/Staffing).

2.1.14 Prescribing. Practices providing this service will take clinical responsibility for prescribing the required IUD/IUS or implants.

2.1.15 General
Information may also be required where not specified in this service specification, including issues based on principles and arrangements of clinical governance or best value and will be negotiated if and when they arise.

2.2 Accessibility / Acceptability

The LARC service increases access to contraceptive choice as a specialised service in addition to those contraceptive services provided by all practices as essential services.

The Accredited Provider must ensure that the service offered is accessible to all, sensitive to the needs of individual patients, and respects the relevant 'protected characteristics' specified in the Equality Act 2010 (age, disability, marriage and civil partnership, race, religion or belief, sexual orientation).

DCHS will provide access to a telephone translation service to ensure that non-English speaking women are able to access the same high level of service as described above.
The telephone service will be accessed using a unique PIN supplied by DCHS. The service is

provided under contract with Capita and the PIN will only be used to support the delivery of LARC and signposting to 'Your Sexual Health Matters' (see below). Use of the PIN will be audited and any use of the PIN outside of this service may incur a charge.

2.3 Whole System Relationships

The Accredited Provider should be aware of the importance of effective partnership working with other providers and stakeholders within the wider Derbyshire and Derby City sexual health network – known as 'Your Sexual Health Matters' (YSHM) - to facilitate access from and to this local specialised service. These include:

- DCHS (Primary Contractor of 'YSHM') http://www.yoursexualhealthmatters.org.uk/ including sexual health clinics and Young People's Sexual Health Services
- Other GP practices
- Pharmacies
- School Nursing service
- Antenatal services
- Midwifery services
- Termination of pregnancy services
- East Midlands Sexual Assault Service (EMSAS)
- Child and Adolescent Mental Health Services (CAMHS), Young Persons Specialist Support Services (YPSS) and adult psychiatric services
- Interpreter services
- Social care
- Youth services
- Family Nurse Partnership
- Health Visiting service
- Voluntary services

The list is not exhaustive.

The Accredited Provider should support the objectives of local Teenage Pregnancy Partnerships and Children's Centres.

For details of how to access to local services, such as C-Card, please signpost patients to http://www.yoursexualhealthmatters.org.uk/

2.4 Interdependencies

Key interdependencies exists with:

- Pharmacies for supply of contraception implants
- Clinical appraisal processes and training providers to support development and verification of skills and competencies
- ISHS to maintain skills and required numbers annually and 5 yearly to maintain revalidation

The service is underpinned by local safeguarding and vulnerable adult protection procedures (see Section 3.3.1).

The service provider should support the objectives of local sexual health networks, the National Chlamydia Screening Programme, local Teenage Pregnancy Partnerships or equivalent, Family Nurse Partnership and Children's Centres.

2.5 Relevant Networks and Screening Programmes

- National Chlamydia Screening Programme

- Derbyshire C-Card Scheme
- National Cervical Screening Programme
- Your Sexual Health Matters (see Section 2.3) – advice and support including relationships, sexuality, sex, contraception (including emergency contraception) and STIs.
- HIV prevention and increasing awareness

2.6 Service User and Carer Involvement

Consultation with service users regarding satisfaction with treatment services will be carried out on a regular basis. A strategy for patient involvement in monitoring and developing services will be implemented locally. Feedback will be gathered in a way that engages a wide range and diversity of patients and their carers.

2.7 Subcontractors

- No General Practitioner or Nurse will provide LARC on behalf of the General Practice signing up to this specification unless they have signed Appendix G (which is to be retained at the General Practice), and are deemed competent to deliver the service, in advance of any service provision. This will include all locums.
- No subcontractors will provide any element of this service unless agreed in writing by DCHS prior to the subcontractor starting work.

3. Service Delivery

3.1 Service Model / Care Pathways

The service will be delivered in GP practice premises in line with the Derbyshire Pathway (Appendix D) and NICE guideline (CG30). The LARC selection algorithm for the effective and appropriate use of long acting reversible contraception in NICE CG30 is shown in Appendix B.

3.2 Applicable National Standards

The practice must be compliant with the Care Quality Commission regulations for service providers and managers http://www.cqc.org.uk/content/regulations-service-providers-and-managers

The practice must ensure that they contribute to the wider patient safety agenda including, but not exclusively, the control of infection agenda and the identification, reporting and investigation of incidents and complaints. Where a complaint relates to the delivery of LARC under this contract, pharmacies will be required to inform DCHS of the complaint and the outcome of the investigation. Participation in clinical audit and implementation of changes arising from audits should take place. The service should be able to demonstrate learning and improvement across the quality agenda and in response to local and/or national policy guidance.

It is the responsibility of the practice to:

- Continually improve the quality of service delivery, for example, in response to audit (undertaking and completing the audit cycle), user and staff feedback (complaints, compliments, suggestions) and incidents.
- Continually review and be aware of relevant new and emerging guidance and recommendations and take the appropriate steps to assess and improve services to

achieve current best practice.
- Ensure that appropriate professional standards are maintained, updated and validated through clinical supervision and provision of relevant training to support reflective practice and CPD.
- During the term of this specification fully co-operate in reviewing and improving/re-designing services at the request of DCHS, to include improving quality and performance monitoring.

Accredited Providers must ensure that they adhere to all relevant legislation and best practice including but not exclusively:

- *Long-acting reversible contraception - the effective and appropriate use of long-acting reversible contraception* (NICE CG30, 2005 updated in 2013) https://www.nice.org.uk/guidance/cg30/evidence/full-guideline-194840605
- Nexplanon® Summary of Product Characteristics guidelines
- Faculty of sexual and reproductive- clinical guidance – Progesterone only implant
- *Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health* (DH,2004) Gateway reference3382,
- *Service Standards for Sexual and Reproductive Healthcare* (FSRH, 2013) http://www.fsrh.org/pdfs/ServiceStandardsSexualReproductiveHealthcare.pdf
- Mental Capacity Act 2005 http://www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1
- All current and new equality legislation as it becomes statute and actively meets the requirements of the Public Sector Equality Duty covering race, disability and gender http://www.equalityhumanrights.com/private-and-public-sector-guidance/public-sector-providers/public-sector-equality-duty
- Data Protection Legislation, including General Data Protection Regulations (GDPR). Please see Appendices J and K
- Compliance with the documents which set out the pre-appointment checks that are required by Law, those that are mandated by any Regulatory Body policy, and those that are required for access to the NHS Care Records Services and include: verification or identity checks right to work checks, registration and qualification checks, employment history and reference checks, criminal record checks and occupational health checks.
- Accredited Providers must notify DCHS at dchst.derbyshireishs.ap@nhs.net of any breaches of Applicable National Standards.

