

Step 10: Contract

Tool 1: Commissioning Contract (front end)

This tool is for use in conjunction with Step 10 of the Commissioning Toolkit document

Document No.	Date	Draft

Private & Confidential

SUBJECT TO CONTRACT

[DN: THIS IS THE DRAFT COMMISSIONING CONTRACT TO ACCOMPANY THE COMMISSIONING GUIDANCE/TOOLKIT]

DATED 20[]

[NAME OF SOLE OR LEAD CLINICAL COMMISSIONING GROUP] (1)

[AS CO-ORDINATING COMMISSIONER
FOR ITSELF AND AS AGENT FOR AND ON BEHALF OF THE ASSOCIATES]

and

[PREFERRED PROVIDER] (2)

AGREEMENT

FOR THE PROVISION OF COMMUNITY
PATHOLOGY SERVICES

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THIS AGREEMENT is made on

20[]

BETWEEN:

- (1) **[[•] CLINICAL COMMISSIONING GROUP]** whose registered office is at [] [, for itself and on behalf of the Associates] ("**Commissioner**"); and
- (2) **[PREFERRED PROVIDER]** whose registered office is at [] ("**Provider**").

BACKGROUND:

- (A) The Commissioner has a responsibility to commission a range of healthcare and/or social care services to meet the needs of the populations for which it is responsible, and this responsibility includes the commissioning of community pathology services throughout the Commissioning Region.
- (B) The Commissioner has undertaken a competitive tender process to identify the best provider to provide the Services. The Provider has been selected to provide the Services throughout the Commissioning Region **[DN: team to consider if region is appropriate/desirable]**
- (C) In order to fulfil the Commissioner’s responsibilities, the Commissioner wishes to secure the provision of the Services from the Provider and the Provider wishes to provide the Services to the Commissioner throughout the Commissioning Region on the terms of this Agreement.

In consideration of the mutual covenants and undertakings set out below **THE PARTIES AGREE** as follows:

1 DEFINITIONS AND INTERPRETATION

- 1.1 References to clauses and Schedules are to clauses and Schedules in this Agreement, unless expressly stated otherwise.
- 1.2 This Agreement shall be interpreted in accordance with Schedule 1 (Definitions and Interpretation) and in the event and to the extent only of any conflict between, the clauses and the Schedules, the clauses shall prevail, followed by the Schedules, unless a clause expressly states otherwise or a clause is varied in accordance with clause 34 (Variations).
- 1.3 The Parties shall have regard to the NHS Constitution and the Principles and Rules for Cooperation and Competition.

- 1.4 The Parties shall have regard to the delivery of safe, effective and Patient centred high quality care and the provision of Services to Community Users to a high standard.
- 1.5 The Parties agree that each of them shall at all times act in good faith towards the other Parties.

2 COMMENCEMENT AND DURATION

- 2.1 This Agreement shall come into force on [● 2012] (the “**Effective Date**”) and shall (subject to the provisions for earlier termination set out in this Agreement) terminate automatically without notice on [● 20●●] (the “**Expiry Date**”).
- 2.2 Subject to satisfaction of the Conditions Precedent, the Provider shall commence delivery of the Services on the Service Commencement Date.
- 2.3 If the Conditions Precedent are not satisfied in full by the Service Commencement Date, then, subject to the termination right in clause 31.3(h) not being exercised, the Provider shall commence delivery of the Services on but not before the date that the Conditions Precedent are satisfied.
- 2.4 Subject to the terms of this Agreement, the Provider shall provide the Services from the Service Commencement Date until and including the Expiry Date.
- 2.5 The Provider shall implement the Transformation Plan on or before the Service Commencement Date.

OR use clause 3 instead of clause 2.5 if major region wide reorganisation of services being undertaken and further time for transformation is required

3 [TRANSFORMATION PERIOD]

[DN: Clause 3 will only be required if a Provider requires an interim solution (e.g. the chosen lab or hub will not be operational by the SCD (itself usually 3 to 6 months after the Effective Date) and the Transformation Plan is not expected to be fully implemented by the Service Commencement Date).]

4 COMMISSIONER AND REPRESENTATIVES

- 4.1 The Co-ordinating Commissioner shall in relation to this Agreement act for itself and as agent for its Associates (who are separate principals) provided that sums payable to the Provider

are to be severally attributed to the relevant Associate or to the Co-ordinating Commissioner, as appropriate.

4.2 The Co-ordinating Commissioner and the Provider shall each appoint representatives and deputy representatives to be their key points of contact for day-to-day communications.

5 **[PROVIDER AND REPRESENTATIVES]**

[DN: this clause is only likely to be required if a system side reorganisation of services is being undertaken and a hub and spoke model with joint venture parties is anticipated/expected. The nature and extent of this clause will therefore be driven by the structure of the preferred bidder e.g. jv, hub and spoke etc.]

6 **SERVICES**

Service Provision

6.1 Subject to clause 6.2, and as regards to clause 6.1(b) without prejudice to the provisions of clause 19 (Managing Activity and Requests), the Provider shall provide the Services in accordance with:

- (a) the Services Specification as set out in Schedule 2 Part 1 (Services Specification);
- (b) the Activity Plan set out in Annex 1A to Schedule 3 Part 1 (Activity Plans);
- (c) the Quality Requirements;
- (d) any Utilisation Management Scheme; and
- (e) the Law.

Business Continuity

6.2 The Provider shall maintain a Business Continuity Plan and shall notify the Co-ordinating Commissioner as soon as reasonably practicable of its activation and in any event no later than 5 Operational Days from the date of such activation.

6.3 In the event of any conflict between the Provider's obligation to notify the Co-ordinating Commissioner of the activation of its Business Continuity Plan pursuant to clause 6.2 and the requirements for notification and investigation of Serious Incidents set out in Schedule 12 (Incidents Requiring Reporting Procedure), then the requirements set out in Schedule 12

(Incidents Requiring Reporting Procedure) shall prevail.

Community User Involvement

- 6.4 The Provider shall evidence to the Co-ordinating Commissioner the involvement of Community Users in the development of Services and shall provide to the Co-ordinating Commissioner such evidence on the Co-ordinating Commissioner's reasonable request without undue delay.

Service Development and Improvement Plan

- 6.5 The Parties wish to encourage the improvement of the Services and shall therefore during the term of this Agreement from time to time agree any development and improvements to the Services Specification by way of a Service Variation in accordance with clause 34 (Variations).

7 SERVICES ENVIRONMENT AND EQUIPMENT

- 7.1 The Provider shall at all times comply with the Law and any applicable Quality Requirements in relation to the Services Environment and the Equipment.
- 7.2 The Provider shall ensure that the Services Environment is fit for the purpose of providing the Services and is clean, safe, suitable, sufficient, adequate, functional, accessible (making reasonable adjustments where required) and effective.
- 7.3 The Provider shall consult and co-operate with all appropriate Community Users and any other appropriate third parties to seek to ensure the effective inter-operability of the Equipment with any other equipment used or commissioned by such Community Users or otherwise, so as to enable or facilitate the Provider to comply duly and punctually with its obligations under this Agreement.
- 7.4 Unless provided otherwise in this Agreement, the Provider shall at all times and at its own cost provide all Equipment necessary to provide the Services in accordance with the Law and any necessary Consents.

8 CO-OPERATION

- 8.1 The Provider and the Commissioners shall co-operate in accordance with the Law, Good Clinical Practice and Good Health and/or Social Care Practice to ensure the performance of the Services in accordance with this Agreement.

8.2 The Provider shall co-operate fully and liaise appropriately with:

- (a) the Commissioners;
- (b) the CCGs throughout the Commissioning Region;
- (c) the Community Users throughout the Commissioning Region;
- (d) [primary and social care services];
- (e) relevant Patient groups;
- (f) **[Insert any other groups],**

in order to:

- (g) achieve a continuation of the Services;
- (h) **[Insert any other outcomes].**

8.3 The Provider shall ensure that the provision by it of any activity to any third parties shall not hinder or in any way adversely affect its delivery of the Services to the Commissioners or its performance of this Agreement generally.

9 PRICES AND PAYMENT

Prices

9.1 The Prices are set out in Schedule 2, Part 3 (Prices).

Payment

9.2 Subject to clause 9.1, each month after the Service Commencement Date during the term of this Agreement each Commissioner shall pay to the Provider one twelfth of its individual Annual Contract Value identified in Annex 3 to Schedule 3 Part 1, such payment being a payment on account. To facilitate the making of such payments the Provider shall supply to each Commissioner a monthly statement of account.

Reconciliation

9.3 In order to ascertain the actual sums payable for the Services delivered, the Co-ordinating Commissioner shall provide a separate reconciliation account for itself and each Associate for

each month after the Service Commencement Date, showing the sum equal to the Prices for all the Services delivered and completed in that month. Such reconciliation accounts shall be based on the information submitted by the Provider to the Co-ordinating Commissioner under clause 25 (Information Requirements) and Schedule 5 (Information Requirements) by the Inclusion Date.

- 9.4 Following the First Reconciliation Points, the Co-ordinating Commissioner shall raise with the Provider any data validation queries it has and the Provider shall answer any such queries promptly and fully. The Parties shall use all reasonable endeavours to resolve all such queries by the Post Reconciliation Inclusion Date.
- 9.5 The Co-ordinating Commissioner shall send the Provider a final reconciliation account for the preceding 12 months within 5 Operational Days after the Final Reconciliation Point.
- 9.6 The final reconciliation account shall either be agreed by the Provider, or be wholly or partially contested by the Provider in accordance with clause 9.11.
- 9.7 The Provider's agreement of a final reconciliation account (such agreement not to be unreasonably withheld or delayed) shall trigger a reconciliation payment by the relevant Commissioner to the Provider or by the Provider to the relevant Commissioner, as appropriate, and such payment shall be made within 10 Operational Days of the Provider's agreement of the final reconciliation account.

Aggregation and Disaggregating of Payments

- 9.8 The Co-ordinating Commissioner may make or receive all (but not some only) of the payments becoming due under clauses 9.2, 9.3 and 9.8 in aggregate amounts for itself and on behalf of each of its Associates provided that it gives the Provider 20 Operational Days' written notice of its intent to do so. These aggregated payments shall not prejudice any immunity from liability of the Co-ordinating Commissioner, or any rights of the Provider to recover any overdue payment from the relevant Commissioners individually. However, they shall discharge the separate liability or entitlement of the Commissioners in respect of their separate Services. To avoid doubt, notices to aggregate and reinstate separate payments may be repeated from time to time, but must be recorded in Schedule 11 Part 3.

VAT

- 9.9 Payment is exclusive of any applicable VAT for which the Commissioners shall be additionally

liable to pay the Provider upon receipt of a valid tax invoice at the prevailing rate in force from time to time.

Contested Payments

9.10 If a Party, acting in good faith, contests all or any part of any payment calculated in accordance with this clause 9:

- (a) the contesting Party shall within 5 Operational Days notify the other Party or Parties, setting out in reasonable detail the reasons for contesting such account, and in particular identifying which elements are contested and which are not contested;
- (b) any uncontested amount shall be paid in accordance with this Agreement by the Party from whom it is due; and
- (c) if the matter has not been resolved within 20 Operational Days of the date of notification under clause 9.11(a), the contesting Party shall refer the matter to dispute resolution under clause 26 (Dispute Resolution),

and following the resolution of any Dispute referred to dispute resolution in accordance with this clause 9.11, the relevant Party shall pay any amount agreed or determined to be payable immediately with interest calculated in accordance with clause 9.12.

Interest on Late Payments

9.11 Subject to any express provision of this Agreement to the contrary (including without limitation provisions relating to withholding and/or retention of payment in clauses 27.11, 27.12, 27.13, 28.7, 28.24, 28.28, 28.30, 28.32, 28.33 and paragraph 6 of Schedule 3 Part 1 (Managing Activity and Requests)), each Party shall be entitled, without prejudice to any other right or remedy, to receive interest at the Default Interest Rate on any payment not made from the day after the date on which payment was due up to and including the date of payment.

Set Off

9.12 Whenever any sum of money is due from one Party to another as a consequence of dispute resolution under clause 26 (Dispute Resolution), the Party that is due to be paid such sum may deduct it from any amount that it is due to pay the other, provided that it has given 5 Operational Days notice in writing of its intention to do so.

10 **REVIEW**

- 10.1 The Co-ordinating Commissioner and the Provider shall jointly review and monitor performance under this Agreement and discuss any matters that either considers necessary in relation to it at such intervals as the Parties agree as set out in Schedule 2 Part 4 (Frequency of Review Meetings) which shall not be less than every month during the period from the Effective Date to the [Service Commencement Date] **[DN: Or later date if Clause 3 is applicable]** and thereafter every six months. Unless otherwise agreed all issues raised in such a Review shall be completed by the end of the relevant Contract Year.
- 10.2 Prior to the end of each Contract Year the Co-ordinating Commissioner and the Provider shall review the Schedules where applicable and plan and agree realistic requirements under this Agreement for the following Contract Year.
- 10.3 Each Review shall be completed by the Co-ordinating Commissioner and the Provider signing a Review Record.
- 10.4 If any Dispute which has arisen during the Review is not shown in the Review Record or is not referred to dispute resolution under clause 26 (Dispute Resolution) within 10 Operational Days after signature of that Review Record it shall be deemed to have been withdrawn.
- 10.5 A referral to dispute resolution under clause 26 (Dispute Resolution) in or following a Review shall not of itself give grounds for any suspension or termination of this Agreement, and in accordance with this Agreement the Provider shall deliver and shall be entitled to be paid for Services delivered until such time as the Dispute is resolved.
- 10.6 Notwithstanding clause 10.1, where either the Co-ordinating Commissioner or the Provider reasonably considers a circumstance constitutes an emergency or is materially important, such Party may request that a Review meeting be held as soon as practicable and in any event such Review meeting shall be held within 5 Operational Days of such request.

11 **COMPLAINTS**

- 11.1 The Commissioners and the Provider shall each operate and publicise a complaints procedure that complies with the Law.
- 11.2 The Provider shall implement Lessons Learned from complaints and demonstrate, with appropriate evidence, at Reviews the extent to which Service improvements have been made as a result.

12 STAFF

- 12.1 Whenever applicable, the Provider shall comply with the Fair Deal for Staff Pensions and be aware of the Principles of Good Employment Practice.
- 12.2 The Provider shall have sufficient appropriately qualified and experienced medical, nursing and other clinical and non-clinical Staff to ensure that the Services are provided in all respects and at all times in accordance with this Agreement. If requested by the Co-ordinating Commissioner, the Provider shall as soon as practicable and by no later than 20 Operational Days of receipt of such written request, provide the Co-ordinating Commissioner with evidence of the Provider's compliance with this clause 12.2.
- 12.3 The Provider shall ensure that the Staff:
- (a) if applicable, are registered with and where required have completed their revalidations by the appropriate professional regulatory body;
 - (b) possess the appropriate qualifications, experience, skills and competencies to perform the duties required of them and be appropriately supervised, managerially and professionally;
 - (c) are covered by the Provider's Indemnity Arrangements (as identified and to the extent set out in clause 24 (Liability and Indemnity)) for the provision of the Services;
 - (d) carry, and where appropriate display, valid and appropriate identification in accordance with Good Health and/or Social Care Practice; and
 - (e) are aware of and respect equality and human rights of colleagues and the public.
- 12.4 The Provider shall have in place systems for seeking and recording specialist professional advice and shall ensure that every member of Staff involved in the provision of the Services receives:
- (a) proper and sufficient continuous professional and personal development, training and instruction;
 - (b) full and detailed appraisal (in terms of performance and on-going education and training) utilising where applicable the Knowledge and Skills Framework or a similar equivalent framework; and

- (c) professional leadership commensurate with the Services,
- each in accordance with Good Clinical Practice and Good Health and/or Social Care Practice and the standards of their relevant professional body, if any.
- 12.5 Where the Provider's Staff are members of the NHS pension scheme the Provider shall participate in any applicable data collection exercise and shall ensure that all data relating to Staff membership of the NHS pension scheme is up to date.
- 12.6 The Provider shall carry out Staff Surveys in relation to the Services at reasonable intervals in accordance with the Law and shall implement any actions it identifies to be taken as a result of such Staff Surveys. The Provider shall co-operate with any surveys that the Commissioners may reasonably carry out. Subject to the requirements of the Law or as otherwise required by this Agreement, the form, frequency and reporting of such surveys shall be in accordance with the requirements of Schedule 3 Part 5 or as otherwise agreed between the Parties from time to time.
- 12.7 Subject to clause 12.8, before the Provider engages or employs any person in the provision of the Services, or in any activity related to, or connected with, the provision of Services, the Provider, at its own cost, shall without limitation, comply with the following Guidance as amended from time to time:
- (a) NHS Employment Check Standards; and
 - (b) such other checks as required by the ISA or which are to be undertaken in accordance with current and future national guidelines and policies.
- 12.8 The Provider may engage a person in an ECR Position or CRC Position (as applicable) pending receipt of the Standard Disclosure or Enhanced Disclosure (as applicable), provided such person is at all times properly supervised in the delivery of the Services.
- 12.9 The Provider shall comply at all times with the Law on anti-discrimination and equal opportunities in relation to its Staff.
- 12.10 Persons employed by the Provider shall have the right to enforce this Agreement as and to the extent shown in clause 40 (Third Party Rights).
- 12.11 On request of the Commissioner the Provider shall provide to the Commissioner a copy of its workforce or human resources policies which must comply with law.

- 12.12 The Provider shall deliver to the Co-ordinating Commissioner on the Effective Date, a copy of all agreements entered into by the Provider to deliver accredited supervisory support commitments which are in force on the Effective Date and such agreements shall be listed in Schedule 14 (Documents Relied On).
- 12.13 The Provider during the term of this Agreement shall deliver to the Co-ordinating Commissioner a copy of any agreement it enters into to deliver accredited supervisory support commitments within 15 Operational Days of entering into such agreement. Such agreements shall be added in Schedule 14 (Documents Relied On) and such additions or variations to Schedule 14 (Documents Relied On) shall not be subject to the variation procedure set out in clause 34 (Variations) and Schedule 6 Part 1 (Variation Procedure).
- 12.14 Without prejudice to clause 12.4, the Provider shall have regard to the Joint Statement on Access to Skills, Trade Unions and Advice in Government Contracting, including without limitation, adopting the Government's Skill Pledge where the Provider receives central funding for education and training.
- 12.15 Where the Commissioner has notified the Provider that it intends to tender or retender any Services, the Provider shall on written request and in any event within 20 Operational Days of such request (unless otherwise agreed in writing) provide the Commissioner with anonymised details of Staff engaged in the provision of such Services to be tendered or retendered that may be subject to TUPE.

13 CLINICAL AND OTHER NETWORKS AND SCREENING PROGRAMMES

13.1 The Provider shall:

- (a) participate in the Clinical Networks and Screening Programmes listed in Schedule 20;
- (b) participate in the national clinical audits within the National Clinical Audit Patients Outcome Programme (NCAPOP) if relevant to the Services; and
- (c) where it deems it to be appropriate having regard to its obligations under clause 8 (Co-operation), participate in such other partnership arrangements as may be in place in the relevant local health economies,

and the Provider shall adhere to all protocols and procedures they operate or recommend, unless they conflict with existing protocols and procedures agreed between the Parties, in which case the Parties shall review any such conflict and shall resolve it.

14 DEATH OF A PATIENT

14.1 The Provider shall maintain and operate a policy that complies with Good Clinical Practice, Good Health and/or Social Care Practice and the Law which details the procedures that it shall follow in the event of the death of a Patient whilst in the Provider's care.

15 INCIDENTS REQUIRING REPORTING

15.1 The Provider shall comply with the arrangements for notification of Serious Incidents to CQC and to any other regulatory body as appropriate, in accordance with the Law.

15.2 The Provider shall, in accordance with the timescales set out in Schedule 12 (Incidents Requiring Reporting Procedure), send the Commissioner a copy of any notification it gives to CQC or Monitor where that notification directly or indirectly concerns any Patient.

15.3 The Parties shall comply with the:

- (a) arrangements for investigating Serious Incidents; and
- (b) procedures for implementing and sharing the Lessons Learned in relation to Serious Incidents,

that are agreed between the Provider and the Co-ordinating Commissioner and set out in Schedule 12 (Incidents Requiring Reporting Procedure).

15.4 The Provider shall comply in all respects with the procedures:

- (a) relating to Patient Safety Incidents; and
- (b) for implementing and sharing the Lessons Learned in relation to Patient Safety Incidents,

that are agreed between the Provider and the Co-ordinating Commissioner and set out in Schedule 12 (Incidents Requiring Reporting Procedure).

15.5 The Commissioners shall have complete discretion to use the information provided by the Provider under this clause 14 and Schedule 12 (Incidents Requiring Reporting Procedure) in any report which they make to Monitor, CQC, any NHS Body, any Strategic Health Authority, any office or agency of the Crown, or any other appropriate regulatory or official body in connection with such Serious Incidents, or in relation to the prevention of Serious Incidents,

provided that they shall in each case notify the Provider of the information disclosed, and the body to which they have disclosed it.

16 QUALITY AND SERVICE REQUIREMENTS

16.1 The Provider shall carry out the Services in accordance with the Law, Good Clinical Practice and Good Health and/or Social Care Practice, and shall, unless otherwise agreed with the Co-ordinating Commissioner in writing:

- (a) comply with the registration and regulatory compliance guidance of CQC and any
- (b) standards or recommendations issued from time to time by CQC (where applicable);
- (c) respond to CQC requirements and any CQC enforcement action;
- (d) comply with the UKAS accreditation standards;
- (e) comply with MHRA standards;
- (f) comply with the standards and recommendations from time to time issued by Monitor (where applicable);
- (g) consider and respond to the recommendations arising from any audit, Serious Incident report or Patient Safety Incident report;
- (h) comply with the recommendations issued from time to time by a Competent Body;
- (i) comply with the standards and recommendations issued from time to time by any relevant professional body and agreed in writing between the Co-ordinating Commissioner and the Provider;
- (j) comply with the recommendations from time to time contained in technology appraisals issued by the National Institute for Health and Clinical Excellence (or any successor);
- (k) comply with the Quality Requirements.

16.2 The Parties shall comply with their duties under the Law to improve the quality of clinical services for Patients through the integrated governance arrangements set out in the National Standards and having regard to Guidance, in particular the Department of Health guidance on clinical governance.

- 16.3 The Provider shall carry out any surveys reasonably requested by the Commissioners in relation to the Services and shall co-operate with any surveys that the Commissioners may, acting reasonably, carry out. Subject to the Law the form, frequency and reporting of such surveys shall be in accordance with the requirements set out in Schedule 3 Part 5 or as otherwise agreed between the Parties in writing from time to time.
- 16.4 Where required by Law, the Provider shall meet its obligations in relation to the production and publication of Quality Accounts in accordance with such Law.
- 16.5 For the avoidance of doubt, nothing in this Agreement is intended to prevent this Agreement from setting higher quality requirements than those laid down under the Provider's Terms of Authorisation (if any) or required by CQC.
- 16.6 Prior to the end of the Contract Year, the Co-ordinating Commissioner and the Provider shall agree the Quality Requirements that shall apply in the following Contract Year (if any), and in order to secure continual improvement in the quality of the Services, such Quality Requirements shall not, other than in exceptional circumstances, be lower than those which they are to supersede. The Co-ordinating Commissioner and the Provider shall give effect to the revised Quality Requirements that will apply in the following Contract Year by means of a Service Variation made under clause 34 (Variations).

17 PROCEDURES AND PROTOCOLS

- 17.1 If requested by the Co-ordinating Commissioner or the Provider, the Co-ordinating Commissioner or the Provider (as the case may be) shall within 5 Operational Days of receipt of the request send or make available to the Co-ordinating Commissioner or the Provider (as applicable) copies of any Services guide or other written policy, procedure or protocol implemented by the Co-ordinating Commissioner or Provider (as applicable).
- 17.2 The Co-ordinating Commissioner shall notify the Provider and the Provider shall notify the Co-ordinating Commissioner of any material changes to any items it has disclosed under clause 17.1.

18 GOVERNANCE, TRANSACTION RECORDS AND AUDIT

- 18.1 The Provider shall comply with all reasonable written requests made by Monitor, CQC, the National Audit Office, the Audit Commission or its appointed auditors, any Authorised Person or the authorised representatives of Local Involvement Networks for entry to the Provider's

Premises and/or the Services Environment and/or the premises of any sub-contractor for the purposes of auditing, viewing, observing or inspecting such premises and/or the provision of the Services, and for information relating to the provision of the Services.

- 18.2 Subject to Law, an Authorised Person may enter the Provider's Premises and/or the Services Environment and/or the premises of any sub-contractor without notice for the purposes of auditing, viewing, observing or inspecting such premises and/or the provision of the Services, and for information relating to the provision of the Services. During such visits, subject to Law, Good Clinical Practice and Good Health and/or Social Care Practice, the Provider shall not restrict access and shall give all reasonable assistance and provide all reasonable facilities.
- 18.3 Within 10 Operational Days of the Co-ordinating Commissioner's reasonable request, the Provider shall send the Co-ordinating Commissioner the results of any audit, evaluation, inspection, investigation or research in relation to the Services, the Services Environment or services of a similar nature to the Services delivered by the Provider, to which the Provider has access and which it can disclose in accordance with the Law.
- 18.4 Subject to compliance with the Law and Good Clinical Practice and Good Health and/or Social Care Practice or unless otherwise agreed with the Co-ordinating Commissioner, the Parties shall implement all relevant recommendations:
- (a) in any report by CQC or Monitor;
 - (b) agreed with the National Audit Office or the Audit Commission following any audit;
 - (c) of any appropriate clinical audit; and
 - (d) that are otherwise agreed by the Provider and the Co-ordinating Commissioner to be implemented.
- 18.5 The Parties shall maintain Transaction Records.
- 18.6 The Provider shall maintain such clinical records relating to the provision of the Services (including Patient identifiers, associated Test results and Clinical Coding, whether in hardcopy or electronic form).
- 18.7 The Co-ordinating Commissioner and the Provider shall each have the right to appoint an Auditor who:

- (a) for the Co-ordinating Commissioner, may audit the Provider's coding and units of measurement in relation to the Prices or any other matters in respect of which the Co-ordinating Commissioner appoints an Auditor; and
- (b) for the Provider, may audit payment of the Annual Contract Values, any non-payment made by a Commissioner and any other matters in respect of which the Provider appoints an Auditor,

and subject to any applicable Patient consent requirements, the Party being audited shall allow the Auditor a right of reasonable access to (and the right to take copies of) the Transaction Records, books of account and other sources of relevant information, and any Confidential Information so disclosed shall be treated in accordance with clause 20 (Confidential Information of the Parties).

- 18.8 In relation only to a Co-ordinating Commissioner required audit of the Provider shall provide the Auditor with particulars of its costs (including the costs of sub-contractors and suppliers) and permit the costs to be verified by inspection of accounts and other documents and records, and any Confidential Information so disclosed shall be treated in accordance with clause 20 (Confidential Information of the Parties).
- 18.9 If the Auditor concludes that the Provider has overcharged, the Provider shall, within 10 Operational Days of receiving written notice of the overcharge, reimburse the overcharged Commissioner the amount of the overcharge and shall pay the reasonable costs of the audit.
- 18.10 If the Auditor concludes that the Provider has undercharged, the undercharged Commissioner shall, within 10 Operational Days of receiving notice of the undercharge, pay to the Provider the amount of the undercharge and shall pay the reasonable costs of the audit.
- 18.11 Each Commissioner shall on request provide to the Provider the results of any annual Clinical Coding Audit relating to the Provider.
- 18.12 If the Auditor concludes that the Provider has charged the correct amount, the costs of the audit shall be borne by the appointing Party.

19 MANAGING ACTIVITY AND REQUESTS

- 19.1 The Commissioners and the Provider shall each monitor and manage activity for the Services in accordance with Schedule 3 Part 1 (Managing Activity and Requests).

19.2 The Provider shall accept all Requests howsoever made by Community Users and, for the avoidance of doubt, the Provider (acting in accordance with Good Clinical Practice, Good Health and/or Social Care Practice) may not reject a Request.

20 CONFIDENTIAL INFORMATION OF THE PARTIES

20.1 Other than as allowed in this Agreement, Confidential Information is owned by the Disclosing Party and the Receiving Party has no right to use it.

20.2 Subject to clauses 20.3 and 20.4, the Receiving Party agrees:

- (a) to use the Disclosing Party's Confidential Information only in connection with the Receiving Party's performance under this Agreement;
- (b) not to disclose the Disclosing Party's Confidential Information to any third party or to use it to the detriment of the Disclosing Party; and
- (c) to maintain the confidentiality of the Disclosing Party's Confidential Information and to return it immediately on receipt of written demand from the Disclosing Party.

20.3 The Receiving Party may disclose the Disclosing Party's Confidential Information:

- (a) in connection with any dispute resolution under clause 26 (Dispute Resolution);
- (b) in connection with any litigation between the Parties;
- (c) to comply with the Law;
- (d) to CQC and/or to Monitor as required;
- (e) to its staff, who shall in respect of such Confidential Information be under a duty no less onerous than the Receiving Party's duty set out in clause 20.2;
- (f) to NHS Bodies for the purpose of carrying out their duties; and
- (g) as permitted under or as may be required to give effect to clause 28 (Contract Management).

20.4 The obligations in clauses 20.1 and 20.2 shall not apply to any Confidential Information which:

- (a) is in or comes into the public domain other than by breach of this Agreement;

- (b) the Receiving Party can show by its records was in its possession before it received it from the Disclosing Party; or
 - (c) the Receiving Party can prove that it obtained or was able to obtain from a source other than the Disclosing Party without breaching any obligation of confidence.
- 20.5 Subject to clause 35.1(c) and clause 35.2(c), the Disclosing Party does not warrant the accuracy or completeness of the Confidential Information.
- 20.6 The Receiving Party shall indemnify the Disclosing Party and shall keep the Disclosing Party indemnified against Losses and Indirect Losses suffered or incurred by the Disclosing Party as a result of any breach of this clause 20.
- 20.7 The Parties acknowledge that damages would not be an adequate remedy for any breach of this clause 20 by the Receiving Party, and in addition to any right to damages the Disclosing Party shall be entitled to the remedies of injunction, specific performance and other equitable relief for any threatened or actual breach of this clause 20.
- 20.8 This clause 20 shall survive the expiry or the termination of this Agreement for any reason, for a period of 5 years.
- 20.9 This clause 20 shall not limit the Public Interest Disclosure Act 1998 in any way whatsoever.

21 PATIENT HEALTH RECORDS

- 21.1 The Provider shall create, maintain, store and retain Patient Health Records for all Patients. The Provider shall retain such records for the periods of time identified in Law and securely destroy them thereafter.
- 21.2 The Provider shall:
- (a) use Patient Health Records solely for the execution of the Provider's obligations under this Agreement; and
 - (b) give each Patient full and accurate information regarding his/her treatment and shall evidence that in writing in the relevant Patient Health Record.
- 21.3 If the Provider replaces its Caldicott Guardian or Senior Information Risk Owner at any time during the term of this Agreement, it shall promptly notify the Co-ordinating Commissioner of the identity and contact details of such replacements.

21.4 Subject to Guidance, the Patient Health Records for Patients shall include the verified NHS number.

22 INTELLECTUAL PROPERTY

22.1 Except as set out expressly in this Agreement no Party shall acquire the IPR of any other Party.

22.2 The Provider now grants the Commissioners a fully paid up non-exclusive licence to use Provider IPR for the duration of this Agreement for the purposes of the exercise of their functions and obtaining the full benefit of the Services which shall include the dissemination of best practice within the NHS.

22.3 The Commissioners now grant the Provider a fully paid up non-exclusive licence to use Commissioner IPR for the duration of this Agreement for the sole purpose of providing the Services.

22.4 Where Provider IPR is software the Provider shall enter into an Escrow Arrangement on the Effective Date.

22.5 In the event that the Provider, or the Commissioners at any time devise, discover or acquire rights in any Improvement it shall promptly notify the owner of the IPR to which such Improvement relates giving full details of the Improvement and such information and explanations as that party may reasonably require to be able to use such Improvement effectively and shall assign to that party all rights and title in any such Improvement without charge.

22.6 The Provider shall disclose all documents and information concerning the development of Best Practice IPR to the Co-ordinating Commissioner at Reviews and shall grant the Commissioners a fully paid up non-exclusive perpetual licence to use Best Practice IPR solely for the purpose of teaching, training and research within their own organisations.

23 NHS BRANDING, MARKETING AND PROMOTION

23.1 The Provider shall comply with the applicable NHS brand policy and guidelines, as revised, updated or re-issued from time to time by the Department of Health, and which are currently accessible at www.nhsidentity.nhs.uk (or such replacement website as is made available from time to time). In addition, where appropriate to the Services the Provider shall comply with the applicable local authority brand guidance and guidelines.

24 **LIABILITY AND INDEMNITY**

24.1 Without prejudice to its liability for breach of any of its obligations under this Agreement, each Commissioner shall be severally liable to the Provider for, and shall indemnify and keep the Provider indemnified against, and [each][the] Provider shall be [jointly and severally] liable to each Commissioner for, and shall indemnify and keep each Commissioner indemnified against:

(a) any loss, damages, costs, expenses, liabilities, claims, actions and/or proceedings (including the cost of legal and/or professional services) whatsoever in respect of:

(i) any loss of or damage to property (whether real or personal); and

(ii) any injury to any person, including injury resulting in death; and

(b) any Losses of the indemnified Party,

that result from or arise out of the indemnifying Party's negligence or breach of contract in connection with the performance of this Agreement or the provision of the Services (including, in the case of the Provider (without limitation) its use of Equipment or other materials or products, and the actions or omissions of the Staff or sub-contractors in the provision of the Services), except insofar as such loss, damage or injury has been caused by any act or omission by, or on the part of, or in accordance with the instructions of the indemnified Party, its employees or agents.

24.2 The Provider shall put in place and/or maintain in force (and/or procure that its sub-contractors shall maintain in force) at its own cost appropriate Indemnity Arrangements in respect of:

(a) employers' liability;

(b) clinical negligence where the provision or non-provision of any part of the Services (or any other services under this Agreement) may result in a clinical negligence claim;

(c) public liability; and

(d) professional negligence.

24.3 The Provider shall where requested by the Co-ordinating Commissioner and in any event within 5 Operational Days of a written demand from the Co-ordinating Commissioner,

provide documentary evidence to the Co-ordinating Commissioner that any Indemnity Arrangements required under clause 24.2 are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.

- 24.4 For the avoidance of doubt, the Provider shall be liable to make good any deficiency in the event that the proceeds of any Indemnity Arrangement are insufficient to cover the settlement of any claim relating to this Agreement.
- 24.5 The Provider warrants that it shall not take any action or fail to take any reasonable action or (in so far as it is reasonable and within its power) permit or allow others to take or fail to take any action, as a result of which any Indemnity Arrangements put in place pursuant to clause 24.2 may be rendered void, voidable, unenforceable, or be suspended or impaired in whole or in part, or which may otherwise render any sum paid out under such Indemnity Arrangements repayable in whole or in part.
- 24.6 Upon the expiry or termination of this Agreement, the Provider shall (and shall use its reasonable endeavours to procure that each of its Material Sub-contractors shall) procure that any ongoing liability it has or may have in negligence to any Patient or Commissioner arising out of a Patient's care and treatment under this Agreement shall continue to be the subject of appropriate Indemnity Arrangements for the period of 21 years from termination or expiry of this Agreement or until such earlier date as that liability may reasonably be considered to have ceased to exist.
- 24.7 In connection with the Services, unless the Co-ordinating Commissioner and the Provider otherwise agree in writing, the Provider shall not require, and shall ensure that no other person shall require, any Patient to sign any document whatsoever containing any waiver of the Provider's liability (other than a waiver in reasonable terms relating to personal property) to that Patient, except for where such a document is required pursuant to medical research procedures approved by the local research ethics committee and the Patient has given consent in accordance with the Patient Consent Policy.
- 24.8 Nothing in this Agreement shall exclude or limit the liability of either Party for death or personal injury caused by negligence or for fraud or fraudulent misrepresentation.
- 24.9 Each Party shall at all times take all reasonable steps to minimise and mitigate any loss for which one Party is entitled to bring a claim against the other pursuant to this Agreement.