3.3 Applicable Local Standards

3.3.1 Safeguarding Accredited Providers must ensure that they adhere to applicable local standards including but not exclusively:

- The Derby and Derbyshire Safeguarding Children Procedures http://derbyshirescbs.proceduresonline.com/
- **If you are concerned that a child is suffering or is at risk of significant harm please contact Starting Point on 01629 533190 immediately**.
- To request early help services for Derbyshire children and young people please complete the Starting Point referral form: https://www.derbyshire.gov.uk/social_health/children_and_families/support_for_families/Starting_point_referral_form/default.asp
- Derbyshire and Derby Safeguarding Adults Protection Policy and Procedures https://www.saferderbyshire.gov.uk/site-elements/documents/pdf/safeguarding-adults-policy-and-procedure.pdf

This should include understanding safeguarding referral procedures and referral pathways to social care.

Clinicians will need to share relevant information with other healthcare professionals and agencies, in line with locally determined confidentiality arrangements, including, where appropriate, the need for the permission of the patient to share the information. This will include concerns regarding Child Sexual Exploitation (CSE) and Female Genital Mutilation (FGM).

3.3.2 Clinical and Corporate Governance It is a condition of delivery of this specification that practices will give notification, in addition to their statutory obligations, within 72 hours of the information becoming known to them, to DCHS (see below) of all emergency admissions or harm/potential harm to patients under this service, where such events may be due to the LARC device or attributable to the relevant underlying medical condition using the NHS's 'General Practice Patient Safety Incident Report Form' . This must be scanned and emailed to the DCHS Head of Patient Safety and Risk Management adelle.clements@nhs.net and dchst.derbyshireishs.ap@nhs.net

Accredited Providers must notify DCHS at dchst.derbyshireishs.ap@nhs.net of any breaches of Applicable Local Standards.

4. Referral, Access and Acceptance Criteria

4.1 Geographic Coverage / Boundaries

This specification covers GP practices contracted by NHS England for residents of Derbyshire County wishing to provide an IUD/IUS or contraceptive implant service to their own patients, as well as those wishing to provide a service to patients who are registered with other practices who are contracted to provide services for Derbyshire residents.

4.2 Location(s) of Service Delivery

The service will be delivered in GP practice premises (including branch surgeries) which are as accessible as reasonably possible and compliant with Health and Safety legislation.

4.3 Days / Hours of Operation

The service will be offered within the normal hours of operation of the practice.

4.4 Referral Criteria & Sources

Those wishing to provide a service to patients who are registered with other practices must have in place auditable processes and written procedures to ensure timely responses to referrals and effective reporting.

4.5 Referral Route

The service will be available to women who request contraception and who choose either an IUCD/IUS or a contraceptive implant as the most acceptable method for them, provided that it is not contraindicated.

4.6 Exclusion Criteria

This specification excludes the provision of IUS (Mirena/Levosert) in response to a clinical diagnosis such as HMB / Menorrhagia or HRT, even if the patient may receive contraceptive

benefit. These women should be appropriately investigated and should have the fit done. This fit is NOT included under the LARC specification 2018. Also women for whom the contraception implant is contraindicated will be excluded from the service. Such women must be offered a choice of alternative suitable methods of contraception.

4.7 Equality Issues (EIRA)

It is the responsibility of the Accredited Provider to comply with all current (and all future) equality legislation and actively meet the requirements of the Public Sector Equality Duty covering the protected characteristics of age, disability, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.

The requirements include taking action to:

- Eliminate discrimination, harassment or bullying
- Promote equality of access to services and employment opportunities
- Ensure effective data capture and analysis of service provision
- Conduct Equality Impact Assessments (EIAs) on policies, procedures and services to ensure that there is no unlawful discrimination against those with one or more protected characteristics and that equality, diversity, inclusion and Human Rights are actively promoted.

It is recommended that Accredited Providers have a clear published plan of action to achieve the requirements of these equality duties.

An EIA must be undertaken and documented as part of any service review process or if any change is being proposed or made to the provision of the LARC service which could impact (either negatively or positively) on those in receipt of the service.

All staff involved with the delivery of this service will recognise and respect the identity and religious, cultural and social backgrounds of all service users in accordance with the DCHE Way values, good equalities practice and equalities legislation.

5. Workforce / Staffing

5.1 Accreditation, CPD and Activity

Doctors and nurses fitting IUDs/IUSs and implants will have completed the relevant Faculty of Sexual and Reproductive Healthcare Letter of Competence in Intrauterine Techniques and / or Subdermal Contraceptive Implant Techniques. For further information see http://www.fsrh.org/pages/Training.asp

Established fitters will need to have maintained their competencies in accordance with FSRH recommendations. Practitioners who hold other qualifications should contact the local Faculty approved General Training Programme Directors for advice – please email dchst.derbyshireishs.ap@nhs.net

5.2 Appraisal

At appraisal clinicians are expected to demonstrate evidence of CPD and activity for either IUD / IUS and / or implant fitting and removal as specified in Appendix A and Appendix B and have logbooks available for review. Logbooks can be asked for by any member of DCHS at any point

and must be produced. Failure to do so will result in ability to fit and remove IUDs, IUSs and implants under this specification being removed.

Serious adverse events analysis relating to either IUD / IUS or implant procedures should be considered, as with other procedures, as part of the general appraisal process.

5.3 Maintaining Competence

Each practitioner providing the LARC service within the practice is required to adhere to the number of procedures required to maintain competence as per the FSRH and NICE guidelines. If a practitioner falls below the threshold as per Faculty guidelines in two consecutive years they will cease to be accredited by DCHS to perform the procedure without evidence of retraining. Practitioners need to be up to date with current local safeguarding policies and procedures (see Section 3.3.1).

5.4 Practice Responsibilities

On signing this contract, practices as Accredited Providers are confirming to DCHS that all clinicians (including sessional, salaried and non-core clinical staff) who undertake either IUD/IUS or implant procedures over the life of this contract:

- Meet the minimum qualification requirements and
- Meet the minimum CPD and activity requirements according to FSRH and NICE guidelines

The practice will keep an up to date register of all clinicians who deliver the service, in such a way as to be able to provide audit data to DCHS on skills and competencies and to assess capacity to deliver LARC in primary care. This should be available to DCHS for review at any time and should include:

- Clinician name
- Clinical role
- Type of LARC device fitted/removed
- Relevant qualifications held
- Whether CPD and activity logs are maintained and meet requirements specified in Appendix A / B.
- Maintaining skills and revalidation cycle every 5 years with the Faculty of Sexual and Reproductive Healthcare (FSRH)

6. Self-Care and Patient and Carer Information

6.1 In line with NICE guidance women considering LARC methods should receive detailed information – both verbal and written – that will enable them to choose a method and use it effectively. This information should take into consideration their individual needs and should include:

- contraceptive efficacy
- duration of use
- risks and possible side effects
- non-contraceptive benefits
- the procedure for initiation and removal/discontinuation
- when to seek help while using the method.