25 DATA PROTECTION, FREEDOM OF INFORMATION AND TRANSPARENCY

25.1 The Parties acknowledge their respective duties under the DPA and the FOIA and shall give all reasonable assistance to each other where appropriate or necessary to comply with such duties.

Data Protection

25.2 The Provider shall achieve a minimum level 2 performance against all requirements in the relevant NHS information governance toolkit applicable to it. Where the Provider has not achieved level 2 performance by the Service Commencement Date, the Co-ordinating Commissioner may, in its sole discretion, agree a plan with the Provider to enable the Provider to achieve level 2 performance within a reasonable time.

25.3 To the extent that the Provider is acting as a Data Processor on behalf of a Commissioner, the Provider shall, in particular, but without limitation:

- (a) only process such Personal Data as is necessary to perform its obligations under this Agreement, and only in accordance with any instruction given by the Commissioner under this Agreement;
- (b) put in place appropriate technical and organisational measures against any unauthorised or unlawful processing of such Personal Data, and against the accidental loss or destruction of or damage to such Personal Data having regard to the specific requirements in clause 25.4(c) below, the state of technical development and the level of harm that may be suffered by a Data Subject whose Personal Data is affected by such unauthorised or unlawful processing or by its loss, damage or destruction;
- (c) take reasonable steps to ensure the reliability of Staff who will have access to such Personal Data, and ensure that such Staff are aware of and trained in the policies and procedures identified in clauses 25.4(d), 25.4(e) and 25.4(f) below; and
- (d) not cause or allow such Personal Data to be transferred outside the European Economic Area without the prior consent of the relevant Commissioner.

25.4 The Provider and each Commissioner shall ensure that Personal Data is safeguarded at all times in accordance with the Law, which shall include without limitation obligations to:

- (a) perform an annual information governance self-assessment using the NHS information governance toolkit;
- (b) have an information governance lead able to communicate with the Provider's board, who will take the lead for information governance and from whom the Provider's board shall receive regular reports on information governance matters including, but not limited to, details of all incidents of data loss and breach of confidence;
- (c) where transferred electronically) only transfer data (i) where this is essential having regard to the purpose for which the transfer is conducted; and (ii) that is encrypted to the higher of the international data encryption standards for healthcare and the National Standards (this includes, but is not limited to, data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes);
- (d) have policies which are rigorously applied that describe individual personal responsibilities for handling Personal Data;
- (e) have a policy that allows it to perform its obligations under the NHS Care Records Guarantee;
- (f) have agreed protocols for sharing Personal Data with other NHS organisations and (where appropriate) with non-NHS organisations; and
- (g) 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 such recordings.

Freedom of Information and Transparency

25.5 Where the Provider is not a Public Authority, the Provider acknowledges that the Commissioners are subject to the requirements of the FOIA and shall assist and co-operate with each Commissioner to enable the Commissioner to comply with its disclosure obligations under the FOIA. Accordingly the Provider agrees:

- (a) that this Agreement and any other recorded information held by the Provider on the Commissioners' behalf for the purposes of this Agreement are subject to the obligations and commitments of the Commissioners under the FOIA;

- (b) 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 is a decision solely for the Commissioner to whom the request is addressed;
- (c) that where the Provider receives a request for information under the FOIA, it will not respond to such request (unless directed to do so by the relevant Commissioner to whom the request is addressed) and will promptly (and in any event within 2 Operational Days) transfer the request to the relevant Commissioner;
- (d) that the Commissioners, acting in accordance with the codes of practice issued and revised from time to time under both section 45 of the FOIA, and regulation 16 of the Environmental Information Regulations 2004, may disclose information concerning the Provider and this Agreement either without consulting with the Provider, or following consultation with the Provider and having taken its views into account; and
- (e) to assist the Commissioners in responding to a request for information, by processing information or environmental information (as the same are defined in the FOIA) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of the FOIA, and providing copies of all information requested by a Commissioner within 5 Operational Days of such request and without charge.

25.6 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, the content of this Agreement is not Confidential Information.

25.7 Notwithstanding any other term of this Agreement, the Provider hereby consents to the publication of this Agreement in its entirety including from time to time agreed changes to the Agreement subject to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA.

25.8 In preparing a copy of this Agreement for publication pursuant to clause 25.7 the Commissioners may consult with the Provider to inform decision making regarding any redactions but the final decision in relation to the redaction of information shall be at the Commissioners' absolute discretion.

25.9 The Provider shall assist and cooperate with the Commissioners to enable the Commissioners to publish this Agreement.

26 DISPUTE RESOLUTION

Escalated Negotiation

26.1 Except to the extent that any injunction is sought relating to a matter arising out of clause 20 (Confidential Information of the Parties), if any Dispute arises out of or in connection with this Agreement, the Parties in Dispute shall first attempt to settle it by either of them making a written negotiation offer to the other, and during the Negotiation Period each of the Parties in Dispute shall negotiate and be represented:

- (a) for the first 10 Operational Days, by a senior person who ideally has not had any direct day-to-day involvement in the matter and who has authority to settle the Dispute; and
- (b) for the last 5 Operational Days, by its chief executive, director, or board member who has authority to settle the Dispute,

provided that no Party in Dispute where practicable shall be represented by the same individual under clauses 26.1(a) and 26.1(b).

Mediation

26.2 If the Parties in Dispute are unable to settle the Dispute by negotiation, they shall within 5 Operational Days after the end of the Negotiation Period submit the Dispute:

- (a) to mediation arranged by the relevant Strategic Health Authority where the Commissioners are PCTs and the Provider is an NHS Trust; and
- (b) to mediation by CEDR or other independent body or organisation agreed between the Parties prior to the Service Commencement Date as set out in paragraph 1 of Schedule 9 Part 1, in all other cases.

26.3 In relation to mediation in accordance with clauses 26.2(a), during the mediation phase and in advance of the mediation session, each Party to the Dispute must submit to the mediator within 5 Operational Days of the mediator's request a signed position statement describing the precise points on which the Parties in Dispute disagree, and describing its own solution to the Dispute.

26.4 The provisions of clauses 26.5, 26.6, 26.7 and 26.8:

- (a) shall apply to mediations under clause 26.2(a); and
 - (b) shall not apply to mediations under clause 26.2(b) which shall follow the mediation process of CEDR or other independent body or organisation set out in paragraph 1 of Schedule 9 Part 1.
- 26.5 Where the mediator is satisfied that the nature of the Dispute has been adequately documented in accordance with clause 26.3, the mediator will allow each Party in Dispute 5 Operational Days in which to comment to him/her in writing on the other Party in Dispute's solution to the Dispute. The mediator may, in his/her absolute discretion, request any Party in Dispute to clarify any aspects of its signed position statement and upon receipt of such clarification, will forward the same to the other Party in Dispute. Following distribution by the mediator of the signed position statements and any clarification to the respective Parties in Dispute, the mediator will arrange a mediation session at a venue chosen by him/her to facilitate negotiation and settlement of the Dispute. The mediation session shall be fixed for a date at least 10 Operational Days following receipt by the Parties in Dispute of the later of the other's signed position statement and any clarification.
- 26.6 Save that each Party in Dispute shall make an opening presentation of its position to the other and that the mediator will then meet each of the Parties in Dispute separately for such time as the mediator considers appropriate, the mediator shall determine the procedure of the mediation session. Neither Party in Dispute will terminate its participation in the mediation session until after the opening presentations have been given and the mediator has met both Parties in Dispute as provided for above.
- 26.7 The Parties in Dispute will keep confidential and not use for any collateral or ulterior purpose all information, whether given orally, in writing or otherwise, arising out of or in connection with the mediation, including the fact of any settlement and its terms, save for the fact that the mediation is to take place or has taken place.
- 26.8 All information, whether oral, in writing or otherwise, arising out of or in connection with the mediation will be without prejudice, privileged and not admissible as evidence or disclosable in any current or subsequent litigation or other proceedings whatsoever, provided that the provisions of this clause 26.8 shall not apply to any information which would in any event have been admissible or disclosable in any such proceedings.

Independent Binding Pendulum Adjudication

- 26.9 If the Parties in Dispute are unable to settle the Dispute through mediation, then:
- (a) the Dispute shall be referred to independent binding pendulum adjudication by a written request, made within 10 Operational Days of the termination or failure of any mediation, from either Party in Dispute to:
 - (i) CEDR to appoint an independent panel for that purpose, which independent panel shall have a maximum of 3 members. None of the members of the independent panel shall be, or have been, employed, or engaged, in any capacity by, nor have any interest in, any of the Parties in Dispute; or
 - (ii) any other independent organisation or body agreed between the Parties prior to the Service Commencement Date and set out in paragraph 2 of Schedule 9 Part 1;
 - (b) the procedures for an independent binding pendulum adjudication shall be determined by CEDR or by the organisation or body appointed pursuant to clause 26.9(a)(ii), as applicable; and
 - (c) the independent panel appointed by CEDR pursuant to clause 26.9(a)(i) or other independent organisation or body appointed pursuant to clause 26.9(a)(ii) is authorised to determine the Dispute, but may do so only by making a finding wholly in favour of one of the Parties in Dispute.
- 26.10 The Parties in Dispute agree that a final and binding decision on a Dispute submitted to independent binding pendulum adjudication under clause 26.9 shall be enforceable in court as if it were an agreement made directly between the Parties in Dispute.
- 26.11 The costs of any mediation under this clause 26 will be borne equally by the Parties in Dispute.
- 26.12 The costs of any independent binding pendulum adjudication under this clause 26 will be borne by the unsuccessful Party in Dispute.
- 26.13 Unless this Agreement shall have been repudiated or terminated and notwithstanding that a Dispute remains unresolved, the Parties in Dispute shall continue to carry out their respective obligations in accordance with this Agreement and its Variations recorded in Schedule 6 Part 2. All agreements and decisions resulting from dispute resolutions shall be recorded in Schedule 6 Part 2.

27 INFORMATION REQUIREMENTS

- 27.1 The Provider shall provide the information specified in this clause 27 and in Schedule 5 (Information Requirements):
- (a) within the applicable time period identified in clause 9 (Prices and Payment) and Schedule 5 (Information Requirements); or
 - (b) where clause 27.1(a) does not apply, in a timely manner.
- 27.2 Where the Provider is an NHS Foundation Trust, the Co-ordinating Commissioner shall not require the Provider to supply any information for the purposes of national reporting which the Provider is not obliged to supply under its Terms of Authorisation.
- 27.3 The Provider and Co-ordinating Commissioner shall ensure that any information provided to the other Party in relation to this Agreement is accurate and complete.
- 27.4 The Provider shall where and to the extent applicable:
- (a) comply with all relevant published NHS information and data standards and Information Standards Board recommendations; and
 - (b) implement any other datasets and information requirements agreed from time to time between it and the Co-ordinating Commissioner.
- 27.5 The Parties shall 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.
- 27.6 The Provider may implement any change of practice in the counting and coding of activity as may be agreed from time to time between it and the Co-ordinating Commissioner. The Provider shall give the Co-ordinating Commissioner at least 6 months notice of such proposed change and any such change agreed by the Parties may only be implemented on 1 April of the following Contract Year, unless:
- (a) the Parties agree a different date for the implementation; or
 - (b) the changes are mandated by the Department of Health, in which case the provisions of clause 27.4 shall apply.

27.7 The Co-ordinating Commissioner may request from the Provider any other information it reasonably requires in order to monitor the Provider's performance in relation to this Agreement and the Provider shall supply such information in a timely manner.

27.8 All information to be provided pursuant to this clause 27 and Schedule 5 (Information Requirements) and which is necessary for the purposes of clause 9 (Prices and Payment) shall be provided:

- (a) to the Co-ordinating Commissioner in aggregate form, and in disaggregated form for each Commissioner and its use of the Services; and
- (b) direct to each Commissioner in disaggregated form relating to its own use of the Services.

27.9 Where the Co-ordinating Commissioner reasonably believes that the Provider has failed to meet the requirements of this clause 27 and/or Schedule 5 (Information Requirements), the Co-ordinating Commissioner shall inform the Provider of this by notice in writing, detailing the Provider's breaches and the Co-ordinating Commissioner's intention to instruct the Commissioners to withhold the sums specified in clause 27.10 unless the information is rectified and/or provided within 5 Operational Days of such written notice.

27.10 If:

- (a) the information described in clause 27.9 is not provided and/or rectified by the Provider within 5 Operational Days of the date of the notice served in accordance with clause 27.9 ("**Information Breach**"); and
- (b) such information is required for the purposes of clause 9 (Prices and Payment); or
- (c) such information is required for purposes other than those under clause 9 (Prices and Payment),

and provided that the Information Breach is not due to any act or omission of any Commissioner, then the Co-ordinating Commissioner may instruct the Commissioners to withhold up to 5% (five percent) of all the monthly sums payable by them pursuant to clause 9 (Prices and Payment) in relation to each Information Breach and thereafter for each and every month such Information Breach continues.

27.11 Subject to clauses 27.12 and 27.13, the Commissioners shall withhold the sums withheld

under clause 27.10 for each Information Breach until the Provider reasonably rectifies the relevant Information Breach and the Commissioners shall then pay the Provider the withheld sums within 10 Operational Days and no interest shall be payable by the Commissioners to the Provider on any sum withheld under clause 27.10.

27.12 The Commissioners shall not release to the Provider any withheld sum under clause 27.9 relating to an Information Breach where the Provider fails to reasonably rectify such Information Breach:

- (a) within 6 months of the written notice served under clause 27.9; or
- (b) prior to the Expiry Date; or
- (c) prior to the termination of this Agreement, for any reason,

whichever is the earlier, in which event the Commissioners shall be entitled to permanently retain such withheld sums.

27.13 Where within 20 Operational Days of the date of the first payment by the Commissioner to the Provider of a sum withheld under clauses 27.10 the Provider produces evidence satisfactory to the Co-ordinating Commissioner that the relevant sums were withheld unjustifiably, then the Commissioners shall pay interest to the Provider on their respective sums withheld at the Default Interest Rate for the period of their withholding. If the Co-ordinating Commissioner does not accept the Provider's evidence, the Provider may refer the matter to dispute resolution under clause 26 (Dispute Resolution).

Data Quality Improvement Plan

27.14 The Parties may at any time during the term of this Agreement agree a Data Quality Improvement Plan (which shall be appended at Schedule 5 Part 4) setting out milestones and subject to the maximum monthly sums identified in clause 27.10, consequences for failing to meet such milestones. Where the Provider fails to meet a milestone by the agreed date for its completion, the Co-ordinating Commissioner may exercise the relevant agreed consequence.

28 CONTRACT MANAGEMENT, INFORMATION, REPORTING AND AUDIT

28.1 The Provider shall comply with the Contract Management provisions of Schedule 21 (Contract Management).

Records and Samples

- 28.2 The Provider shall during the term of this Agreement and for the period of three (3) years thereafter:
- (a) maintain such clinical records relating to the provision of the Services (including Patient identifiers and associated Test results, whether in hardcopy or electronic form) (“**Records**”);
 - (b) store and preserve the integrity of all Samples in such manner as the Commissioner may reasonably require;
 - (c) on request produce the Records and Samples for inspection by the Commissioner or, on receipt of reasonable notice, allow or procure for the Commissioner and/or its authorised representatives access to any premises where any such Records and Samples are stored for the purposes of inspecting and/or taking copies of and extracts from any such Records free of charge; and
 - (d) preserve the integrity of the Records and Samples in the possession or control of the Provider and all data which is used in, or generated as a result of, providing the Services and to prevent any corruption or loss of that data.

Financial Records

- 28.3 The Provider shall during the term of this Agreement and for the period of eighteen (18) months thereafter:
- (a) maintain such records relating to the calculation of the Prices under this Agreement (“**Financial Records**”) as the Commissioners may reasonably require in such form as the Commissioner may reasonably require (including any hardcopy or electronic form);
 - (b) on request produce the Financial Records for inspection by the Commissioners (or an appropriate third party) for the purposes of carrying out an audit of the Provider’s compliance with this Agreement, in relation to the Prices.

Performance Records

28.4 The Provider shall during the term of this Agreement and for the period of eighteen (18) months thereafter:

- (a) maintain such records relating to the performance by the Provider of its obligations under this Agreement ("**Performance Records**") as the Commissioners may reasonably require in such form as the Commissioners may reasonably require (including any hardcopy or electronic form);
- (b) on request produce the Performance Records for inspection by the Commissioners (or an appropriate third party) for the purposes of carrying out an audit of the Provider's compliance with this Agreement, including all activities carried out by the Provider, its performance, and the security and integrity of the Provider in providing the Services in under this Agreement.

Other Contract Management Provisions

28.5 At the Commissioners' request, the Provider shall attend review meetings with the Commissioners concerning the results of any inspection and shall act in accordance with all reasonable requests made by the Commissioners arising from any such inspection.

28.6 The Provider shall ensure that during any inspection of Records, Tests or Samples that the Commissioner and/or its authorized representatives receive all reasonable assistance and with access to all relevant Provider Staff, premises, systems, data and other information and records relating to this Agreement (whether manual or electronic) at the Facility and at all locations from which the Services are being performed and any other locations where the foregoing are located.

28.7 The provisions of this clause 28 are without prejudice to any other rights and obligations the Parties may have under this Agreement.

28.8 Clauses 28.24, 28.28, 28.30, 28.32 and 28.33 shall not apply if the Provider's failure to agree or comply with a Remedial Action Plan (as the case may be) is as a result of an act or omission of the Co-ordinating Commissioner or relevant Commissioner.

Contract Query

28.9 Where the Co-ordinating Commissioner or the Provider has a Contract Query it may issue ("**Issuing Party**") to the other party ("**Other Party**") a Contract Query Notice.

Excusing Notice

28.10 Where in the view of the Other Party:

- (a) the matter or matters giving rise to the Contract Query Notice may be clearly explained or justified; or
- (b) the matter or matters giving rise to the Contract Query Notice are:
 - (i) due in whole or in part to an act or omission by the Issuing Party; or
 - (ii) a direct result of the Other Party following the instructions of the Issuing Party; or
 - (iii) due to circumstances beyond the Other Party's reasonable control which do not constitute an Event of Force Majeure or a Major Incident,

then the Other Party may issue an Excusing Notice within 5 Operational Days of the date of the Contract Query Notice setting out its explanation based on the applicable reasons identified above.

28.11 The Issuing Party shall consider the contents of any Excusing Notice, and if the Issuing Party accepts the validity of the detailed reasons in the Excusing Notice, the Issuing Party shall cancel the Contract Query Notice in writing within 10 Operational Days of the date of the Contract Query Notice.

Contract Management Meeting

28.12 Subject to clause 28.11, the Parties shall hold a Contract Management Meeting within 10 Operational Days of the date of the Contract Query Notice unless otherwise agreed by the Parties in writing.

28.13 If no Excusing Notice is issued in respect of a Contract Query Notice or an Excusing Notice's contents are considered not to be valid by the Issuing Party at the Contract Management Meeting, in order to rectify the subject matter of the Contract Query Notice, the Parties shall agree either:

- (a) to implement a Remedial Action Plan, in which case clauses 28.18 to 28.33 inclusive shall apply; or

- (b) to conduct a joint investigation into the matters referred to in the Contract Query Notice, in which case, the Parties shall agree without limitation the terms of reference, the timescale for the investigation which shall be no longer than 2 months, and the appropriate clinical and/or non-clinical representatives from each Party who shall participate in such investigation (“**Joint Investigation**”), and clauses 27.16 and 27.17 shall apply to the Joint Investigation.

28.14 Where a Joint Investigation is to be undertaken under clause 28.13(b) the Parties may agree an Immediate Action Plan and where such plan is agreed the Immediate Action Plan shall be implemented concurrently with the Joint Investigation.

Joint Investigation

28.15 On completion of a Joint Investigation, the Parties shall produce and agree a JI Report which shall include (without limitation) a recommendation to be considered at the next Review meeting (under clause 10 (Review)) that either:

- (a) the Contract Query be closed; or
- (b) a Remedial Action Plan be agreed and implemented.

28.16 Either Party may call an emergency Review meeting under clause 10.6 to consider a JI Report (including its recommendations) and such Review meeting shall be held within the time limits set out in clause 10.6.

Remedial Action Plan

28.17 A Remedial Action Plan shall set out:

- (a) milestones and timescales within which performance shall be remedied;
- (b) the date by which each milestone must be completed; and
- (c) subject to the maximum sums identified in clause 28.21, the consequences for failing to meet each milestone by the specified date.

28.18 The Parties shall agree the contents of any Remedial Action Plan within:

- (a) 5 Operational Days of the Contract Management Meeting; or
- (b) 5 Operational Days of the Review meeting in the case of a Remedial Action Plan

recommended under clause 28.23.

- 28.19 Each Party shall implement or meet the milestones applicable to it in any Remedial Action Plan within the timescales set out in such plan.
- 28.20 Each Party (as relevant) shall detail progress made or developments under any Remedial Action Plan in accordance with the time intervals agreed in a Remedial Action Plan and such update reports shall be considered at the next Review meeting under clause 10 (Review).
- 28.21 If following implementation of a Remedial Action Plan:
- (a) the matters that gave rise to the relevant Contract Query Notice have been resolved, it should be noted in writing, within 5 Operational Days of the next Review meeting, that the Remedial Action Plan has been completed; or
 - (b) any matter that gave rise to the relevant Contract Query Notice remains in the reasonable opinion of either Party unresolved, nothing in this clause 28 shall prevent either Party (as applicable) issuing a further Contract Query Notice and the relevant provisions of this clause 28 shall apply to such Contract Query Notice.

Withholding Payment for Failure to Agree Remedial Action Plan

- 28.22 Subject to clause 28.8, if the Parties fail to agree a Remedial Action Plan within the applicable time period specified in clause 28.18, the Parties shall issue a joint notice to the Board of Directors of the Provider and Co-ordinating Commissioner (or where a joint notice is not agreed each Party shall notify its own Board of Directors) informing them of the failure to agree a Remedial Action Plan ("**RAP Failure to Agree Notice**").
- 28.23 If the Parties fail to agree a Remedial Action Plan within 10 Operational Days of the date of the RAP Failure to Agree Notice, the Co-ordinating Commissioner may instruct the Commissioners to withhold up to 2% of all the monthly sums payable by them under clause 9 (Prices and Payment) for each month the Remedial Action Plan is not agreed.
- 28.24 The Commissioners shall pay the Provider any sums withheld under clause 28.23 within 10 Operational Days of receiving the Provider's agreement to the Remedial Action Plan, which sums, subject to clause 28.30, shall be paid without interest.

Exception Reports

- 28.25 If either Party breaches a Remedial Action Plan and fails to remedy such breach within 5

Operational Days of its occurrence, the Provider or the Co-ordinating Commissioner (as the case may be) may issue a First Exception Report to the relevant Commissioner's or the Provider's Board of Directors (as the case may be) and the Co-ordinating Commissioner may also instruct the Commissioners to withhold payment from the Provider in accordance with clause 28.27.

28.26 If following receipt of the First Exception Report, the Board of Directors receiving such report fails to procure rectification of the breach or breaches of the Remedial Action Plan within the timescales indicated in the First Exception Report, the Co-ordinating Commissioner or the Provider (as the case may be) may issue a Second Exception Report to:

- (a) the relevant Commissioner's or the Provider's Board of Directors (as the case may be); and/or
- (b) any relevant Strategic Health Authority; and/or
- (c) CQC (if appropriate); and/or
- (d) Monitor (if applicable),

in order that each of them may take such steps as they think appropriate.

Withholding of Payment at First Exception Report for Breach of Remedial Action Plan

28.27 Subject to clause 28.8, the Co-ordinating Commissioner may from the date of issuing a First Exception Report and for each month the Provider's breach of the relevant Remedial Action Plan relating to such First Exception Report continues, instruct the Commissioners to withhold up to 5% of all the monthly sums payable by the Commissioners under clause 9 (Prices and Payment), in respect of each milestone not met in the relevant Remedial Action Plan, subject to a maximum monthly withholding of 5% of all the monthly sums payable by the Commissioners under clause 9 (Prices and Payment) in relation to each Remedial Action Plan.

28.28 The Commissioners shall pay the Provider any sums withheld under clause 28.27 within 10 Operational Days of a Review meeting confirming that the Remedial Action Plan has been implemented, which sums, subject to clause 28.30, shall be paid without interest.

Retention of Sums Withheld at Second Exception Report for Breach of Remedial Action Plan

28.29 Subject to clause 28.8 the Co-ordinating Commissioner may at the date of issuing any Second Exception Report in respect of a Provider's breach of a Remedial Action Plan, instruct the Commissioners to permanently retain any sums withheld pursuant to clause 28.27.

Unjustified Withholding or Retention of Payment

28.30 Where the Commissioners withhold under clauses 28.24 or 28.28 or retain under clause 28.29 a sum otherwise payable to the Provider, and within 20 Operational Days of the date of its withholding the Provider produces evidence satisfactory to the Co-ordinating Commissioner that the relevant sum was withheld or retained unjustifiably, then the Commissioners shall pay the withheld or retained sum to the Provider within 10 Operational Days of the date of the Co-ordinating Commissioner's acceptance of the Provider's evidence, together with interest on the withheld sum at the Default Interest Rate for the period of its withholding and, where applicable, interest on the retained sum at the Default Interest Rate for the period of its retention. If the Co-ordinating Commissioner does not accept the Provider's evidence, the Provider may refer the matter to dispute resolution under clause 26 (Dispute Resolution).

Retention of Sums Withheld on Expiry or Termination of this Agreement

28.31 Subject to clause 28.8 and without prejudice to any other provision in this clause 28, where the Provider fails to agree a Remedial Action Plan:

- (a) within 6 months of the relevant time period set out in clause 28.18 for agreeing a Remedial Action Plan; or
- (b) prior to the Expiry Date; or
- (c) prior to the termination of this Agreement, for any reason,

whichever is the earlier, the Co-ordinating Commissioner may instruct the Commissioners to permanently retain any withheld sums under clause 28.23.

28.32 Subject to clause 28.8 and without prejudice to any other provision in this clause 28, where the Provider fails to rectify a breach of a Remedial Action Plan:

- (a) prior to the Expiry Date; or
- (b) prior to the termination of this Agreement, for any reason,

whichever is the earlier, the Co-ordinating Commissioner may instruct the Commissioners to permanently retain any withheld sums under clauses 28.28.

29 SERVICE QUALITY REVIEW

29.1 The Provider shall for each month of this Agreement produce and in accordance with Schedule 5 Part 2 (National Requirements Reported Locally) deliver to the Co-ordinating Commissioner a report (the “**Service Quality Performance Report**”) detailing its performance against the Quality Requirements and including, without limitation:

- (a) details of all Quality Requirements satisfied; and
- (b) details of, and reasons for, any failure to meet the Quality Requirements; and
- (c) details of progress towards satisfying any Service Requirements, including details of all Service Requirements satisfied or not satisfied.

29.2 The Provider, unless agreed otherwise with the Co-ordinating Commissioner, shall submit each Service Quality Performance Report to the Co-ordinating Commissioner within 10 Operational Days of the end of the month to which it relates or as soon as practicable, whichever is the earlier.

29.3 The Provider and the Co-ordinating Commissioner shall review the Provider’s Service Quality Performance Report pursuant to clause 10 (Review) or as otherwise agreed.

30 SUSPENSION

30.1 A Suspension Event shall have occurred if:

- (a) the Co-ordinating Commissioner reasonably considers that a breach by the Provider of any obligation under this Agreement:
 - (i) may create an immediate and serious threat to the health or safety of any Patient; or
 - (ii) may result in a material interruption in the provision of any one or more of the Services; or
- (b) the Provider has received a Contract Query Notice in respect of a Service or Services within 12 months of having agreed to implement a Remedial Action Plan in respect of

the same issue with such Service or Services as is identified in the Contract Query Notice; or

- (c) clauses 30.1(a) and 30.1(b) do not apply, but the Co-ordinating Commissioner, acting reasonably, considers that the circumstances constitute an emergency, including an Event of Force Majeure affecting provision of a Service or Services; or
- (d) a Second Exception Report has been issued under clause 28.26 (Contract Management) and the Provider's Board of Directors has failed to rectify a breached Remedial Action Plan within the timescales indicated in that Second Exception Report; or
- (e) the Provider is prevented, or will be prevented, from providing a Service due to the termination, suspension, restriction or variation of any Consent; or
- (f) where the Provider is an NHS Foundation Trust, the Provider's Terms of Authorisation are amended such that the Provider is no longer able to provide the Services; or
- (g) the Co-ordinating Commissioner is advised in writing by the applicable SHA to suspend this Agreement in accordance with Guidance.

30.2 Where a Suspension Event occurs the Co-ordinating Commissioner:

- (a) may suspend the affected Service, or part of the Service, until the Provider demonstrates to the reasonable satisfaction of the Co-ordinating Commissioner that it is able to and will perform the suspended Service, or part of the Service (as applicable) to the required standard; and
- (b) shall promptly notify CQC, if appropriate, of such suspension.

30.3 The right to suspend a Service or part of a Service under clause 30.2 may only be exercised by the issue of a Suspension Notice by the Co-ordinating Commissioner to the Provider.

30.4 When the Co-ordinating Commissioner becomes reasonably satisfied that the Provider is able to and will perform the suspended Service, or part of the Service (as applicable) to the required standard, it may require the Provider to restore the provision of the suspended Service or part of the Service (as applicable) by issuing a Restoration Notice to the Provider.

30.5 The Provider must continue to comply with any steps that the Co-ordinating Commissioner

may reasonably specify in order to remedy a Suspension Event, even though the relevant suspension pursuant to clause 30.2(a) has been referred to dispute resolution under clause 26 (Dispute Resolution).

Consequences of Suspension

- 30.6 During the suspension of any Service, or part of a Service, under clause 30.2, the Provider shall not be entitled to claim or receive any payment for the suspended Service or part of the Service.
- 30.7 Except where suspension occurs by reason of an Event of Force Majeure, the Provider shall indemnify the Commissioners and keep the Commissioners indemnified in respect of any Losses directly and reasonably incurred by a Commissioner in respect of a suspension (including for the avoidance of doubt Losses incurred in commissioning the suspended Service or part of a Service from an alternative provider) and the Commissioners shall take all reasonable steps to minimise and mitigate such Losses.
- 30.8 On suspension of a Service, or part of a Service, the Provider shall for a reasonable period after service of the Suspension Notice:
- (a) co-operate fully with the Co-ordinating Commissioner and any successor provider of the suspended Service, or part of the Service in order to ensure continuity and a smooth transfer of the suspended Service, or part of the Service, to avoid any inconvenience or any risk to the health and safety of Patients or employees of the Commissioners or members of the public, and for these purposes the Provider may be required by the Co-ordinating Commissioner to agree with the Co-ordinating Commissioner, and with any alternative successor provider a transition plan; and
 - (b) at the reasonable request of the Co-ordinating Commissioner and at the cost of the Provider:
 - (i) promptly render all reasonable assistance and provide all information necessary to effect an orderly assumption of the suspended Service, or part of the Service by an alternative successor provider; and
 - (ii) deliver to the Co-ordinating Commissioner all materials, papers, documents and operating manuals owned by the Commissioners and utilised by the Provider in the provision of the suspended Service or part of the Service,

and the Parties shall use all reasonable endeavours to minimise any inconvenience caused to or likely to be caused to Patients or prospective patients as a result of the suspension of the Service or part of the Service.

30.9 If it is determined, pursuant to clause 26 (Dispute Resolution), that the Co-ordinating Commissioner acted unreasonably in suspending a Service, or part of a Service, the relevant Commissioner shall indemnify and keep the Provider indemnified in respect of any Losses directly and reasonably incurred by the Provider in respect of such suspension, and the Provider shall take all reasonable steps to minimise and mitigate such Losses.

30.10 [During any period of suspension of a Service, or part of a Service:]

- (a) the Provider receives no further requests for Tests which require the suspended Service or part of the Service;
- (b) the Provider shall cease to accept any requests for Tests which require the suspended Service or part of the Service; and
- (c) the Parties shall co-operate fully with the intention of ensuring that:
 - (i) the suspended Service or part of the Service is commissioned without delay from an alternative provider; and
 - (ii) there is no interruption in the availability to the relevant Commissioner of the Mandatory Goods and Services.

31 TERMINATION

31.1 Either the Co-ordinating Commissioner or the Provider may terminate this Agreement by written notice, with immediate effect, if and to the extent that one of the Commissioners or the Provider suffers an Event of Force Majeure and such Event of Force Majeure persists for more than 20 Operational Days without the Parties agreeing alternative arrangements.

31.2 Subject to any express provision of this Agreement to the contrary (including without limitation the provisions relating to withholding and/or retention of payment clauses 27.11, 27.12, 27.13, 28.7, 28.24, 28.28, 28.32, 28.33 and paragraph 6 of Schedule 3 Part 1 (Managing Activity and Requests))), and provided that the Provider has complied with its obligations under clause 9 (Prices and Payment), if at any time the aggregate undisputed amount due to the Provider from the Co-ordinating Commissioner and/or any one or more of

its Associates exceeds:

- (a) 25% of the Annual Contract Value; or
- (b) where there is no applicable Annual Contract Value, the equivalent to the Provider of 3 months' average income under this Agreement,

and if full payment is not made by the Commissioner(s) within 20 Operational Days of receipt of written notice from the Provider requiring payment to be made, the Provider may terminate this Agreement in respect of the whole (but not part only) of the relevant Services by serving written notice to take effect immediately.

31.3 The Co-ordinating Commissioner may terminate this Agreement, any Services or part of the Services, with immediate effect, by written notice to the Provider if:

- (a) the Provider ceases to carry on its business or substantially the whole of its business; or
- (b) a Provider Insolvency Event of Default occurs; or
- (c) subject to the provisions of clauses 28 (Contract Management), the Provider is in persistent or repetitive breach of the Quality Requirements or regulatory compliance standards issued by CQC or, if applicable, Monitor; or
- (d) the Provider is in persistent or repetitive breach or other material breach of any obligations under Schedule 3 Part 1 (Managing Activity and Requests) and such breach has not been remedied in accordance with this Agreement; or
- (e) pursuant to clause 28.26 two or more Second Exception Reports are issued to the Provider within any rolling 6 month period which are not disputed by the Provider, or if disputed, are upheld under the procedure for dispute resolution in clause 26 (Dispute Resolution); or
- (f) the Provider fails to comply with clause 45.2 or clause 45.5 and the Provider has failed to remedy such breach within 20 Operational Days of receipt of a notice from the Co-ordinating Commissioner identifying such breach; or
- (g) there is:
 - (i) a Provider Change in Control and, within 30 Operational Days following

receipt of the information provided to the Co-ordinating Commissioner in the Change in Control Notification, the Co-ordinating Commissioner reasonably considers that, as a result of such Provider Change in Control, there is (or is likely to be) an adverse effect on the ability of the Provider to provide the Services in accordance with this Agreement (and, in reaching such conclusion regarding the effect that the Provider Change in Control may have on the ability of the Provider to provide the Services, the Co-ordinating Commissioner may consider any factor, in its absolute discretion, that it considers relevant including any concerns or issues raised by CQC (or other relevant regulatory body), Monitor or the Charity Commission); or

- (ii) a breach of clause 45.9(a); or
 - (iii) a breach of clause 45.9(b) and the Provider has failed to replace the Material Sub-contractor within the relevant period specified in the notice served upon the Provider pursuant to clause 45.10; or
 - (iv) a Material Sub-contractor Change in Control and the Provider has failed to replace the Material Sub-contractor within the relevant period specified in the notice served upon the Provider pursuant to clause 45.8(c); or
- (h) the Conditions Precedent are not met by the Longstop Date; or
- (i) the Provider:
- (i) fails to obtain any Consent; or
 - (ii) loses any Consent; or
 - (iii) has any Consent varied or restricted,
- the effect of which might reasonably be considered by the Co-ordinating Commissioner to have a material adverse effect on the provision of the Services; or
- (j) the Provider materially fails to comply with the requirements of clause 23 (NHS Branding, Marketing and Promotion); or
- (k) the Provider has breached any of its obligations under this Agreement and such breach materially and adversely affects the performance of the Provider's obligations under this Agreement, and the Provider has failed to remedy such breach(es) within

40 Operational Days of receipt of notice from the Co-ordinating Commissioner identifying such breach(es); or

(l) the Provider has breached the terms of clause 33 (Prohibited Acts); or

(m) any of the Provider's registrations are cancelled by CQC.