7. KPIs and Quality Standards

7.1 KPIs

KPI	Evidence required	Frequency
Assurance that all staff clinical and IG training is in date and that processes exist for IG training to be refreshed every year.	• Signed contract • Providers will be required to keep a record of clinical, IG and training as detailed in **Section 5 – Workforce and Staffing.**	Ad hoc as required
Care to be delivered by staff with the correct competency level and training standards required by the Faculty of family planning and reproductive health. Ensure that all clinicians delivering the LARC service are suitably trained, qualified and competent. Clinicians maintain their Letters of Competence for implant and intrauterine procedures. They undertake at least the minimum number of cases required by the Faculty	• Signed contract • Appendix G to be completed and retained by the GP Practice for additional clinician(s) prior to carrying out LARC procedures • Ad hoc evidence to be provided upon request.	Ad hoc as required
Ensure procedures are in place for patient safety; ensure service delivery is compliant with regulatory bodies and establish systems to monitor and review procedures. Procedures shall include incident reporting, risk management, patient confidentiality, patient record keeping.	Signed contract	At contract start and ad hoc as required
Ensure the service is fully compliant with Derbyshire Safeguarding procedures for children and vulnerable adults, including compliance with local policy for: • Female Genital Mutilation (FGM) • Child Sexual Exploitation (CSE)	Signed contract. Ad hoc evidence to be provided upon request.	At contract start and ad hoc as required
All sub-contracted providers are in compliance with national standards for sexual health services.	Full compliance against individual Standard thresholds	Quarterly audit reports and annual summary report
Improve retention rates for contraceptive implants. Establish a baseline in year 1 for contraceptive implant removals within 3 months of fitting across all ISHS settings and reduce this year on year.	Anonymised patient level data returned to DCHS via the online Activity and Payment System. The data required is identified in the table **2.1.4**.	Monthly – by 6th of the following month
Participate in regional and national sexual health promotion campaigns.	Participation in campaign.	N/a
Agree to be audited / participate in audit on an ad hoc basis to provide	Practice contraception	Ad hoc audits

assurance for the claimant process.	register / individual clinical records	

7.2 Activity Plan

Activity levels must meet the required levels in order to maintain competence. Clinicians at risk of not completing this in line with Faculty guidance must make arrangements with the ISHS to attend clinic/s as required in order for competence level to be maintained. Activity information supplied to the commissioner should be provided for each surgery (where there are branch surgeries) to allow effective monitoring of LARC uptake to take place.

8. Continual Service Improvement Plan

No improvement plans are envisaged in the first 12 months other than ensuring engagement, participation and utilisation of the scheme, however the commissioners reserve the right to implement any improvements plans when and if required.

9. Prices and Payments

The payment for the LARC service is tariff-based(see table below).

Accredited Providers will be required to keep a record of activity as detailed in section 2.1.4 under the appropriate read codes on practice computerised systems in order to report activity to DCHS. Payment will be made by DCHS via the online Activity and Payment System (APS) upon receipt of satisfactory data. Accredited Providers will be provided with access to the APS via the web-portal at http://shaps.dchs.nhs.uk (see Appendix E for further details)

Item of service	Tariff (excluding the cost of drugs)
Insertion of implant and management (including removal and replacement at same consultation) – does not include drug/consumable cost (*see below)	£64.00
Implant Removal	£41.00
Insertion of IUS and Management (including removal and replacement at same consultation) – does not include drug/consumable cost (*see below) **for contraception reasons only**	£81.00
Insertion of IUD and Management (including removal and replacement at same consultation) – does not include drug/consumable cost (*see below)	£81.00

*Drugs / consumables: the cost for drugs and consumables falls to the CCGs which maintain the budget for this purpose

References:

- Long-acting reversible contraception - the effective and appropriate use of long-acting reversible contraception (2005 updated 2014) Clinical Guideline 30 http://www.nice.org.uk/nicemedia/pdf/CG030fullguideline.pdf
- NICE implementation update report (2009): Long-acting reversible contraception (LARC)
- Harrison PF, Rosenfield A. research, introduction and use: Advancing from Norplant Contraception 1998: 58;323-34
- Chikamata DM, Miller S. The health services at the clinic level and implantable contraception for women. Contraception 2002; 65: 97-106
- Churchill D et al. 2000. Consultation patterns and provision of contraception in general practice before teenage pregnancy: case-control study. *British Medical Journal* 321(7259): 486–489.
- Department of Health (2012) Improving outcomes and supporting transparency. Part 1: A public health outcomes framework for England, 2013-2016
- Nexplanon® Summary of Product Characteristics http://www.nexplanontraining.co.uk/HcpInfo.aspx

Appendix A: Training requirements – Letter of Competence for insertion and/or removal of subdermal implants

https://www.fsrh.org/education-and-training/letter-of-competence-subdermal-implants-loc-sdi/

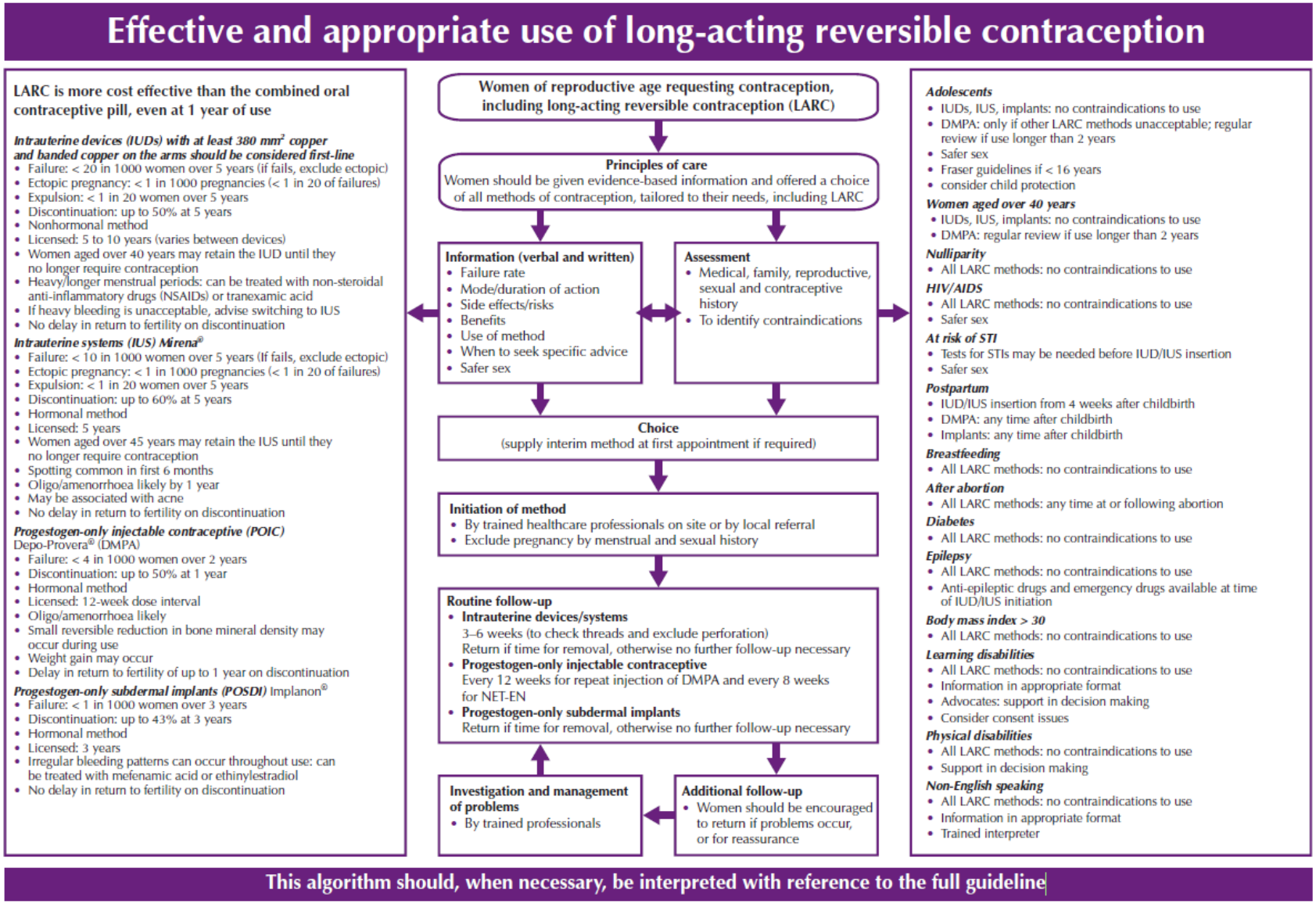
https://www.fsrh.org/education-and-training/letter-of-competence-subdermal-implants-loc-sdi-insertion-only/