31.4 In addition to the Co-ordinating Commissioner's rights under clause 31.3 (and without limitation to any other rights it may have under this Agreement), if the Provider is an NHS Foundation Trust the Co-ordinating Commissioner may terminate this Agreement, with immediate effect, by written notice to the Provider, if:

(a) an Order is made pursuant to section 54 of the 2006 Act to dissolve the Provider; or

(b) Monitor exercises any one or more of the powers in sections 52(3) or 52(4) of the 2006 Act or requires action under section 53 of the 2006 Act; or

(c) Monitor transfers the Provider's responsibility for Mandatory Goods and Services and/or Protected Assets, and such transfer materially affects the Provider's ability to perform its obligations under this Agreement; or

(d) the Provider's Terms of Authorisation are amended such that the Provider is no longer able to provide the Services; or

(e) the Provider applies to Monitor for its dissolution and transfer of its property and liabilities to another body corporate pursuant to section 56 of the 2006 Act.

31.5 The right to terminate under clause 31.4 shall not apply when the Secretary of State indicates to the Co-ordinating Commissioner in writing his intention to make an Order, or Monitor indicates to the Co-ordinating Commissioner in writing its intention to issue an Authorisation for an NHS Foundation Trust to offer a complete novation of this Agreement to a successor provider. When such Order is made or Authorisation is issued (and the successor provider is able and willing), the Commissioners shall enter into a novation agreement with the successor provider.

31.6 If the Order is not made or the Authorisation is not issued pursuant to clause 31.5 within 3 months, or the successor provider is not willing to enter into a novation agreement within a further month, the Co-ordinating Commissioner may terminate this Agreement, with immediate effect, by written notice to the Provider.

31.7 If the Co-ordinating Commissioner becomes entitled to terminate this Agreement under this clause 31 then, without prejudice to any other right or remedy it may have under this Agreement:

- (a) the Co-ordinating Commissioner may instead of terminating this Agreement elect to issue a written notice to the Provider terminating any of the Services and/or part of the Services, and such notice shall take immediate effect; and
- (b) each Commissioner may itself provide or procure the provision of the terminated Services.

In exercising its rights under this clause 31.7, each of the Commissioners shall have due regard for other Services provided by the Provider, and in particular for the effect on the Provider's ability to maintain the provision of relevant Mandatory Goods and Services.

31.8 The Provider may terminate this Agreement, with immediate effect, by written notice to the Co-ordinating Commissioner if any Commissioner is in persistent material breach of its obligations under this Agreement which has a material and adverse effect on the ability of the Provider to provide the Services, and the Commissioner fails to remedy such breach within 40 Operational Days of the Co-ordinating Commissioner's receipt of the Provider's notice identifying the breach.

31.9 Where a Service becomes a duly designated service during the term of this Agreement and the Provider is unable or fails to meet the designated service standards, the Commissioner may terminate that part of this Agreement which relates to that designated service by written notice with immediate effect.

31.10 Expiry or termination of this Agreement shall not affect any rights or liabilities of the Parties that have accrued prior to the date of expiry or termination.

32 CONSEQUENCES OF EXPIRY OR TERMINATION

32.1 Except where termination occurs under clauses 31.1, 31.2, 31.8 or 34.10(b), if as a result of termination of this Agreement, or termination of any Services or part of the Services in accordance with this Agreement, any Commissioner either procures the Services or part of them from an alternative provider or executes the Services or part of them itself, and the reasonable cost of doing so exceeds the amount that would have been payable to the Provider for providing the same Services or part of them, then that Commissioner, acting

reasonably, shall be entitled to recover the excess cost, together with all reasonable administration costs, in addition to any other sums payable by the Provider to the Co-ordinating Commissioner in respect of any termination, from the Provider for a period of 6 months after termination.

32.2 In the event that this Agreement expires or is terminated by reason of an Event of Force Majeure, each Commissioner shall pay the Provider pro rata for any Services delivered by the Provider following such expiration or termination in accordance with clause 9 (Prices and Payment) until the Provider ceases to provide the Services.

32.3 On termination of this Agreement or termination of any Services or part of the Services, and where reasonable and appropriate on the expiry of this Agreement, the Provider shall for a reasonable period before (during any applicable notice period) and after such termination or expiry:

(a) co-operate fully with the Co-ordinating Commissioner and any successor provider of the Services or part of the Services that have been terminated in order to ensure continuity and a smooth transfer of the Services or such part of the Services, and to avoid any inconvenience or any risk to the health and safety of Patients or employees of any Commissioner or members of the public and to that end the Provider may agree with the Co-ordinating Commissioner, and where appropriate with any successor provider, a transition plan; and

(b) at the reasonable cost and reasonable request of the Co-ordinating Commissioner:

(i) promptly render all reasonable assistance and information to the extent necessary to effect an orderly assumption of the Services or such part of the Services by a successor provider;

(ii) deliver to the Co-ordinating Commissioner all materials, papers, documents and operating manuals owned by the Commissioners and utilised by the Provider in the provision of any Services or such part of the Services which have been terminated; and

(iii) in so far as it is in the power of the Provider to do so, use all reasonable efforts to obtain the consent of third parties to the assignment, novation or termination of existing contracts between the Provider and any third party which relate to or are associated with the Services or such part of the

Services which have been terminated.

- 32.4 Each Commissioner shall pay the Provider pro rata for any Services properly delivered by the Provider following termination of this Agreement, or termination of any Services or any part of the Services until the Provider ceases to provide the Services or such part of the Services and, for the avoidance of doubt, clause 9 (Prices and Payment) (including without limitation the provisions concerned with reconciliation) shall survive termination of this Agreement, whether in connection with such Services delivered before or after termination.
- 32.5 On expiry or termination of this Agreement or termination of any Services or any part of the Services:
- (a) the Commissioners shall use reasonable efforts to ensure that no further requests for Tests which are sent to the Provider which require any expired or terminated Services or part of the Services;
 - (b) the Provider shall cease to accept any requests for Tests that require any expired or terminated Services or part of the Services; and
 - (c) subject to any appropriate arrangements made under clause 32.3(a), the Provider shall immediately cease to administer any Tests requiring the terminated or expired Services.
- 32.6 Where any termination of this Agreement or termination of any Services or part of the Services takes place with immediate effect in accordance with clause 31, and therefore the Provider is not able or is not permitted to continue to provide the Services or part of the Services under any transition plan, or implement arrangements for the transition to a successor provider, then the Provider shall co-operate fully with the Co-ordinating Commissioner and any relevant Commissioners to ensure that:
- (a) the relevant Services are, or any part of the Services is commissioned without delay from an alternative provider; and
 - (b) there is no interruption in the availability to the relevant Commissioners of the Mandatory Goods and Services.
- 32.7 The provisions that survive the expiry or termination of this Agreement are set out in clause 48.

32.8 If as part of any procurement exercise for the award of this Agreement any exit arrangements are agreed and/or it was agreed that costs on termination (over and above any other termination sums payable in accordance with the terms of this Agreement) shall be payable by any of the Parties (as appropriate) upon termination of this Agreement or any Service or any part of a Service, and the relevant exit arrangements and/or termination costs have been set out in Schedule 8, such exit arrangements and/or agreed termination costs shall be completed and/or paid on the terms set out in Schedule 8.

33 PROHIBITED ACTS

33.1 The Provider shall not do any of the following ("**Prohibited Acts**"):

- (a) offer, give, or agree to give the Co-ordinating Commissioner (or any of its or their officers, employees or agents) any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining of performance of this Agreement or any other contract with the Provider, or for showing or not showing favour or disfavour to any person in relation to this Agreement or any other contract with the Provider; and
- (b) in connection with this Agreement, pay or agree to pay any commission, other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the Co-ordinating Commissioner.

33.2 If the Provider or its employees or agents (or anyone acting on its or their behalf) commits any Prohibited Act or commits any offence under the Prevention of Corruption Acts 1889 – 1916 with or without the knowledge of the Co-ordinating Commissioner in relation to this Agreement, the Co-ordinating Commissioner shall be entitled:

- (a) to exercise its right to terminate under clause 31.3(l) and to recover from the Provider the amount of any loss resulting from the termination; and
- (b) to recover from the Provider the amount or value of any gift, consideration or commission concerned; and
- (c) to recover from the Provider any loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence.

34 VARIATIONS

- 34.1 This Agreement may not be amended other than in accordance with this clause 34 (Variations).
- 34.2 The Parties:
- (a) subject to clause 45.4 may agree to vary any part of the Variable Schedules (as defined in Schedule 1); and
 - (b) shall not vary any provision of this Agreement that is not a Variable Schedule without the approval of the Secretary of State or the Department of Health.
- 34.3 Subject to clauses 34.2 and 45.4, the provisions of this Agreement may be varied at any time by agreement in writing, signed by the Co-ordinating Commissioner's representative on behalf of the Commissioners, and by the Provider's representative on behalf of the Provider.
- 34.4 Subject to clause 45.4, where any Party, with a view to reaching agreement on a proposed Variation requests that it be considered in detail, then the provisions of Schedule 6 Part 1 shall apply.
- 34.5 All requests for Variations shall be made in writing and all Variations shall be recorded in Schedule 6 Part 2.
- 34.6 Each Party that requests a Variation shall have regard to its impact on the other Services, and in particular the Mandatory Goods and Services.
- 34.7 Where a Co-ordinating Commissioner proposed Variation would have the effect of increasing the Annual Contract Value, then that increase shall be in line with the Prices agreed under clause 9 (Prices and Payment). In all other circumstances agreement over such Variation must include agreement in respect of the costs associated with implementing it.
- 34.8 Where a Variation would have a cost implication for the Commissioners, including for the avoidance of doubt and without limitation, additional activity, new treatments, drugs or technologies, then:
- (a) the Provider shall provide a full and detailed cost and benefit analysis of the requested or proposed Variation; and
 - (b) the Co-ordinating Commissioner shall, after consultation with the Provider, in its

absolute discretion have the right to refuse or withdraw the requested or proposed Variation; and

- (c) the Commissioners shall have no liability to the Provider for any costs arising from the requested or proposed Variation should the Provider implement it other than in accordance with this Agreement.

34.9 Where a Service Variation is agreed which involves the withdrawal of a Service and the Provider withdraws the Service prior to the date agreed for such withdrawal then the Provider shall be liable to the Commissioners for all reasonable costs and losses directly attributable to the early withdrawal of such Service. Where a Service Variation is agreed which involves the withdrawal of a Service and a Commissioner ceases to commission the Service prior to the date agreed for such withdrawal then the Commissioner shall be liable to the Provider for all reasonable costs and losses directly attributable to the early cessation of such commissioning.

34.10 Where the Parties fail to agree a National Variation, having followed the procedure in Schedule 6 Part 1, the Co-ordinating Commissioner may (at its option):

- (a) terminate any one or more of the Services by giving the Provider not less than 3 months' written notice, or 6 months' written notice where the Service Variation is likely to have a material adverse effect on Staff, following the issue of a notice that such Service Variation is refused; or
- (b) terminate this Agreement on giving the Provider not less than 3 months' written notice following the issue of a notice that a National Variation is refused.

34.11 Where the Parties fail to agree a Service Variation, having followed the procedure in Schedule 6 Part 1, then (unless the circumstances in clause 34.12 apply):

- (a) terminate any one or more of the Services affected by the Service Variation pursuant to Clause 34.10(a); or
- (b) the Co-ordinating Commissioner may terminate this Agreement pursuant to clause 34.10(b).

34.12 The right of the Co-ordinating Commissioner under clause 24.10(b) to terminate a Service or part of a Service shall not apply where:

- (a) the proposed Service Variation is substantially a proposal that a Service should be performed for a different price from that agreed under this Agreement and without material change to the delivery of that Service commensurate with such proposed change in price; or
- (b) the proposed Service Variation does not reasonably relate to a variation reflecting:
 - (i) the assessment by a Commissioner/Commissioners of the availability of alternative providers and demand for Services; and/or
 - (ii) the joint assessment of the Provider and a Commissioner of the quality and clinical viability of the relevant Service/s and the Services Environment.

35 WARRANTIES

35.1 The Provider warrants to the Commissioners that:

- (a) it has full power and authority to enter into this Agreement and all governmental or official approvals and consents and all necessary Consents have been obtained and are in full force and effect;
- (b) its execution of this Agreement does not and will not contravene or conflict with its constitution, Terms of Authorisation, any Law, or any agreement to which it is a party or which is binding on it or any of its assets;
- (c) the copies of all documents supplied to the Commissioners or any of their advisers by or on its behalf and listed in Schedule 14 (Documents Relied On) from time to time are complete and their contents are true;
- (d) it has the right to permit disclosure and use of Confidential Information for the purpose of this Agreement;
- (e) to the best of its knowledge, nothing will have, or is likely to have, a material adverse effect on its ability to perform its obligations under this Agreement;
- (f) any Material Sub-contractor shall have and shall maintain all Indemnity Arrangements and Consents and deliver the subcontracted services in accordance with the Provider's obligations under this Agreement; and
- (g) all information supplied by it to the Commissioners during the award procedure

leading to the execution of this Agreement is, to its reasonable knowledge and belief, true and accurate and it is not aware of any material facts or circumstances which have not been disclosed to the Commissioners which would, if disclosed, be likely to have an adverse effect on a reasonable public sector entity's decision whether or not to contract with the Provider substantially on the terms of this Agreement.

35.2 Each Commissioner warrants to the Provider that:

- (a) it has full power and authority to enter into this Agreement and all necessary governmental or official approvals and consents have been obtained and are in full force and effect;
- (b) its execution of this Agreement does not and will not contravene or conflict with its constitution, any Law, or any agreement to which it is a party or which is binding on it or any of its assets;
- (c) the copies of all documents supplied to the Provider or any of its advisers by it or on its behalf and listed in Schedule 14 (Documents Relied On) from time to time are complete and their contents are true;
- (d) it has the right to permit disclosure and use of Confidential Information for the purpose of this Agreement; and
- (e) to the best of its knowledge, nothing will have, or is likely to have, a material adverse effect on its ability to perform its obligations under this Agreement.

35.3 The warranties set out in this clause 34 (Warranties) are given on the Effective Date and repeated on every day during the term of this Agreement.

36 NOTICES

36.1 Any notices given under this Agreement shall be in writing and shall be served by hand, post, or electronic mail by sending the same to the address for the relevant party set out in Schedule 17 (Notices).

36.2 Notices:

- (a) by post shall be effective upon the earlier of actual receipt, or 5 Operational Days after mailing;

- (b) by hand shall be effective upon delivery;
- (c) by e-mail shall be effective when sent in legible form, but only if, following transmission, the sender does not receive a non-delivery message.

37 FORCE MAJEURE

- 37.1 Where a Party is (or claims to be) affected by an Event of Force Majeure, it shall take all reasonable steps to mitigate the consequences of it, resume performance of its obligations as soon as practicable and use all reasonable efforts to remedy its failure to perform.
- 37.2 Subject to clause 37.1, the Party claiming relief shall be relieved from liability under this Agreement to the extent that because of the Event of Force Majeure it is not able to perform its obligations under this Agreement.
- 37.3 The Co-ordinating Commissioner shall not be entitled to exercise its rights relating to withholding and/or retention (under clauses 27.10, 27.11, 27.12 28.24, 28.28, 28.30, 28.32, 28.33 and paragraph 6 of Schedule 3 Part 1 (Managing Activity and Requests)), to the extent that the circumstances giving rise to such rights arise as a result of an Event of Force Majeure.
- 37.4 The Party claiming relief shall serve an initial written notice on the other Party immediately it becomes aware of the Event of Force Majeure. This initial notice shall give sufficient details to identify the particular event. The Party claiming relief shall then serve a detailed written notice within a further 5 Operational Days. This detailed notice shall contain all relevant available information relating to the failure to perform as is available, including the effect of the Event of Force Majeure, the mitigating action being taken and an estimate of the period of time required to overcome it and resume full delivery of Services.

38 EMERGENCY PREPAREDNESS AND RESILIENCE INCLUDING MAJOR INCIDENTS

- 38.1 The Parties shall contribute to and co-operate in the development and review of any relevant Major Incident Plan.
- 38.2 The Provider and each Commissioner shall have and maintain an up-to-date Emergency Response Plan, to which the provisions of clause 17 (Procedures and Protocols) shall apply.
- 38.3 If required, the Parties shall assist in the development of and participate in joint planning and training exercises connected with any relevant Major Incident Plans and shall participate in

joint planning and training exercises for emergency preparedness with other NHS organisations, contracted healthcare providers, local authorities and other local organisations.

38.4 The Provider shall act in accordance with national and local civil contingency plans and comply with the Civil Contingencies Act 2004 to the extent applicable.

38.5 If there is a Major Incident the Parties shall:

(a) comply with any relevant Major Incident Plan; and

(b) implement their Emergency Response Plans,

and the provisions of Schedule 2 Part 2 (Major Incidents) shall apply as appropriate and where relevant.

38.6 In the event of a Major Incident the Provider shall provide the Commissioners with such further assistance as may reasonably be required by the Commissioners to deal with the Major Incident, and the right of any Commissioner to withhold or retain sums under clauses 28.7 and 28.24, 28.28, 28.30, 28.32 and 28.33 and to suspend under clause 30.2 shall not apply where the relevant right to withhold, retain or suspend has arisen as a result of the Provider complying with its obligations under this clause 38.

38.7 In the event of a Major Incident the Commissioners shall provide the Provider with such further assistance as may reasonably be required by the Provider to deal with the Major Incident.

38.8 The Provider, where appropriate, shall have plans to manage surges in activity.

39 NHS COUNTER-FRAUD AND SECURITY MANAGEMENT

39.1 Where the Provider is either an NHS Trust, or an NHS Foundation Trust or is otherwise an NHS Body, it shall comply with Schedule 13 (NHS Counter-fraud and Security Management) as amended from time to time.

40 THIRD PARTY RIGHTS

40.1 A person who is not a Party to this Agreement has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce or enjoy the benefit of this Agreement, provided that:

- (a) to the extent that this Agreement applies in their favour, it may be enforced by:
- (i) a person who is the Provider's employee and is performing the Services for the Provider, where the matter to be enforced or the benefit to be enjoyed arises under clause 12, other than clauses 12.2 and 12.3(b); and
 - (ii) the Secretary of State; and
 - (iii) the Department of Health; and
 - (iv) any relevant Strategic Health Authority; and
 - (v) CQC; and
 - (vi) Monitor; and
 - (vii) the Counter Fraud and Security Management Service; and
 - (viii) the National Audit Office; and
 - (ix) the Audit Commission; and
 - (x) any PCT.

40.2 Subject to clause 34.2(b), the rights of the Parties to terminate, rescind or agree any Variation, waiver or settlement under this Agreement are not subject to the consent of any person that is not a party to this Agreement.

41 WAIVER

41.1 Any relaxation or delay of any Party in exercising any right under this Agreement shall not be taken as a waiver of that right and shall not affect the ability of that Party subsequently to exercise that right.

42 ENTIRE AGREEMENT

42.1 This Agreement constitutes the entire agreement and understanding of the Parties and supersedes any previous agreement between the Parties relating to the subject matter of this Agreement, except for any contract entered into between the Commissioners and the Provider to the extent that it relates to the same or similar services and is designed to remain effective until the Service Commencement Date.

42.2 Each of the Parties acknowledges and agrees that in entering into this Agreement it does not rely on and shall have no remedy in respect of any statement, representation, warranty or understanding (whether negligently or innocently made) of any person (whether a party to this Agreement or not) other than as expressly set out in this Agreement as a warranty or in any document agreed by the Parties to be contractually binding and listed in Schedule 14 (Documents Relied On).

42.3 Nothing in this clause 42 shall exclude any liability for fraud or any fraudulent misrepresentation.

43 SEVERABILITY

43.1 If any provision or part of any provision of this Agreement is declared invalid or otherwise unenforceable, the provision or part of the provision as applicable shall be severed from this Agreement and this shall not affect the validity and/or enforceability of the remaining part of the provision or other provisions.

44 ASSIGNMENT AND SUB-CONTRACTING

44.1 Subject to clause 44.4, the Provider shall not assign, delegate, sub-contract, transfer, charge or otherwise dispose of all or any of its rights or obligations under this Agreement without the prior written consent of the Co-ordinating Commissioner.

44.2 No Commissioner shall assign, delegate, sub-contract, transfer, charge or otherwise dispose of all or any of its rights or obligations under this Agreement without the prior written consent of the Provider, except that the Commissioners may assign, delegate, sub-contract, transfer, charge or otherwise dispose of all or any of their rights and/or obligations under this Agreement without the prior written consent of the Provider to any appropriate body or organisation identified in the Health and Social Care Bill, and the Provider shall promptly execute any documents necessary to give effect to such transfer.

44.3 Notwithstanding clause 20 (Confidential Information of the Parties), a Commissioner that assigns, delegates, sub-contracts, transfers, charges or otherwise disposes of all or any of its rights or obligations under this Agreement may disclose to the assignee any information in its possession that relates to this Agreement or its subject matter, the negotiations relating to it and the Provider.

44.4 The Provider is permitted to provide the Services using, or using the assistance of, the

Material Sub-contractors specified in Schedule 10 (Provider's Material Sub-contractors).

- 44.5 The Provider shall be responsible for the performance of and shall be liable to the Commissioners for the acts and omissions of its sub-contractors. The Provider shall ensure that any sub-contractor meets all Quality Requirements and complies with all quality assurance measures required of the Provider under this Agreement.
- 44.6 The Provider shall be responsible for the performance of and shall be liable to the Commissioners for the acts and omissions of any other party to which it may assign, transfer or otherwise dispose of any obligation under this Agreement ("New Party") as if they were the acts or omissions of the Provider, unless:
- (a) the Provider has obtained the prior written consent of the Co-ordinating Commissioner in accordance with clause 44.1; and
 - (b) the terms of such assignment, transfer or disposal have been approved and accepted by the New Party so that the New Party is liable to the Commissioners for its acts and omissions.
- 44.7 This Agreement shall be binding on and shall be to the benefit of the Provider and each Commissioner and their respective successors and permitted transferees and assigns.
- 44.8 Where the Provider enters into a sub-contract with a supplier or contractor for the purpose of performing any of its obligations under the Agreement, it shall ensure that a provision is included in such a sub-contract which requires payment to be made of all sums due by the Provider to the sub-contractor within a specified period not exceeding 30 days from the receipt of a valid invoice.

45 CHANGE IN CONTROL

45.1 This clause 45 applies to any:

- (a) Provider Change in Control; and/or
- (b) Material Subcontractor Change in Control,

but this clause 45 shall not apply to a Change in Control of a company which is a Public Company.

45.2 The Provider shall,

- (a) as soon as possible upon, and in any event within 5 Operational Days following, a Provider Change in Control; and/or
- (b) immediately upon becoming aware of a Material Sub-contractor Change in Control, notify the Co-ordinating Commissioner of such Change in Control and submit to the Co-ordinating Commissioner a completed Change in Control Notification.

45.3 If the Provider indicates in the Change in Control Notification an intention or proposal to make any changes as a result of or in connection with such Change in Control, then to the extent that such intended or proposed changes shall require a change to the terms of this Agreement in order to be effective, such intended or proposed change shall only be effective when a Variation is made in accordance with clause 34 (Variations). The Co-ordinating Commissioner shall not and shall not be deemed, by a failure to respond or comment on the Change in Control Notification, to have either assented to or to otherwise have waived its rights pursuant to clause 34 (Variations) or Schedule 6 (Variations) in respect of any such intended or proposed change.

45.4 If the Provider does not specify in the Change in Control Notification an intention or proposal to make a change, which would or would be likely to have an adverse effect on the Provider's ability to provide the Services in accordance with this Agreement as a result of or in connection with such Change in Control, then, unless the Co-ordinating Commissioner shall provide its written consent to the relevant action, the Provider shall not be entitled to a Service Variation in respect of such proposed change for a period of 6 months from the date of such Change in Control Notification.

45.5 If the Provider does not specify in the Change in Control Notification an intention or proposal to sell or otherwise dispose of any legal or beneficial interest in the Provider's Premises as a result of or in connection with such Change in Control then, unless the Co-ordinating Commissioner shall provide its written consent to the relevant action, the Provider shall:

- (a) procure that there is no sale or other disposal of the legal or beneficial interest in the Provider's Premises which would or would be likely to have an adverse effect on the Provider's ability to provide the Services in accordance with this Agreement; and
- (b) continue providing the Services from the Provider's Premises,
- (c) in each case for a period of 12 months from the date of such Change in Control Notification. The provisions of this clause 45.5 shall not apply to an assignment by

way of security or the grant of any other similar rights by the Provider consequent upon a financing or re-financing of the transaction resulting in Change of Control.

45.6 Without prejudice to clause 45.2, the Provider shall supply (and shall use its reasonable endeavours to procure that a Material Sub-contractor shall supply) to the Co-ordinating Commissioner, such further information relating to the Change in Control as the Co-ordinating Commissioner may reasonably request, provided that the Co-ordinating Commissioner makes any such request within 20 Operational Days of receiving the Change in Control Notification.

45.7 The Provider shall use its reasonable endeavours to ensure that the terms of its contract with any Material Sub-contractor shall include a provision obliging the Material Sub-contractor to inform the Provider in writing upon, and in any event within 5 Operational Days of, a Material Sub-contractor Change in Control in respect of such Material Sub-contractor.

45.8 If:

- (a) there is a Material Sub-contractor Change in Control; and
- (b) following consideration of the information provided to the Co-ordinating Commissioner in the Change in Control Notification or pursuant to clause 45.6, the Co-ordinating Commissioner reasonably considers that, as a result of such Material Sub-contractor Change in Control, there is (or is likely to be) an adverse effect on the ability of the Provider and/or the Material Sub-contractor to provide Services in accordance with this Agreement (and, in reaching such conclusion, the Co-ordinating Commissioner may consider any factor, in its absolute discretion, that it considers relevant to the provision of Services),

then:

- (c) the Co-ordinating Commissioner may, by serving a written notice upon the Provider, require the Provider to replace the relevant Material Sub-contractor within 10 Operational Days (or such other period as the Co-ordinating Commissioner may, acting reasonably, consider appropriate taking into account the interests of Patients and the need for the continuity of Services), and such other period shall be specified in the written notice or notified to the Provider as soon as practicable thereafter; and
- (d) the Provider shall replace the relevant Material Sub-contractor within the relevant

period specified in the notice served by the Co-ordinating Commissioner pursuant to clause 45.8(c); and

- (e) for the avoidance of doubt, the provisions of clause 44 (Assignment and Sub-contracting) shall apply in relation to such replacement Material Sub-contractor and, upon the granting of the consent referred to in clause 44.1 or 44.2, the provisions of Schedule 10 Part 2 shall be amended accordingly.

45.9 Notwithstanding any other provision of this Agreement, a Restricted Person shall not, and:

- (a) the Provider shall not permit a Restricted Person to, at any time hold five (5) per cent or more of the total value of any Security in the Provider or in the Provider's Holding Company or any of the Provider's subsidiaries (as defined in the Companies Act 2006); and
- (b) the Provider shall not permit (and shall procure that a Material Sub-contractor shall not at any time permit) a Restricted Person to, at any time hold five (5) per cent or more of the total value of any Security in a Material Sub-contractor or in any Holding Company or any of the subsidiaries (as defined in the Companies Act 2006) of a Material Sub-contractor.

45.10 If the Provider breaches clause 45.9(b), the Co-ordinating Commissioner may by serving a written notice upon the Provider, require the Provider to replace the relevant Material Sub-contractor:

- (a) within 5 Operational Days; or
- (b) within such other period specified in the written notice (including immediately), where the Co-ordinating Commissioner reasonably considers that such other period is necessary or appropriate (taking into account any factors which the Co-ordinating Commissioner considers relevant in its absolute discretion, including without limitation, the interests of Patients and the need for the continuity of Services), and

the Provider shall replace the relevant Material Sub-contractor within the relevant period specified in such notice.

45.11 Nothing in this clause 45 shall prevent or restrict the Provider from discussing with the Co-ordinating Commissioner a proposed Change in Control in advance of the same occurring. In such circumstances, all and any such information provided to or received by the Co-

ordinating Commissioner in relation to such proposed Change in Control shall be Confidential Information for the purposes of clause 20 (Confidential Information of the Parties) of this Agreement.

45.12 Subject to the Law and to the extent reasonable the Parties shall co-operate in any public announcements arising out of a Change in Control.

46 EXCLUSION OF PARTNERSHIP

46.1 Nothing in this Agreement shall create a partnership or joint venture or relationship of employer and employee or principal and agent between any Commissioner and the Provider.

47 NON-SOLICITATION

47.1 During the life of this Agreement neither the Provider nor any Commissioner shall solicit any medical, clinical or nursing staff engaged or employed by the other without the other's prior written consent.

47.2 Subject to Guidance, it shall not be considered to be a breach of the obligation under clause 47.1 where an individual becomes an employee of a Party as a result of a response by that individual to an advertisement placed by or on behalf of the relevant Party for the recruitment of clinical or nursing staff or consultants and where it is apparent from the wording of the advertisement, the manner of its publication or otherwise that the advertisement was equally likely to attract applications from individuals who were not employees of the relevant Party.

48 PROVISIONS SURVIVING TERMINATION

Any rights, duties or obligations of any of the Parties which are expressed to survive, or which otherwise by necessary implication survive the expiry or termination for any reason of this Agreement, together with all indemnities, shall continue after such expiry or termination, subject to such limitations of time as are expressed in this Agreement. For the avoidance of doubt (and without limiting the scope of this clause), the Parties agree that the provisions of clause 9 (Prices and Payment), clause 11 (Complaints), clause 12 (Staff), clause 14 (Incidents Requiring Reporting), clause 18 (save for clause 18.7) (Governance, Transaction Records and Audit), clause 20 (Confidential Information of the Parties), clause 22 (Intellectual Property), clause 24 (Liability and Indemnity), clause 25 (Data Protection, Freedom of Information and Transparency), clause 27 (Information Requirements), clause 28 (Contract Management),

clause 31 (Termination), clause 32 (Consequences of Expiry or Termination), clause 33 (Prohibited Acts), clause 38 (NHS Counter-fraud and Security Management) and the reconciliation provisions of Schedule 18 (Incentive Schemes) shall continue after such expiry or termination.

49 CONFLICTS OF INTEREST

If a Party becomes aware of any conflict of interest which is likely to have an adverse effect on another Party's decision (acting reasonably) to determine whether or not to contract or continue to contract with that other Party substantially on the terms of this Agreement, the Party aware of the conflict shall immediately declare such an interest to the other and the other Party may take such action under this Agreement as it deems necessary without prejudice to any other right it may have under Law.

50 EQUITY OF ACCESS, EQUALITY AND NO DISCRIMINATION

50.1 The Provider shall, in consultation with the Co-ordinating Commissioner, and upon reasonable request, provide a plan or plans setting out how it will comply with its obligations under clauses 50.4, 50.5, 50.6 and 50.7. For the avoidance of doubt, where the Provider has previously produced any such plan in order to comply with the Law, then the Provider may submit such plan to the Co-ordinating Commissioner in order to comply with this clause 50.3.

50.2 Subject to clause 50.7 the Provider shall have due regard in its performance of this Agreement to the need contemplated by section 76A Sex Discrimination Act 1975 and the Equality Act 2006 (as amended) to:

- (a) eliminate unlawful discrimination and harassment; and
- (b) promote equality of opportunity between men and women,

and for the avoidance of doubt this obligation shall apply irrespective of whether the Provider is a public authority for the purposes of such section.

50.3 Subject to clause 50.7 the Provider shall have due regard in its performance of this Agreement to the need contemplated by section 71 Race Relations Act 1976 and Race Relations (Amendment) Act 2000 (as amended) to:

- (a) eliminate unlawful racial discrimination; and
- (b) promote equality of opportunity and good relations between persons of different

racial groups,

and for the avoidance of doubt this obligation shall apply irrespective of whether the Provider is a body or person specified in schedule 1A to such Act or is of a description falling within that schedule.

50.4 Subject to clause 50.7 the Provider shall have due regard in its performance of this Agreement to the need contemplated by section 49A Disability Discrimination Act 1995 (as amended) to:

- (a) eliminate discrimination that is unlawful under such Act;
- (b) eliminate harassment of disabled persons that is related to their disabilities;
- (c) promote equality of opportunity between disabled persons and other persons;
- (d) take steps to take account of disabled persons' disabilities, even where that involves treating disabled persons more favourably than other persons;
- (e) promote positive attitudes towards disabled persons; and
- (f) encourage participation by disabled persons in public life,

and for the avoidance of doubt, this obligation shall apply irrespective of whether the Provider is a public authority for the purposes of such section.

50.5 Where the enactments referred to in clauses 50.4, 50.5 and 50.6 have been repealed the Provider shall have due regard in its performance of this Agreement to the need contemplated by section 149 of the Equality Act 2010 to:

- (a) eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by the Equality Act 2010;
- (b) advance equality of opportunity between persons who share a relevant protected characteristic (as defined in the Equality Act 2010) and persons who do not share it; and
- (c) foster good relations between persons who share a relevant protected characteristic (as defined in the Equality Act 2010) and persons who do not share it,

and for the avoidance of doubt this obligation shall apply irrespective of whether the Provider is a public authority for the purposes of such section.

50.6 The Provider shall provide to the Commissioners such information in addition to that required under clause 27 (Information Requirements) and Schedule 5 (Information Requirements) as the Commissioners may reasonably require to:

- (a) monitor the equity of access to the Services; and
- (b) fulfil their obligations under the Law.

50.7 The Commissioners and the Provider shall each have and at all times maintain an Equality Impact Assessment in accordance with the Law.

51 COMPLIANCE WITH THE LAW

51.1 The Parties shall comply with the Law in performing their obligations under this Agreement, provided that, where an obligation under this Agreement to comply with the Law would oblige a Party to comply with Guidance where in exceptional individual circumstances to do so would:

- (a) not be consistent with Good Clinical Practice; or
- (b) not be consistent with Good Health and/or Social Care Practice; or
- (c) not be in the best interests of a Patient; or
- (d) otherwise be substantially inconsistent with the aims of this Agreement,

such Party may in its reasonable discretion elect not to follow the relevant Guidance, without taking a substantially different course to it.

52 COUNTERPARTS

52.1 This Agreement may be executed in any number of counterparts, each of which shall be regarded as an original, but all of which together shall constitute one agreement binding on all of the Parties, notwithstanding that all of the Parties are not signatories to the same counterpart.

53 REMEDIES

- 53.1 Save as may be expressly set out in this Agreement, no remedy conferred by any provision of this Agreement is intended to be exclusive of any other remedy and each and every remedy shall be cumulative and shall be in addition to every other remedy given hereunder or existing at law or in equity, by statute or otherwise.
- 53.2 Neither the expiry nor the termination of this Agreement shall prejudice or affect any right of action or remedy which shall have accrued or shall thereafter accrue to any Commissioner or to the Provider.

54 COSTS AND EXPENSES

- 54.1 Each Party shall be responsible for paying its own costs and expenses incurred in connection with the negotiation, preparation and execution of this Agreement.

55 GOVERNING LAW AND JURISDICTION

- 55.1 This Agreement shall be considered as a contract made in England and sand any issues, disputes or claims arising out of or in connection with it (whether contractual or non-contractual in nature such as claims in tort, from breach of statute or regulation or otherwise) shall be governed by, and construed in accordance with, English law.
- 55.2 Subject to the provisions of clause 26 (Dispute Resolution) of this Agreement, the Parties agree that the courts of England shall have exclusive jurisdiction to hear and settle any action, suit, proceeding or dispute in connection with this Agreement.