https://www.fsrh.org/education-and-training/letter-of-competence-subdermal-implants-loc-sdi-removal-only/

Appendix B: Training requirements – Letter of Competence for intrauterine techniques

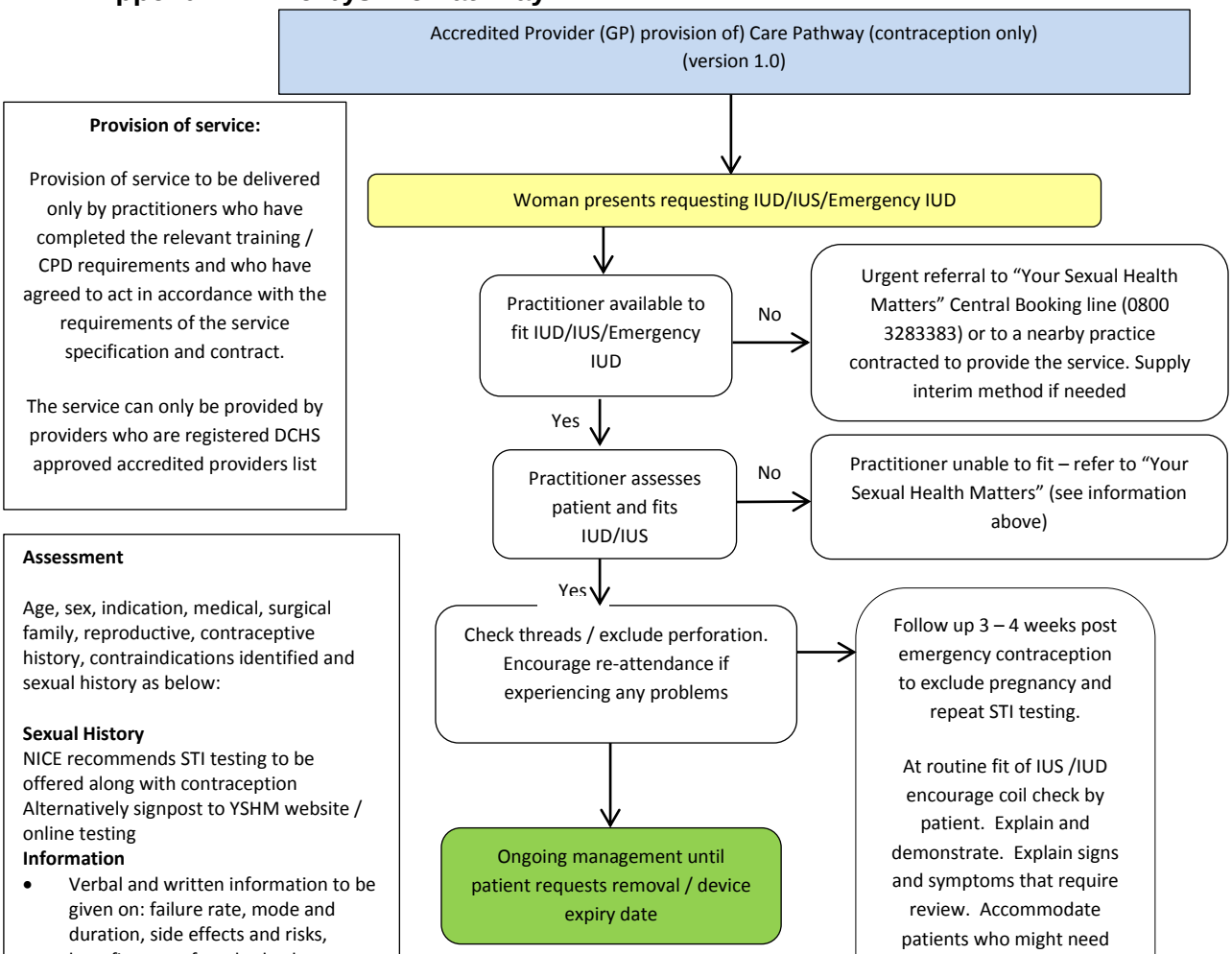
https://www.fsrh.org/education-and-training/letter-of-competence-intrauterine-techniques-loc-iut/

Appendix C: LARC selection algorithm (NICECG30: chapter 2, section 3)



Source: LARC – the effective and appropriate use of long-acting reversible contraception CG30 (NICE 2005 update 2013)

Appendix D - Derbyshire Pathway



Provision of service:

Provision of service to be delivered only by practitioners who have completed the relevant training / CPD requirements and who have agreed to act in accordance with the requirements of the service specification and contract.

The service can only be provided by providers who are registered DCHS approved accredited providers list

Assessment

Age, sex, indication, medical, surgical family, reproductive, contraceptive history, contraindications identified and sexual history as below:

Sexual History
NICE recommends STI testing to be offered along with contraception
Alternatively signpost to YSHM website / online testing
Information

- Verbal and written information to be given on: failure rate, mode and duration, side effects and risks, benefits, use of method, when to seek advice.
- Consent – verbal / written
- Offer support with decision making
- Advise on safer sex/additional protection

Adapted from NICE guidance CG30 and FRSH CEU guidance

'Your Sexual Health Matters' (Integrated Sexual Health Service) clinic locations:
The central booking line covers Derbyshire and Derby City – to book an appointment or for information about clinic dates and times – call the central booking line on:
0800 3283383
And/or visit:
www.yoursexualhealthmatters.org.uk
On line booking available

For further details about this service please contact: 0800 3283383

Appendix E - Prices and Payment

Process

The funding for the service will be as follows:

The payment for the service will be tariff-based, this can be found in the table below. The payment will be made upon receipt of satisfactory data using the GEM Accredited Provider system.

Item of service	Tariff
Insertion of Implant and Management (including removal and replacement at same consultation) – does not include drug/consumable cost (*see below)	£64.00
Implant Removal	£41.00
Insertion of IUS and Management (including removal and replacement at same consultation) – does not include drug/consumable cost (*see below)	£81.00
Insertion of IUD and Management (including removal and replacement at same consultation) – does not include drug/consumable cost (*see below)	£81.00

*Drugs / Consumables: The cost for drugs and consumable falls to the CCGs who maintain the budget for this purpose.

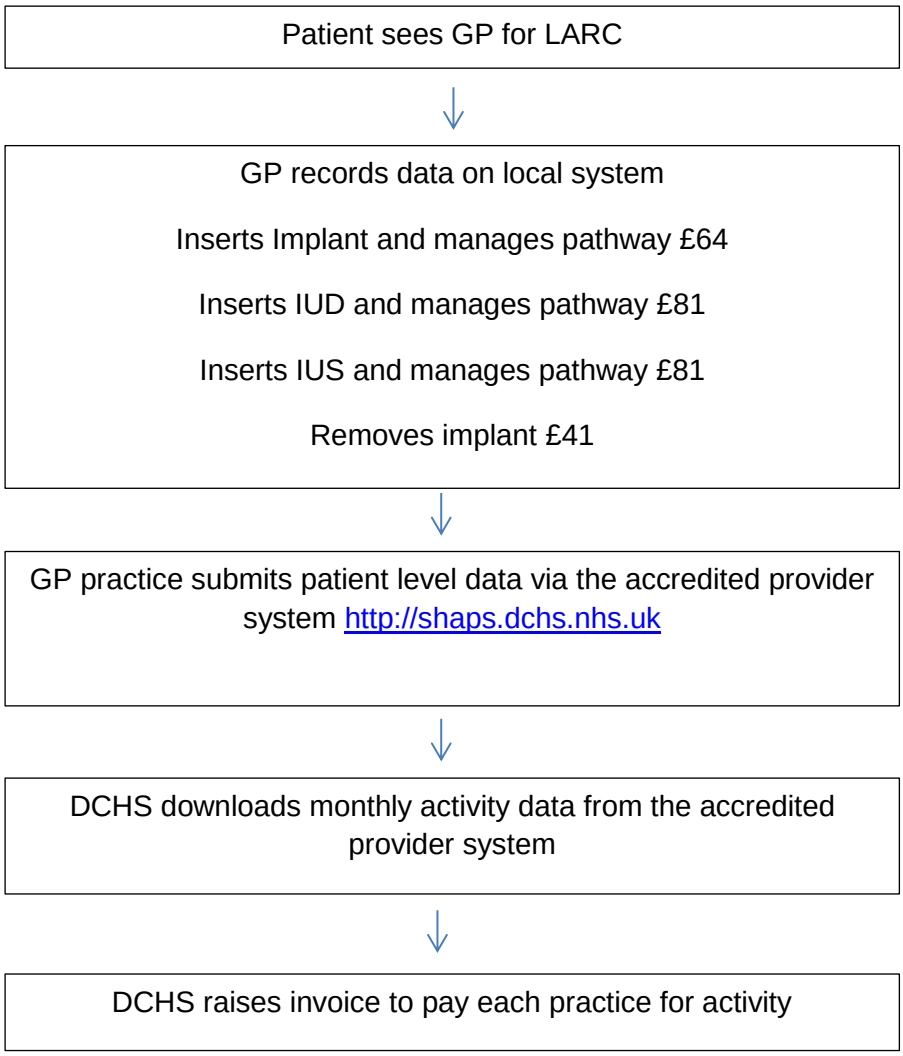
Payments are checked in order to be authorised by the commissioner on receipt of monthly activity claims by participating general practices through the Accredited Provider portal – address below:

http://shaps.dchs.nhs.uk

Claims for back-payments for activity must be made no later than 3 months after the procedure was carried out (i.e. latest date to claim back-payment from procedure carried out in April 2017 is by the end of the first week in July). Claims can only be made for activity that took place during the life of the contract and by accredited providers who are signed up to operate as such within the ISHS.

.

Appendix E continued - Prices and Payment Process



Payment Process

GP inputs activity data onto the accredited provider system (http://shaps.dchs.nhs.uk).

1. DCHS download activity data by General Practice which must include relevant KPI data as indicated in the KPI section above
2. DCHS raise invoice to pay each General Practice for activity

Appendix F - Agreement to provide LARC service

Please tick the relevant box/es below to confirm which services you will be providing

- ☐ Insertion of Implant and Management (including removal and replacement)
- ☐ Implant Removal
- ☐ Insertion of IUS and Management (including removal and replacement)
- ☐ Insertion of IUD and Management (including removal and replacement
- ☐ Provision of the above services to patients from other practices

I / We* the Accredited Provider confirm that the terms and conditions of the specification document produced by DCHS for the above service will be met in full and that I will inform commissioners immediately if I move premises. I/We also confirm that each member of staff (including any Locums) is, and will remain, competent to deliver LARC services as defined by The Faculty of Sexual and Reproductive Healthcare as detailed in appendix G. A copy of appendix G for each member of staff delivering this service will be retained at the Practice and made available upon request.

Signed: _____

(eg Practice Manager, Senior Partner etc)

Name: _____

Position: _____

Date: _____

Organisation: _____

Organisation stamp

Please sign and return completed appendix F prior to service delivery

Appendix G - Evidence of competence to deliver service

ONE FORM TO BE COMPLETED FOR EACH MEMBER OF STAFF PROVIDING LARC SERVICES (TO BE RETAINED AT THE GP PRACTICE – TO BE MADE AVAILABLE UPON REQUEST)

Name of staff member: _____

Signed: _____

Position: _____

GMC Number _____

LOC SDI number _____

LOC IUT/IUS Number _____

Date: _____

Evidence	Date original LoC issued	Recertification completed date	Date recertification next due	Tick to confirm that evidence (LoC) is attached
Faculty of Sexual and Reproductive Healthcare Letter of Competence in Intrauterine Techniques (LoC IUT)				
Faculty of Sexual and Reproductive Healthcare Letter of Competence in Subdermal Contraceptive Implant Techniques (LoC SDI)				

Appendix H - Glossary of terms, abbreviations and acronyms

Term	Definition
CASH	Contraception and Sexual Health
CC	Certificate of Competence
DFFP	Diploma of the Faculty of Sexual and Reproductive Healthcare (previously DFFP)EMSAS East Midlands Sexual Assault Service
FP	Family Planning
FPA	Family Planning Association
FSRH	Faculty of Sexual and Reproductive Healthcare
GP	General Practitioner/General Practice
GUM	Genito-Urinary Medicine
HIV	Human Immunodeficiency Virus
IUCD	Intra-Uterine Contraception Device
IUD	Intra-Uterine Device
IUS	Intra-Uterine System
IUT	Intra-Uterine Techniques
LARC	Long Acting Reversible Contraception
LES	Local Enhanced Service
LoC	Letter of Competence
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
ONS	Office of National Statistics
PCT	Primary Care Trust
PSA	Public Service Agreement
RCN	Royal College of Nursing
REGARDS	Race, Ethnicity, Gender, Age, Religion, Disability, Sexual Orientation
SARC	Sexual Assault and Referral Centre
SDI	Sub-dermal Implant
STIs	Sexually Transmitted Infections
TOP	Termination of Pregnancy

Department of Health & Social Care

NHS

COVER NOTES

As part of the January 2018 update, the standard NHS Terms and Conditions for the supply of goods and the provision of services have been updated to reflect the coming into force of the General Data Protection Regulation (**GDPR**). Please see the relevant Crown Commercial Service Procurement Policy Notice (**PPN**) and related model clauses (Changes to Data Protection Legislation & General Data Protection Regulation) here: https://www.gov.uk/government/publications/procurement-policy-note-0317).