[DN: if the Preferred Provider is not an NHS organisation but from the independent sector there are a number of additional provisions which Commissioners should consider including in this contract. They include the following:

- **insurance and indemnity protection**
- **additional warranties**
- **step in rights**
- **appropriate clinical governance regime and protections]**

Schedule 1

DEFINITIONS AND INTERPRETATION

1. The headings in this Agreement shall not affect its interpretation.
2. References to any statute or statutory provision include a reference to that statute or statutory provision as from time to time amended, extended or re-enacted.
3. References to a statutory provision shall include any subordinate legislation made from time to time under that provision.
4. References to any body, organisation or office shall include reference to its applicable successor from time to time.
5. Any references to this Agreement or any other documents includes reference to this Agreement or such other documents as varied, amended, supplemented, extended, restated and/or replaced from time to time.
6. Use of the singular includes the plural and vice versa.
7. The following terms shall have the following meanings:

“2006 Act” means the National Health Service Act 2006 as amended by the 2009 Act;

“2008 Act” means the Health and Social Care Act 2008;

“2009 Act” means the Health Act 2009;

“Activity Management Plan” means a plan agreed by the Parties in accordance with paragraph 5 of Schedule 3 Part 1, which outlines the Parties’ agreed approach to managing activity volumes back to the levels or thresholds outlined within the Activity Plan (Schedule 3 Part 1 Annex 1A) or Commissioning Ambitions (Schedule 3 Part 1 Annex 1B);

“Activity Plan” means the relevant indicative activity plan that may be agreed between the Parties from time to time, the most recent of which shall be attached at Annex 1A to Schedule 3 Part 1 and which shall replace all previous Activity Plans agreed between those Parties in relation to this Agreement;

“Annual Contract Value” means the figure set out in Annex 3 to Schedule 3 Part 1

appropriate to, and identified by the name of the relevant Commissioner as the expected annual contract value of the Services for that Commissioner pursuant to clause 9.4, as amended or updated for each Contract Year;

- “Associates”** means the NHS Bodies listed in Schedule 11 Part 5 and which have entered into the Consortium Agreement or the Establishment Agreement included in Schedule 11 Part 1;
- “Audit Commission”** means the independent public body established under the Audit Commission Act 1998 which is responsible for ensuring that public money is spent economically, efficiently and effectively in the areas of local government, housing, health, criminal justice and the fire and rescue services;
- “Auditor”** means an independent third party auditor;
- “Authorisation”** means an authorisation by Monitor issued pursuant to section 56 of the 2006 Act;
- “Authorised Person”** means the Co-ordinating Commissioner and each of its Associates and any body or person concerned with the treatment or care of a Patient approved by such Commissioner;
- “Best Practice IPR”** means any IPR developed by the Provider (including Improvements) in connection with or as a result of the Services that a Commissioner might reasonably be able to use within its organisation for teaching and training of NHS best practice;
- “Board of Directors”** means, in respect of any Party, the board of directors or other governing body having overall responsibility for the actions of that Party;
- “Business Continuity Plan”** means the Provider’s plan referred to in Schedule 4 Part 1 and clause 6.2 relating to continuity of all of the Services, as agreed with the Co-ordinating Commissioner and as may be amended from time to time, which for the avoidance of doubt shall include a plan in relation to the ongoing provision of the Services Environment and the Equipment or equivalent replacements thereof;
- “Care Quality Commission” or “CQC”** means the Care Quality Commission established under the 2008 Act;
- “CEDR”** means the Centre for Effective Dispute Resolution;

“Change in Control”	<p>means:</p> <ul style="list-style-type: none"> (i) any sale or other disposal of any legal, beneficial or equitable interest in any or all of the equity share capital of a corporation (the effect of which is to confer on any person (when aggregated with any interest(s) already held or controlled) the ability to control the exercise of 50 percent or more of the total voting rights exercisable at general meetings of that corporation on all, or substantially all matters), provided that a Change in Control shall be deemed not to have occurred if after any such sale or disposal the same entities directly or indirectly exercise the same degree of control over the relevant corporation; or (ii) any change in the ability to control an NHS Foundation Trust, NHS Trust or NHS Body by virtue of the entering into of any franchise, management or other agreement or arrangement, under the terms of which the control over the management of the relevant NHS Foundation Trust, NHS Trust or NHS Body is conferred on another person in circumstances where the Co-ordinating Commissioner has not given its prior written consent to such agreement or arrangement, <p>and shall include a Provider Change in Control and a Material Sub-contractor Change in Control;</p>
“Change in Control Notification”	means a notification in the form set out in Schedule 15, completed as appropriate;
“Charity Commission”	means the Charity Commission established under the Charities Act 2006;
“Clinical Coding”	means the coding for each Test as set out in Schedule 2 (Services Specification);
“Clinical Coding Audit”	means the annual audit conducted by a Commissioner in relation to the Clinical Coding provided under clause 18 (Governance, Transaction Records and Audit) of this Agreement;
“Clinical Networks”	means groups of commissioners and providers of health or social care concerned with the planning and/or delivery of integrated health or social care across organisational boundaries;
“Commissioner IPR”	means any IPR owned by or licensed to a Commissioner which is relevant and necessary to the performance of the Services by the Provider, including without limitation the IPR set out in Schedule 16 Part 2, including Improvements;

“Commissioners”	means the Co-ordinating Commissioner and its Associates, or such of them as the context requires, and “Commissioner” means any one of them;
“Commissioning Ambitions”	means the ratios and/or obligations to be met and satisfied by the Provider in relation to patient flows and activity regarding the Services as identified in the Activity Plan;
“Commissioning Guidance”	means guidance issued to Commissioners from time to time by the Department of Health or other applicable body in relation to the commissioning of services;
“Commissioning Region”	[geography can be identified by CCG area/ lists of GP practices etc] as set out in Schedule 19, Part 1;
“Competent Authority”	means [●];
“Competent Body”	means any body that has authority to issue standards or recommendations with which the Parties must comply;
“Community Users”	means designated users within primary and community care that are entitled, by Commissioners, to send Requests and Samples to the Provider, including general medical practitioners, general dental practitioners, out-of-hours services, community services and prison services;
“Conditions Precedent”	means the conditions precedent to commencement of service delivery set out in Schedule 4 Part 1;
“Confidential Information”	means any information or data in whatever form disclosed, which by its nature is confidential or which the Disclosing Party acting reasonably states in writing to the Receiving Party is to be regarded as confidential, or which the Disclosing Party acting reasonably has marked ‘confidential’ (including, without limitation, financial information, or marketing or development or work force plans and information, and information relating to services or products) but which is not Patient Health Records or information relating to a particular Patient, or Personal Data, or information which is disclosed in accordance with clause 25, pursuant to an FOIA request, or information which is published as a result of government policy in relation to transparency;
“Consent”	means: <ul style="list-style-type: none"> (iii) any permission, consent, approval, certificate, permit, licence, statutory agreement, authorisation, exception or declaration required by Law for or in

connection with the performance of Services; and/or

- (ii) any necessary consent or agreement from any third party needed either for the performance of the Provider's obligations under this Agreement or for the provision by the Provider of the Services in accordance with this Agreement,

including any registration with Monitor or CQC;

“Consultant”

means a person employed or engaged by the Provider of equivalent standing and skill as a person appointed by an NHS Body in accordance with the Law governing the appointment of consultants;

“Consortium Agreement”

means the agreement between the Co-ordinating Commissioner and its Associates included within Schedule 11 (Consortium Agreement, Local Commissioning Plans, Notices To Aggregate/Disaggregate Payments, Safeguarding Policy, Associates);

“Contract Management Meeting”

means a meeting between the Parties in respect of a Contract Query Notice and any related Excusing Notice;

“Contract Query”

means a Party:

- (a) has a query regarding the other's performance; or
- (b) considers a performance deficiency has occurred under this Agreement; or
- (c) considers there has been a breach of a term of this Agreement;

“Contract Query Notice”

means a written notice setting out the nature and details (to the extent reasonably practicable) of a Contract Query;

“Contract Year”

means the period commencing on the Service Commencement Date until the following 31 March and each subsequent period of twelve (12) calendar months commencing on 1 April, provided that the final Contract Year shall be such period as commences on the 1 April that falls in the year in which this Agreement expires or is terminated (for whatever reason) and ends on the Expiry Date or termination date pursuant to clause 31, whichever is the earlier;

“Counter Fraud and Security

means the Counter-Fraud and Security Management Service

Management Service “or CFSMS”	Division established and maintained by the NHS Business Services Authority pursuant to the NHS Business Services Authority Directions issued by the Secretary of State under the 2006 Act;
“CPA”	means Clinical Pathology Accreditation (UK) Limited, an organisation who provides formal accreditation for clinical pathology services;
“CRC Position”	means any position in relation to which Standard Disclosure is permitted in accordance with section 113 of the Police Act 1997;
“Data Processor”	has the meaning set out in the DPA;
“Data Quality Improvement Plan” or “DQIP”	means a plan setting out specific data and information improvements to be achieved by the Provider in accordance with the timescales in such plan completed on the basis of and appended at Schedule 5 Part 4;
“Data Subject”	has the meaning set out in the DPA;
“Debt Securities”	means debentures, debenture or loan stock, bonds and notes, whether secured or unsecured;
“Default Interest Rate”	means LIBOR plus 2% per annum, and LIBOR means the London Interbank Offered Rate for 6 months sterling deposits in the London market;
“Department of Health”	means the Department of Health in England of HM Government or other relevant body, or such other body that may supersede or replace them from time to time;
“Disclosing Party”	means the Party disclosing Confidential Information to the other Party;
“Dispute”	means a dispute between the Parties in Dispute arising out of or in connection with this Agreement;
“DPA”	means the Data Protection Act 1998;
“ECR Position”	means any position in relation to which Enhanced Disclosure is permitted in accordance with section 115 of the Police Act 1997;
“Effective Date”	means the date of this Agreement;
“Emergency Response Plan”	means each Party’s operational plan to respond to Major Incidents in accordance with the requirements of any relevant

Major Incident Plans;

“Enhanced Disclosure”	has the meaning given to it in the Code of Practice on Disclosure;
“Equality Impact Assessment”	means a published process for narrowing the health inequalities that exist in England between people from different ethnic backgrounds, people with disabilities, men and women (including trans-gendered people), people with different sexual orientations, people in different age groups, people with different religions or beliefs and people from different social and economic groups;
“Equipment”	means anything save for the Provider’s Premises, the Services Environment and the Staff that the Provider may use in the delivery of the Services (including without limitation vehicles);
“Escrow Arrangement”	means an agreement between the Provider and the National Computing Centre (“NCC”) or other similar body for the benefit of the Commissioners for the current version of the source code of software, on the basis of the appropriate NCC or other similar body’s standard terms approved by the Co-ordinating Commissioner;
“Establishment Agreement”	means the agreement between NHS Bodies establishing a Specialised Commissioning Group and allocating certain functions and responsibilities to it relating to the procurement of specialised services;
“Event of Force Majeure”	means an event or circumstance which is beyond the reasonable control of the Party claiming relief under clause 37 (Force Majeure), including without limitation war, civil war, armed conflict or terrorism, strikes or lock outs, riot, fire, flood or earthquake, and which directly causes that Party to be unable to comply with all or a material part of its obligations under this Agreement, but excluding Major Incidents;
“Excusing Notice”	means a notice in writing made under clause 28.10 (Contract Management);
“Expiry Date”	means [DATE];
“Fair Deal for Staff Pensions”	means the guidance note issued by HM Treasury in June 2004 titled “FAIR DEAL FOR STAFF PENSIONS: PROCUREMENT OF BULK TRANSFER AGREEMENTS AND RELATED ISSUES” relating to the treatment of pension issues in compulsory transfers of public sector staff including NHS staff, as amended, superseded or

otherwise from time to time;

“Final Reconciliation Point”	[means 31 December in each year of the term of this Agreement];
“First Exception Report”	means an exception report setting out breaches of the Remedial Action Plan and timescales for rectification of such breaches;
“First Reconciliation Points”	[means the last Operational Day in each Quarter;]
“FOIA”	means the Freedom of Information Act 2000;
“Good Clinical Practice”	means using standards, practices, methods and procedures conforming to the Law and using that degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled, efficient and experienced clinical services provider and a person providing services the same as or similar to the Services at the time the Services are provided, including assigning a Consultant to each Patient who will be clinically responsible for that Patient at all times during the Patient’s care by the Provider;
“Good Health and/or Social Care Practice”	means using standards, practices, methods and procedures conforming to the Law and exercising that degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled, efficient and experienced provider and a person engaged in the provision of services the same as or similar to the Services at the time the Services are provided;
“Community User”	means a general medical practitioner or general dental practitioner registered on a Performers List of a Primary Care Trust in England;
“Guidance”	means any applicable health or social care guidance, direction or determination which the Co-ordinating Commissioner and/or the Provider has a duty to have regard to, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Provider by the Co-ordinating Commissioner and/or the Department of Health and which for the avoidance of doubt shall include the NHS Operating Framework;
“Health and Social Care Bill”	means the Health and Social Care Bill (Bill 132 2010-11) presented to Parliament on 19 January 2011 and as amended from time to time, and including as relevant the Act of Parliament resulting from it, and any secondary legislation contemplated in it or passed under such Act of Parliament;

“Healthcare Professional”	means a person qualified in a healthcare-related profession;
“HM Government”	means the government of the United Kingdom of Great Britain and Northern Ireland;
“Holding Company”	has the definition given to it in section 1159 of the Companies Act 2006;
“Immediate Action Plan”	means a plan setting out immediate actions to be undertaken by the Provider to protect the safety of Services to Patients, the public and/or Staff;
“Improvement”	means any improvement, enhancement or modification to the Provider IPR which cannot be used independently of the Provider IPR or any improvement, enhancement or modification to the Commissioner IPR which can not be used independently of the Commissioner IPR;
“Inclusion Date”	means the latest date by which the Provider must submit data for all activity for the month in question, such date being specified by the Commissioner from time to time;
“Indemnity Arrangement”	means either: <ul style="list-style-type: none"> (i) a policy of insurance; (ii) an arrangement made for the purposes of indemnifying a person or organisation; or (iii) a combination of a policy of insurance and an arrangement made for the purposes of indemnifying a person or organisation;
“Indirect Losses”	means loss of profits (other than profits directly and solely attributable to provision of the Services), loss of use, loss of production, increased operating costs, loss of business, loss of business opportunity, loss of reputation or goodwill or any other consequential or indirect loss of any nature, whether arising in tort or on any other basis;
“Information Breach”	has the meaning given to it in clause 27.10;
“Information Standards Board” or “ISB”	means the body established to govern information standards. The Information Standards Board for Health and Social Care in England is tasked with the independent approval, assurance and governance of information standards for adoption by the NHS and Adult Social Care and its website is www.isb.nhs.uk ;
“Institutional Investor”	means an organisation whose primary purpose is to invest its own assets or those held in trust by it for others, including banks, mutual funds, pension funds, private equity firms, venture capitalists, insurance companies and investment trusts;

“IPR”	means inventions, copyright, patents, database right, trade marks, designs and confidential know-how and any similar rights anywhere in the world whether registered or not, including applications and the right to apply for all such rights;
“ISA”	means the Independent Safeguarding Authority established pursuant to the Safeguarding Vulnerable Groups Act 2006;
“Issuing Party”	has the meaning given to it in clause 28.9;
“JI Report”	means a report detailing the findings and outcomes of the Joint Investigation;
“Joint Investigation”	has the meaning given to it in clause 28.13;
“Joint Statement on Access to Skills, Trade Unions and Advice in Government Contracting”	means the joint statement launched by the Cabinet Office, to improve the quality of services delivered under Government contracts, by raising the skills of service providers’, employees and by helping to ensure fair treatment;
“Knowledge and Skills Framework”	means the career and pay progressions strand of the NHS pay system known as “Agenda for Change”. Agenda for Change is a single pay system in operation in the NHS, which applies to all directly employed NHS staff with the exception of doctors, dentists and some very senior managers. The three core elements that make up Agenda for Change are: (i) job evaluation; (ii) harmonised terms and conditions, and; (iii) the Knowledge and Skills Framework. The Knowledge and Skills Framework is mandatory for all Agenda for Change staff and should be fully implemented by all NHS organisations;
“Law”	means: <ul style="list-style-type: none"> (i) any applicable statute or proclamation or any delegated or subordinate legislation or regulation; (ii) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (iii) any NHS Requirement, applicable code of practice, National Standard, Guidance, direction or determination with which the Provider is bound to comply; and (iv) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales, <p>in each case in force in England and Wales;</p>
“Lessons Learned”	means experience derived from provision of the Services, the sharing and implementation of which would be reasonably likely to lead to an improvement in the quality of the Provider’s

	provision of the Services;
“Local Authority”	means a county council in England, a district council in England or a London borough council;
“Local Commissioning Plans”	means the documents detailing the plans of the Commissioners to commission Services prepared in accordance with the principles of the NHS Operating Framework and Commissioning Guidance;
“Local Counter Fraud Specialist” or “LCFS”	means a local counter-fraud specialist appointed by the Provider in accordance with Schedule 13;
“Local Involvement Network” or “LiNks”	means an entity established pursuant to contractual arrangements made by a local authority under section 221(1) of the Local Government and Public Involvement in Health Act 2007, the function of which is to carry on in such local authority’s area the activities specified in section 221(2) of the Local Government and Public Involvement in Health Act 2007;
“Local Security Management Specialist” or “LSMS”	means a local security management specialist for the purposes of Schedule 13;
“Longstop Date”	means [●];
“Losses”	means all damage, loss, liabilities, claims, actions, costs, expenses (including the cost of legal and/or professional services), proceedings, demands and charges whether arising under statute, contract or at common law but, to avoid doubt, excluding Indirect Losses;
“Major Incident”	means an event or occurrence which is designated as such by Category 1 Responders (as designated by the Civil Contingencies Act 2004) or by the Major Incident Plan;
“Major Incident Plan”	means the plan implemented in each local authority area in accordance with the Civil Contingencies Act 2004 to plan for and co-ordinate responses to civil emergencies;
“Mandatory Goods and Services”	means goods and/or services classified as protected or mandatory under the Provider’s Terms of Authorisation;
“Material Sub-contractor”	has the meaning set out in Schedule 10;
“Material Sub-contractor Change in Control”	means a Change in Control of a Material Sub-contractor or any of its Holding Companies (if any);
“Monitor”	means the public office established under the Health and Social Care (Community Health and Standards) Act 2003 with responsibility for authorising NHS Foundation Trusts and

accountable to Parliament, and continuing under section 31 of the 2006 Act, and any successor body or bodies from time to time, as appropriate;