As part of this update, the Department of Health and Social Care's policy approach has been to:

1. Adopt the Crown Commercial Service PPN model clauses with only minor changes to ensure consistent use of terminology with the NHS terms and conditions. This has been achieved by developing the Data Protection Protocol below containing such model clauses for completion in connection with relevant Contracts where the Supplier will be processing personal data on behalf of the Authority. Schedule 3 (Information and Data Provisions) of the NHS terms and conditions has been amended to refer to this Protocol accordingly;

2. Make any necessary changes to relevant definitions in the NHS Terms and Conditions to refer to the GDPR and to ensure consistency with the Protocol; and

3. Make some very limited changes to other Clauses as necessary to ensure consistency with the Protocol and to ensure that the Protocol is referred to as appropriate. For example, depending on the version being used, as well as changes to Schedule 3, there are changes to the Supplier as data processor provisions in Schedule 1 (Key Provisions), the consequences of expiry or earlier termination provisions in Schedule 2 (General Terms and Conditions) and the change management provisions in Schedule 2.

This Protocol can also be used when varying existing Contracts to comply with the GDPR in circumstances where the Supplier is processing personal data on behalf of the Authority. In these circumstances, a change note will need to be agreed in compliance with the Contract change provisions to replace the existing data protection provisions (e.g. paragraph 2.2 of Schedule 3 in the standard NHS Terms and Conditions) with a completed version of the Protocol (which can be annexed to the change note accordingly). The consequential changes, as referred to at points 2 and 3 above, will also be relevant to any such change notes and can be viewed as part of the comparison documents published as part of the January 2018 update. Whether a new or existing Contract, the Protocol should be completed and/or tailored to reflect the actual data processing activities taking place. In the context of more complex data sharing arrangements, for example, the Protocol will need more substantial changes and tailoring to reflect any data controlled by the Supplier and processed by the Authority and/or any data shared with third parties as part of such arrangements.

Developed in partnership with MILLS & REEVE *January 2018*

Schedule 2

DATA PROTECTION PROTOCOL

Guidance: This Data Protection Protocol is for use alongside the NHS terms and conditions where the Supplier will be processing personal data on behalf of the Authority. In these circumstances, the table below should be completed by the Authority setting out the nature of the processing that will be taking place under the Contract. This Protocol is based on the model provisions set out in the Procurement Policy Note – Changes to Data Protection Legislation and General Data Protection Regulation (PPN 03/17) issued by the Crown Commercial Service (December 2017).

Table A – Processing, Personal Data and Data Subjects

Description	Details
Subject matter of the Processing	*Data relating to the provision of a Long Acting Reversible Contraception (LARC) service within pharmacies*
Duration of the Processing	*In accordance with the duration of the contract between Derbyshire Community Health Services NHS Foundation Trust (DCHSFT) and the Accredited Provider*
Nature and purposes of the Processing	***Nature**:* *Client personal and medical information collected and recorded during patient consultation with GP or nurse* *Patient level anonymised activity data provided to DCHSFT* ***Purpose**:* *•Assessment of the client's suitability for provision of LARC* *•Assessment of need for STI testing* *•Maintenance of a contraceptive register* *•Sharing for safeguarding purposes, of relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements, including concerns regarding Child Sexual Exploitation (CSE) and Female Genital Mutilation (FGM)* *•Facilitation of payment by DCHSFT to Accredited Provider* *•Collection of anonymised data to enable activity reporting by DCHSFT to service Commissioner*
Type of Personal Data	*• Patient's name, age, NHS number and postcode* *• Clinical, reproductive and sexual history* *• Counselling process* *• Consent: verbal/written* *• Results of any STI testing* *• Any contraindications* *• Site of insertion for implant* *• Reason for fitting IUD/IUS* *• Problems with insertion/removal* *• How long removed device was in situ and was this patient-reported or from GP records* *• Type and batch number of the IUD/IUS or implant* *• expiry date of the device and follow-up arrangements* *• Any adverse reactions* *• Name and designation of person(s) completing the procedure* *• Referring practice if applicable* *• Name and address of practice providing service* *• Date procedure took place* *• GMC/NMC number of clinician* *• Confirmation GP/nurse has LoC for technique*

Categories of Data Subject	*Patients*
Plan for return and destruction of the data once the Processing is complete UNLESS requirement under union or member state law to preserve that type of data	*The data will be retained in line with the NHS Records Management Code of Practice.*

Definitions

The definitions and interpretative provisions at Schedule 4 (Definitions and Interpretations) of the Contract shall also apply to this Protocol. Additionally, in this Protocol the following words shall have the following meanings unless the context requires otherwise:

"Data Loss Event"	means any event that results, or may result, in unauthorised access to Personal Data held by the Supplier under this Contract, and/or actual or potential loss and/or destruction of Personal Data in breach of this Contract, including any Personal Data Breach**;**
"**Data Protection Impact Assessment**"	means an assessment by the Controller of the impact of the envisaged Processing on the protection of Personal Data;
"**Data Protection Officer**" and **"Data Subject**"	shall have the same meanings as set out in the GDPR;
"**Data Subject Access Request"**	means a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data.
"**Personal Data Breach**"	shall have the same meaning as set out in the GDPR;
"**Protective Measures"**	**means appropriate technical and organisational measures which may include:** pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of such measures adopted by it;
"Protocol" or "Data Protection Protocol"	means this Data Protection Protocol;
"**Sub-processor"**	means any third party appointed to Process Personal Data on behalf of the Supplier related to this Contract.

1 DATA PROTECTION

1.1 The Parties acknowledge that for the purposes of the Data Protection Legislation the only Processing that the Supplier is authorised to do is listed in Table A of this Protocol and may not be determined by the Supplier. The Supplier shall notify the Authority immediately if it considers that any of the Authority's instructions infringe the Data Protection Legislation.

1.2 The Supplier shall provide all reasonable assistance to the Authority in the preparation of any Data Protection Impact Assessment prior to commencing any Processing. Such assistance may, at the discretion of the Authority, include:

1.2.1 a systematic description of the envisaged Processing operations and the purpose of the Processing;

1.2.2 an assessment of the necessity and proportionality of the Processing operations in relation to the Services;

1.2.3 an assessment of the risks to the rights and freedoms of Data Subjects; and

1.2.4 the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.

1.3 The Supplier shall, in relation to any Personal Data Processed in connection with its obligations under this Contract:

1.3.1 process that Personal Data only in accordance with Table A of this Protocol, unless the Supplier is required to do otherwise by **Law. If it is so required the Supplier** shall promptly notify the Authority before Processing the Personal Data unless prohibited by Law;

1.3.2 ensure that it has in place Protective Measures, which have been reviewed and approved by the Authority as appropriate to protect against a Data Loss Event having taken account of the:

(i) nature of the data to be protected;

(ii) harm that might result from a Data Loss Event;

(iii) state of technological development; and

(iv) cost of implementing any measures;

1.3.3 ensure that :

(i) the Supplier Personnel do not Process Personal Data except in accordance with this Contract (and in particular Table A of this Protocol);

(ii) it takes all reasonable steps to ensure the reliability and integrity of any Supplier Personnel who have access to the Personal Data and ensure that they:

(A) are aware of and comply with the Supplier's duties under this Protocol;

(B) are subject to appropriate confidentiality undertakings with the Supplier or any Sub-processor;

(C) are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third party unless directed in writing to do so by the Authority or as otherwise permitted by this Contract; and

(D) have undergone adequate training in the use, care, protection and handling of Personal Data;

1.3.4 not transfer Personal Data outside of the EU unless the prior written consent of the Authority has been obtained and the following conditions are fulfilled:

(i) the Authority or the Supplier has provided appropriate safeguards in relation to the transfer (whether in accordance with Article 46 of the GDPR or Article 37 of the Law Enforcement Directive (Directive (EU) 2016/680)) as determined by the Authority;

(ii) the Data Subject has enforceable rights and effective legal remedies;

(iii) the Supplier complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Authority in meeting its obligations); and

(iv) the Supplier complies with any reasonable instructions notified to it in advance by the Authority with respect to the Processing of the Personal Data;

1.3.5 at the written direction of the Authority, delete or return Personal Data (and any copies of it) to the Authority on termination or expiry of the Contract unless the Supplier is required by Law to retain the Personal Data.

1.4 Subject to Clause 1.6 of this Protocol, the Supplier shall notify the Authority immediately if it:

1.4.1 receives a Data Subject Access Request (or purported Data Subject Access Request);

1.4.2 receives a request to rectify, block or erase any Personal Data;

1.4.3 receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;

1.4.4 receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data Processed under this Contract;

1.4.5 receives a request from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or

1.4.6 becomes aware of a Data Loss Event.

1.5 The Supplier's obligation to notify under Clause 1.5 of this Protocol shall include the provision of further information to the Authority in phases, as details become available.

1.6 Taking into account the nature of the Processing, the Supplier shall provide the Authority with full assistance in relation to either Party's obligations under Data Protection Legislation and any complaint, communication or request made under Clause 1.5 of this Protocol (and insofar as possible within the timescales reasonably required by the Authority) including by promptly providing:

1.6.1 the Authority with full details and copies of the complaint, communication or request;

1.6.2 such assistance as is reasonably requested by the Authority to enable the Authority to comply with a Data Subject Access Request within the relevant timescales set out in the Data Protection Legislation;

1.6.3 the Authority, at its request, with any Personal Data it holds in relation to a Data Subject;

1.6.4 assistance as requested by the Authority following any Data Loss Event;

1.6.5 assistance as requested by the Authority with respect to any request from the Information Commissioner's Office, or any consultation by the Authority with the Information Commissioner's Office.

1.7 The Supplier shall maintain complete and accurate records and information to demonstrate its compliance with this Protocol. This requirement does not apply where the Supplier employs fewer than 250 staff, unless:

1.7.1 the Authority determines that the Processing is not occasional;

1.7.2 the Authority determines the Processing includes special categories of data as referred to in Article 9(1) of the GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the GDPR; and

1.7.3 the Authority determines that the Processing is likely to result in a risk to the rights and freedoms of Data Subjects.

1.8 The Supplier shall allow for audits of its Processing activity by the Authority or the Authority's designated auditor.

1.9 The Supplier shall designate a Data Protection Officer if required by the Data Protection Legislation.

1.10 Before allowing any Sub-processor to Process any Personal Data related to this Contract, the Supplier must:

1.10.1 notify the Authority in writing of the intended Sub-processor and Processing;

1.10.2 obtain the written consent of the Authority;

1.10.3 enter into a written agreement with the Sub-processor which give effect to the terms set out in this Protocol such that they apply to the Sub-processor; and

1.10.4 provide the Authority with such information regarding the Sub-processor as the Authority may reasonably require.

1.11 The Supplier shall remain fully liable for all acts or omissions of any Sub-processor.

1.12 The Authority may, at any time on not less than 30 Business Days' notice, revise this Protocol by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Contract).

1.13 The Parties agree to take account of any guidance issued by the Information Commissioner's Office. The Authority may on not less than 30 Business Days' notice to the Supplier amend this Protocol to ensure that it complies with any guidance issued by the Information Commissioner's Office.

1.14 The Supplier shall comply with any further instructions with respect to Processing issued by the Authority by written notice. Any such further written instructions shall be deemed to be incorporated into Table A above from the date at which such notice is treated as having been received by the Supplier in accordance with Clause 27.2 of Schedule 2 of the Contract.

1.15 Subject to Clauses 1.12, 1.13, and 1.14 of this Protocol, any change or other variation to this Protocol shall only be binding once it has been agreed in writing and signed by an authorised representative of both Parties.

Appendix J Information and data provisions

Schedule 1

Information and Data Provisions

1 Confidentiality

1.1 In respect of any Confidential Information it may receive directly or indirectly from the other Party ("**Discloser**") and subject always to the remainder of Clause 1 of this Schedule 3, each Party ("**Recipient**") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser's prior written consent provided that:

1.1.1 the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Commencement Date;

1.1.2 the provisions of Clause 1 of this Schedule 3 shall not apply to any Confidential Information:

(i) which is in or enters the public domain other than by breach of this Contract or other act or omissions of the Recipient;

(ii) which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;

(iii) which is authorised for disclosure by the prior written consent of the Discloser;

(iv) which the Recipient can demonstrate was in its possession without any obligation of confidentiality prior to receipt of the Confidential Information from the Discloser; or

(v) which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange.

1.2 Nothing in Clause 1 of this Schedule 3 shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable Law, including the Freedom of Information Act 2000 ("**FOIA**"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("**Codes of Practice**") or the Environmental Information Regulations 2004 ("**Environmental Regulations**").

1.3 The Authority may disclose the Supplier's Confidential Information:

1.3.1 on a confidential basis, to any Contracting Authority (the Parties agree that all Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority);

1.3.2 on a confidential basis, to any consultant, contractor or other person engaged by the Authority and/or the Contracting Authority receiving such information;

1.3.3 to any relevant party for the purpose of the examination and certification of the Authority's accounts;

1.3.4 to any relevant party for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources;

1.3.5 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or

1.3.6 on a confidential basis to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Contract;

and for the purposes of this Contract, references to disclosure "on a confidential basis" shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause 1.3 of this Schedule 1.