“MRSA”	means methicillin-resistant staphylococcus aureus;
“National Audit Office”	means the independent office established under the National Audit Act 1983 which conducts financial audits and reports to Parliament on the spending of public money (and any successor body or bodies from time to time);
“National Clinical Audit Patients Outcome Programme” or “NCAPOP”	means a set of centrally-funded national projects that provide provider organisations with a common format to collect audit data for central analysis and provides comparative findings feed back to help participants identify necessary improvements for patients;
“National Information Governance Board for Health and Social Care” or “NIGB”	means the body established under the 2008 Act which supports improvements in information governance practice, monitors information governance trends in the NHS and adult Social Care and administers applications under section 251 of the 2006 Act. The NIGB reports annually to the Secretary of State and is custodian of Care Record Guarantees for Health and Social Care for England. NIGB. Its website is www.nigb.nhs.uk ;
“National Institute for Health and Clinical Excellence” or “NICE”	means the special health authority responsible for providing national guidance on the promotion of good health and the prevention of ill health (or any successor body);
“National Standards”	means those standards applicable to the Provider under the Law and/or Guidance as amended from time to time;
“National Variation”	means a Variation reasonably required by a Party to reflect changes the Department of Health makes to the mandatory elements, including those mandatory elements to be locally defined, of the NHS standard contract relevant to the Services from time to time reflecting the NHS Operating Framework and/or commissioning guidance;
“New Party”	has the meaning given to it in clause 44.7;
“NHS”	means the National Health Service in England;
“NHS Body”	means a health service body as defined in section 9 of the 2006 Act;
“NHS Business Services”	means the Special Health Authority established pursuant to the

Authority”	NHS Business Services Authority (Establishment and Constitution Order) 2005 SI 2414/2005, and any successor or replacement body carrying out its functions;
“NHS Care Records Guarantee”	means the document setting out the rules that govern information held in the NHS Care Records Service, which is reviewed at least annually by the National Information Governance Board for Health and Social Care;
“NHS Care Records Service”	means the electronic patient record management service to enable authorised healthcare professionals to access an individual patient’s integrated electronic care record at any time from any relevant healthcare premises. NHS Care Records Service website is www.nhs-care-records.nhs.uk ;
“NHS Classifications Service”	means the NHS resource responsible for the delivery of national clinical classifications standards and guidance for the NHS clinical coding profession;
“NHS Constitution”	means the constitution for the NHS in England set out in Law and/or Guidance from time to time which establishes the principles and values of the NHS in England and sets out the rights, pledges and responsibilities for patients, the public and staff;
“NHS Data Model and Dictionary”	means the reference source for information standards to support healthcare activities within the NHS in England;
“NHS Employment Check Standards”	means the documents which set out the pre-appointment checks that are required by law, those that are mandated by Department of Health policy, and those that are required for access to the NHS Care Record Service and include, without limitation, verification of identity checks, right to work checks, registration and qualification checks, employment history and reference checks, criminal record checks and occupational health checks;
“NHS Foundation Trust”	means an NHS foundation trust as defined in section 30 of the 2006 Act;
“NHS Operating Framework”	means the national operating framework for the NHS published by the Department of Health which details key deliverables and priorities for the NHS and any revisions, amendments or other variations to the operating framework published from time to time;
“NHS Requirement”	means all directions made by the Secretary of State under Section 8 of the 2006 Act in so far as they apply to the Provider, mandatory NHS requirements, code of practice or conduct and any similar official requests, requirements and NHS standards and recommendations having similar status for the time being in force, but only to the extent the same are published and publicly available (whether on the Department of Health website, on the

website of a [Competent Authority] or otherwise) or the existence and contents of them have been notified to the Provider by the Co-ordinating Commissioner;

“NHS Trust”	means a body established under section 25 of the 2006 Act;
“Operational Day”	means a day other than a Saturday, Sunday or bank holiday in England;
“Order”	means an order made by the Secretary of State for Health pursuant to section 53 or section 54 of the 2006 Act;
“Other Party”	has the meaning given to it in clause 28.9;
“Parties”	means the Commissioners and the Provider, or such of them as the context requires, and “Party” means any one of them;
“Parties in Dispute”	means the Co-ordinating Commissioner and/or those of its Associates directly concerned in the Dispute, as one Party in Dispute, and the Provider, as the other;
“Patient”	means a patient of a Commissioner or any other patient who is referred or presents to the Provider or otherwise receives Services under this Agreement;
“Patient Health Record”	means a record which consists of information relating to the particular physical or mental health or condition of a Patient;
“Patient Safety Incident”	means any unintended or unexpected incident which could have or did lead to harm to one or more Patients;
“Personal Data”	has the meaning set out in the DPA;
“Prices”	means the prices for the Services set out in Schedule 2, Part 3;
“Primary Care Trust” or “PCT”	means a primary care trust established by the Secretary of State in accordance with section 16A of the National Health Service Act 1977 and continuing in existence under section 18 of the 2006 Act;
“Principles and Rules for Cooperation and Competition”	means the rules of procedure published from time to time by the Department of Health, relating to the commissioning and provision of NHS services, to support cooperation and competition in the interests of patients and taxpayers in relation to: (i) commissioning and procurement; (ii) cooperation and collusion; (iii) conduct of individual organisations;

(iv) mergers and vertical integration;

“Principles of Good Employment Practice”

means the guidance note issued by the Cabinet Office in December 2010 titled “SUPPLIER INFORMATION NOTE: WITHDRAWAL OF TWO-TIER CODE” including Annex A of that guidance note setting out a set of voluntary principles of good employment practice, as amended, superseded or otherwise from time to time;

“Prohibited Acts”

has the meaning given to it in clause 33.1;

“Protected Asset”

means an asset classified as protected under the Provider’s Terms of Authorisation;

“Provider Change in Control”

means a Change in Control of the Provider or any of its Holding Companies (if any)

“Provider Insolvency Event of Default”

means the occurrence of any of the following events in respect of the Provider:

- (i) the Provider is, or is deemed for the purposes of any law to be, unable to pay its debts or insolvent;
- (ii) the Provider admits its inability to pay its debts as they fall due;
- (iii) the value of the Provider’s assets is less than its liabilities (taking into account contingent and prospective liabilities);
- (iv) the Provider suspends making payments on any of its debts or announces an intention to do so;
- (v) by reason of actual or anticipated financial difficulties, the Provider commences negotiations with creditors generally with a view to rescheduling any of its indebtedness;
- (vi) a moratorium is declared in respect of any of the Provider’s indebtedness;
- (vii) the suspension of payments, moratorium of any indebtedness, winding-up, dissolution, administration, (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) of the Provider;
- (viii) a composition, assignment or arrangement with any creditor of any member of the Provider;
- (ix) the appointment of a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer (in each case, whether out of court or otherwise) in respect of

the Provider or any of its assets;

- (x) a resolution of the Provider or its directors is passed to petition or apply for the Provider's winding up or administration;
- (xi) the Provider's directors giving written notice of their intention to appoint a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, or administrator (whether out of court or otherwise); or
- (xii) if the Provider suffers any event analogous to the events set out in (i) to (xi) of this definition in any jurisdiction in which it is incorporated or resident;

"Provider IPR"	means any IPR owned by or licensed to the Provider (other than by any Commissioner) that will be used by the Provider in the delivery of the Services, as set out in Schedule 16 Part 1, including Improvements;
"Provider's Premises"	means premises controlled or used by the Provider for any purposes connected with the provision of the Services and listed in Schedule 19, Part 2;
"Public Authority"	means as defined in section 3 of the FOIA which includes NHS Trusts and NHS Foundation Trusts;
"Public Company"	means a company which: <ul style="list-style-type: none">(i) has shares that can be purchased by the public;(ii) has an authorised share capital of at least £50,000 with each of the company's shares being paid up at least as to one quarter of the nominal value of the share and the whole of any premium on it; and(iii) has securities listed on a stock exchange in any jurisdiction.
"Quality Accounts"	has the meaning described in the 2009 Act;
"Quality Requirements"	means the quality requirements set out in the table at Schedule 3 Part 2A (Quality Requirements) as may be amended by the Parties in accordance with this Agreement or with the recommendations or requirements of NICE;
"Quarter"	means each 3-month period commencing on the Services Commencement Date and "Quarterly" shall be construed accordingly;
"QIPP Plan"	means the local and regional quality, innovation, productivity and prevention plan(s) prepared to meet the challenge of driving quality improvements;

“Receiving Party”	means the Party receiving Confidential Information from the other Party;
“Request”	means a request by a Community User for a Test;
“Remedial Action Plan”	means a plan to rectify a breach of or performance failure under this Agreement, including any breach of the Activity Plan, specifying targets and timescales within which such targets shall be achieved;
“Responsible Commissioner”	means the Patient’s responsible Commissioner as determined in accordance with the Law and applicable Guidance (including without limitation ‘Who Pays? Establishing the Responsible Commissioner’, Gateway reference 8448, as amended from time to time);
“Restricted Person”	means: <ul style="list-style-type: none"> (i) any person, other than an Institutional Investor, who has a material interest in the production of tobacco products or alcoholic beverages; or (ii) any person who the Co-ordinating Commissioner otherwise reasonably believes is inappropriate for public policy reasons to have a controlling interest in the Provider or in a Material Sub-contractor;
“Review”	means a review carried out under clause 10 (Review);
“Review Record”	means a written review record containing without limitation a summary of all the matters raised during a Review, actions taken, agreements reached, Disputes referred to dispute resolution under clause 26 (Dispute Resolution) and the outcome of any such referrals, and any Variations agreed;
“Sample”	means a sample provided by a Community User to the Provider for one or more Tests;
“Screening Programmes”	means co-ordinated national and/or local NHS activity that aims to identify early indications of particular conditions in patients;
“Secretary of State”	means the Secretary of State for Health;
“Security”	means Shares, Debt Securities, units in a collective investment scheme (as defined in the Financial Services and Markets Act 2000), miscellaneous warrants, certificates representing debt securities, warrants or options to subscribe or purchase securities, other securities of any description and any other type of proprietary or beneficial interest in a limited company;
“Senior Information Risk Owner”	means the Provider’s nominated person, being an executive or senior manager on the board of the Provider, whose role is to take ownership of the organisation’s information risk policy, act

as champion for information risk on the board of the Provider and provide written advice to the accounting officer on the content of the organisation's statement of internal control in regard to information risk;

“Serious Incident”	means an incident or accident or near-miss where a patient, member of staff, or member of the public suffers serious injury, major permanent harm or unexpected death on the Provider's Premises or where the actions of the Provider, the Staff or the Co-ordinating Commissioner are likely to be of significant public concern;
“Service Commencement Date”	means the date [six (6)] months from and including the Effective Date or such later date as agreed between the parties;
“Service Development and Improvement Plan” or “SDIP”	means the agreed plan setting out improvements to be made by the Provider to the Services and/or Services Environment, in particular without limitation as regards to, the Provider's contribution towards the local and regional QIPP Plan, quality, Patient experience; productivity, efficiency, priority areas, service integration, as appended at Schedule 7;
“Service Quality Performance Report”	has the meaning given to it in clause 34.1;
“Service Requirements”	means [●];
“Services Specification”	means each of the services specification defined by the Commissioners and set out in Schedule 2 Part 1 (Services Specification);
“Service Variation”	means a Variation reasonably requested by a Party that relates to any Service which reflects: (i) the assessment by a Commissioner/Commissioners of the availability of alternative providers and demand for Services; and/or (ii) the joint assessment of the Provider and a Commissioner of the quality and clinical viability of the relevant Service/s and the Services Environment.
“Services”	means the services as set out in the Services Specification;
“Services Environment”	means the rooms, theatres, wards, treatment bays, clinics or other physical location, space, area, accommodation or such other place as may be used or controlled by the Provider from time to time in which the Services are provided, excluding Patients' private residences, Local Authority premises, schools and premises controlled by the Responsible Commissioner;

“Shares”	has the meaning given to the term in section 540 of the Companies Act 2006, including preference shares;
“Specialised Commissioning Group”	means the group established to co-ordinate the commissioning of specialised healthcare services on behalf of the PCTs located within the boundaries of an SHA;
"Staff"	means all persons (whether clinical or non-clinical) employed or engaged by the Provider (including volunteers, agency, locums casual or seconded personnel) in the provision of the Services or any activity related to, or connected with the provision of the Services, including Consultants;
“Standard Disclosure”	has the meaning given to it in the Code of Practice on Disclosure;
“Strategic Health Authority” or “SHA”	means an authority established under section 8 of the National Health Service Act 1977 and continuing in existence under section 13 of the 2006 Act;
“SUS”	means the “Secondary Uses Services”, being the management and information reporting service of the NHS Care Records Service;
“Suspension Event(s)”	means any of the events set out in clause 30.1;
“Suspension Notice”	means a notice in writing to suspend a Service or Services given under clause 30.3;
"Terms of Authorisation"	means, where the Provider is an NHS Foundation Trust, the terms under which the Provider is authorised to operate as an NHS Foundation Trust by Monitor, as amended from time to time;
“Test”	means a pathology test conducted by the Provider for a Community User under the terms of this Agreement;
“Transaction Records”	means accurate accounts and transaction records of all payments, receipts and financial and other information relevant to the provision of the Services;
“Transformation Plan”	means the Transformation Plan agreed between the Parties set out in Schedule 4 Part 3;
“TUPE”	means the Transfer of Undertakings (Protection of Employment) Regulations 2006;
“Turnaround Times”	means , in relation to the production of Test results, the relevant ‘turn-around-time’ from receipt of the Sample to making the Test result available for each individual service, as set out in Schedule 2;
“UKAS”	means the United Kingdom Accreditation Service;

“UNIFY2”	means the Department of Health electronic system for collecting, storing and retrieving activity reports and performance data;
“Utilisation Management Scheme”	means a scheme established to ensure the correct use of resources in relation to provision of the Services and, in relation to phlebotomy, the treatment of an individual or group of patients as may be agreed by the Co-ordinating Commissioner and the Provider in accordance with Schedule 3 (Managing Activity and Requests, Care and Resource Utilisation Techniques and Retention of Payment Scheme);
“Variable Schedules”	<p>means the following Schedules or part of the Schedules that may be varied by the Parties in accordance with clause 34.2(a) (Variations):</p> <ul style="list-style-type: none"> (ii) Schedule 2, Part 1 (Services Specification); (iii) Schedule 2, Part 2 (Major Incidents); (iv) Schedule 2, Part 3 (Prices); (v) Schedule 2, Part 4 (Frequency of Review Meetings); (viii) Schedule 3, Part 1, Annex 1A (Activity Plans) and Annex 1B (Commissioning Ambition); (ix) Schedule 3, Part 1, Annex 2 (Capacity Review Criteria) – percentages only; (x) Schedule 3, Part 1, Annex 3 (Expected Annual Contract Values); (xi) Schedule 3, Part 2A (Quality Requirements) - locally agreed insertions only; (xii) Schedule 3, Part 3 (Staff Surveys); (xiv) Schedule 4, Part 1 (Conditions Precedent) – locally agreed insertions only; (xv) Schedule 4, Part 2 (Documents To Be Delivered By The Co-ordinating Commissioner); (xvi) Schedule 4, Part 3 (Transformation Plan); (xvii) Schedule 5, Part 2 (Information Requirements : National Requirements Reported Locally) – locally defined elements only; (xviii) Schedule 5, Part 3 (Information Requirements: Local Requirements Reported Locally); (xix) Schedule 5, Part 4 (Data Quality Improvement Plan) -

locally agreed insertions only;

- (xx) Schedule 6, Part 2 (Recorded Variations and Dispute Resolutions);
- (xxi) Schedule 7, (Service Development and Improvement Plan) – locally agreed insertions only;
- (xxii) Schedule 8, (Exit Arrangements and Agreements Relating to Termination Costs);
- (xxiii) Schedule 9, Part 1 (Dispute Resolution: Details of Mediator and Independent Binding Pendulum Adjudicator);
- (xxiv) Schedule 9, Part 2 (Dispute Resolution: Procedure for Disputes between Divisions of the Same NHS Body);
- (xxv) Schedule 10, Part 2 (Provider’s Material Sub-contractors);
- (xxvi) Schedule 11, Part 1 (Consortium Agreement);
- (xxvii) Schedule 11, Part 2 (Local Commissioning Plans);
- (xxviii) Schedule 11, Part 3 (Notices to Aggregate/Disaggregate Payments);
- (xxix) Schedule 11, Part 5 (Associates);
- (xxx) Schedule 12 (Incidents Requiring Reporting Procedure);
- (xxxi) Schedule 14 (Documents Relied On);
- (xxxii) Schedule 16 (Intellectual Property);
- (xxxiii) Schedule 17 (Notices);
- (xxxiv) Schedule 18 Part 2 (Commissioning for Quality and Innovation) – locally agreed insertions only;
- (xxxv) Schedule 18 Part 3 (Locally Agreed Incentive Schemes);
- (xxxvi) Schedule 19 (Location of Provider’s Premises);
- (xxxvii) Schedule 20 (Clinical Networks and Screening Programmes);

"Variation"

means an addition, deletion or amendment in the clauses of or Schedules to this Agreement agreed to be made by the Parties in accordance with clause 34 (Variations) which may be a Service Variation, a National Variation, or any other variation; and

"VAT"

means value added tax at the rate prevailing at the time of the relevant supply charged in accordance with the provisions of the

Value Added Tax Act 1994.