1.4 The Supplier may only disclose the Authority's Confidential Information, and any other information provided to the Supplier by the Authority in relation this Contract, to the Supplier's Staff or professional advisors who are directly involved in the performance of or advising on the Supplier's obligations under this Contract. The Supplier shall ensure that such Staff or professional advisors are aware of and shall comply with the obligations in Clause 1 of this Schedule 3 as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at the Authority's written discretion, destroyed securely or returned to the Authority when it is no longer required. The Supplier shall not, and shall ensure that the Staff do not, use any of the Authority's Confidential Information received otherwise than for the purposes of performing the Supplier's obligations in this Contract.

1.5 For the avoidance of doubt, save as required by Law or as otherwise set out in this Schedule 3, the Supplier shall not, without the prior written consent of the Authority (such consent not to be unreasonably withheld or delayed), announce that it has entered into this Contract and/or that it has been appointed as a Supplier to the Authority and/or make any other announcements about this Contract.

1.6 Clause 1 of this Schedule 3 shall remain in force:

1.6.1 without limit in time in respect of Confidential Information which comprises Personal Data or which relates to national security; and

1.6.2 for all other Confidential Information for a period of three (3) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.

2 Data protection

2.1 The Parties acknowledge their respective duties under Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties. For the avoidance of doubt, the Supplier shall take reasonable steps to ensure it is familiar with the Data Protection Legislation and any obligations it may have under such Data Protection Legislation and shall comply with such obligations.

2.2 Where the Supplier is Processing Personal Data under or in connection with this Contract, the Parties shall comply with the Data Protection Protocol.

2.3 The Supplier and the Authority shall ensure that Personal Data is safeguarded at all times in accordance with the Law, and this obligation will include (if transferred electronically) only transferring Personal Data (a) if essential, having regard to the purpose for which the transfer is conducted; and (b) that is encrypted in accordance with any international data encryption standards for healthcare, and as otherwise required by those standards applicable to the Authority under any Law and Guidance (this includes, data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).

2.4 Where, as a requirement of this Contract, the Supplier is Processing Personal Data relating to patients and/or service users as part of the Services, the Supplier shall:

2.4.1 complete and publish an annual information governance assessment using the NHS information governance toolkit;

2.4.2 achieve a minimum level 2 performance against all requirements in the relevant NHS information governance toolkit;

2.4.3 nominate an information governance lead able to communicate with the Supplier's board of directors or equivalent governance body, who will be responsible for information governance and from whom the Supplier's board of directors or equivalent governance body will receive regular reports on information governance matters including, but not limited to, details of all incidents of data loss and breach of confidence;

2.4.4 report all incidents of data loss and breach of confidence in accordance with Department of Health and/or the NHS England and/or Health and Social Care Information Centre guidelines;

2.4.5 put in place and maintain policies that describe individual personal responsibilities for handling Personal Data and apply those policies vigorously;

2.4.6 put in place and maintain a policy that supports its obligations under the NHS Care Records Guarantee (being the rules which govern information held in the NHS Care Records Service, which is the electronic patient/service user record management service providing authorised healthcare professionals access to a patient's integrated electronic care record);

2.4.7 put in place and maintain agreed protocols for the lawful sharing of Personal Data with other NHS organisations and (as appropriate) with non-NHS organisations in circumstances in which sharing of that data is required under this Contract;

2.4.8 where appropriate, have a system in place and a policy for the recording of any telephone calls in relation to the Services, including the retention and disposal of those recordings;

2.4.9 at all times comply with any information governance requirements and/or processes as may be set out in the Specification and Tender Response Document; and

2.4.10 comply with any new and/or updated requirements, Guidance and/or Policies notified to the Supplier by the Authority from time to time (acting reasonably) relating to the Processing and/or protection of Personal Data.

2.5 Where any Personal Data is Processed by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 2 of this Schedule 3, as if such Sub-contractor were the Supplier.

2.6 The Supplier shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings whatsoever or howsoever arising from the Supplier's unlawful or unauthorised Processing, destruction and/or damage to Personal Data in connection with this Contract.

3 Freedom of Information and Transparency

3.1 The Parties acknowledge the duties of Contracting Authorities under the FOIA, Codes of Practice and Environmental Regulations and shall give each other all reasonable assistance as appropriate or necessary to enable compliance with those duties.

3.2 The Supplier shall assist and cooperate with the Authority to enable it to comply with its disclosure obligations under the FOIA, Codes of Practice and Environmental Regulations. The Supplier agrees:

3.2.1 that this Contract and any recorded information held by the Supplier on the Authority's behalf for the purposes of this Contract are subject to the obligations and commitments of the Authority under the FOIA, Codes of Practice and Environmental Regulations;

3.2.2 that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA, Codes of Practice and Environmental Regulations is a decision solely for the Authority;

3.2.3 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier itself is subject to the FOIA, Codes of Practice and Environmental Regulations it will liaise with the Authority as to the contents of any response before a response to a request is issued and will promptly (and in any event within two (2) Business Days) provide a copy of the request and any response to the Authority;

3.2.4 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier is not itself subject to the FOIA, Codes of Practice and Environmental Regulations, it will not respond to that request (unless directed to do so by the Authority) and will promptly (and in any event within two (2) Business Days) transfer the request to the Authority;

3.2.5 that the Authority, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of FOIA, and regulation 16 of the Environmental Regulations, may disclose information concerning the Supplier and this Contract; and

3.2.6 to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section

46 of FOIA, and providing copies of all information requested by the Authority within five (5) Business Days of that request and without charge.

3.3 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations, the content of this Contract is not Confidential Information.

3.4 Notwithstanding any other term of this Contract, the Supplier consents to the publication of this Contract in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations.

3.5 In preparing a copy of this Contract for publication under Clause 3.4 of this Schedule 3, the Authority may consult with the Supplier to inform decision making regarding any redactions but the final decision in relation to the redaction of information will be at the Authority's absolute discretion.

3.6 The Supplier shall assist and cooperate with the Authority to enable the Authority to publish this Contract.

3.7 Where any information is held by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 3 of this Schedule 3, as if such Sub-contractor were the Supplier.

4 Information Security

4.1 Without limitation to any other information governance requirements set out in this Schedule 3, the Supplier shall:

4.1.1 notify the Authority forthwith of any information security breaches or near misses (including without limitation any potential or actual breaches of confidentiality or actual information security breaches) in line with the Authority's information governance Policies; and

4.1.2 fully cooperate with any audits or investigations relating to information security and any privacy impact assessments undertaken by the Authority and shall provide full information as may be reasonably requested by the Authority in relation to such audits, investigations and assessments.

4.2 Where required in accordance with the Specification and Tender Response Document, the Supplier will ensure that it puts in place and maintains an information security management plan appropriate to this Contract, the type of Services being provided and the obligations placed on the Supplier. The Supplier shall ensure that such plan is consistent with any relevant Policies, Guidance, Good Industry Practice and with any relevant quality standards as may be set out in the Key Provisions and/or the Specification and Tender Response Document.

4.3 Where required in accordance with the Specification and Tender Response Document, the Supplier shall obtain and maintain certification under the HM Government Cyber Essentials Scheme at the level set out in the Specification and Tender Response Document.