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NHS Standard Contract (full length) 2017/18 and 2018/19 (May 2018 edition)

National Variation Agreement for existing 2015/16, 2016/17, 2017-19 (November 2016 edition) and 2017-19 (January 2018 edition) form contracts

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**National Variation Agreement for existing 2015/16, 2016/17, 2017-19 (November 2016) and 2017-19 (January 2018 edition) form contracts**

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Prepared by: NHS Standard Contract Team

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*(please do not return completed National Variations to this email address)*

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| Please note that the parties must complete the fields highlighted in yellow in this National Variation Agreement. |

**NHS [ ] CLINICAL COMMISSIONING GROUP (1)**

**[*insert names of other Commissioners*]**

**[ ]**

**[ ]**

**[ ]**

**[*Local Authority*]**

**[*NHS England*]**

**AND**

**[ ] (2)**

**AS PROVIDER**

|  |
| --- |
| **NATIONAL VARIATION AGREEMENT****2017-19 (May 2018 edition)****in relation to the Contract dated [*insert date of original contract*]****in the form of the****[NHS STANDARD CONTRACT 2017-19 (January 2018 edition)] [NHS STANDARD CONTRACT 2017-19 (November 2016 edition)] [NHS STANDARD CONTRACT 2016/17] [NHS STANDARD CONTRACT 2015/16] *[select year of original contract]*** |

**THIS NATIONAL VARIATION AGREEMENT is dated [ ]2018 and made between:**

1. **NHS [ ] CLINICAL COMMISSIONING GROUP** whose principal office is at
[ ]

**[***insert other Commissioners’ names and addresses***]**

**[***insert Local Authority name and address if applicable***]**

**[***insert NHS England name and address if applicable***]**

 (the **Commissioners**)

and

1. **[ ]** whose principal and/or registered office address is at [ ] (the **Provider**).

**WHEREAS**

1. The Commissioners and the Provider entered into a contract dated [*insert date of original 2017-19 (January 2018 edition), 2017-19 (November 2016 edition), 2016/17 or 2015/16 contract*] as varied pursuant to GC13 of that contract (the **Contract**).
2. GC13 of the Contract requires the Parties to vary the Contract to apply National Variations.
3. The Parties wish to vary the Contract in accordance with GC13 so as to bring the Contract into alignment with certain provisions of the NHS Standard Contract 2017-19 (May 2018 edition) published by NHS England.
4. In consideration of their mutual obligations under this National Variation Agreement and the payment by each Party to the other of £1 (receipt of which each Party acknowledges), the Parties have therefore agreed to vary the Contract on the terms set out in this National Variation Agreement.

**IT IS AGREED:**

1. **Definitions and Interpretation**
	1. In this National Variation Agreement unless the context otherwise requires or an expression is defined as a capitalised term in clause 1.2 below, the expression has the meaning given to it in the Contract.
	2. In this National Variation Agreement:

**Contract** has the meaning given to it in Recital A of this National Variation Agreement (and which may be the 2017-19 (January 2018 edition), 2017-19 (November 2016) edition), the 2016/17 Contractor, or the 2015/16 Contract);

**2015/16 Contract** means the NHS Standard Contract published by NHS England for the year 2015/16, as subsequently varied in accordance with applicable National Variations;

**2016/2017 Contract** means the NHS Standard Contract published by NHS England for the year 2016/2017, as subsequently varied in accordance with applicable National Variations;

**2017-19 (November 2016 edition) Contract** means theNHS Standard Contract published by NHS England in November 2016 for the years 2017-19, as subsequently varied in accordance with applicable National Variations;

**2017-19 (January 2018 edition) Contract** means the NHS Standard Contract published by NHS England in January 2018 for the years 2017-19;

**GC** and **SC** mean respectively any General Condition or Service Condition of the 2017-19 (January 2018 edition) Contract or of the applicable 2015/16 Contract, 2016/17 Contract, or 2017-19 (November 2016 edition), as the context requires;

**National Variation Agreement** means this agreement including its recitals and appendices; and

**Variations** means the variations set out in clauses 3 to 16 (inclusive) of this National Variation Agreement.

* 1. Except where otherwise expressly identified, all references in this National Variation Agreement to numbered SCs, GCs or Schedules relate to the SCs, GCs and Schedules of the Contract.
	2. Where the application of any content in the 2017-19 (January 2018 edition)Contract is limited in the 2017-19 (January 2018 edition) Contract to certain Service or Provider categories only, the same limitations will apply where that content is added to the Contract by this National Variation Agreement.
1. **Effective Date of VAriations**

The Variations apply with effect from the dates specified below.

**Particulars**

1. **ParticuLARS Service Requirements**
	1. With effect from 25 May 2018, underneath ‘Prior Approval Response Time Standard’, insert the following:

|  |  |
| --- | --- |
| **Is the Provider acting as a Data Processor in order to deliver the Services?** | **YES/NO** |

1. **ParticuLARS GOVERNANCE AND REGULATORY**
	1. With effect from 25 May 2018, underneath ‘Provider’s Information Governance Lead’, insert the following:

|  |  |
| --- | --- |
| **Provider’s Data Protection Officer (if required by Data Protection Legislation)** | **[ ]****Email: [ ]****Tel: [ ]** |

1. **particulars schedule 4a operational standards AND SCHEDULE 4B NATIONAL QUALITY REQUIREMENTS**
	1. With effect from 1 April 2018, delete the contents of the following Parts of Schedule 4:

Part A: Operational Standards; and

Part B: National Quality Requirements

and replace with the equivalent Parts A and B set out in Appendix 2 completed with local content where applicable. Any references to “Application” (“Applicable Service Category” in the 2015/16 Contract) are to be interpreted as in the 2017-19 (January 2018) Contract.

1. **particulars schedule 6A reporting requirements National requirements reported centrally**
	1. With effect from 1 April 2018, delete the description of lines 1 and 2 and replace with:

|  |
| --- |
| 1. As specified in the list of omnibus, secure electronic file transfer data collections and BAAS schedule of approved collections published on the NHS Digital website to be found at

<https://digital.nhs.uk/services/the-challenging-burden-service/central-register-of-collections>where mandated for and as applicable to the Provider and the Services |
| 1. Patient Reported Outcome Measures (PROMS)

https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/patient-reported-outcome-measures-proms |

1. **particulars schedule 6f**
	1. **Where the Provider is acting as a Data Processor in order to deliver the Services**, with effect from 25 May 2018, the provisions set out in Appendix 3 are added as a new Schedule 6F (2015/16 Contract: Schedule 6G, with cross-references to be read accordingly).

**service conditions**

1. **SC23 (SErvice User Health Records)**
	1. With effect from 25 May 2018, delete the text of SC23.1 and replace with:

|  |  |
| --- | --- |
| * 1. The Provider must create and maintain Service User Health Records as appropriate for all Service Users. The Provider must securely store, retain and destroy those records in accordance with Data Guidance, Information Governance Alliance Guidance and in any event in accordance with Data Protection Legislation.
 | **All** |

* 1. With effect from 25 May 2018, delete the text of 23.2 and replace with:

|  |  |
| --- | --- |
| * 1. The Provider must:

23.2.1 if and as so reasonably requested by a Commissioner, whether during or after the Contract Term, promptly deliver to any third party provider of healthcare or social care services nominated by that Commissioner a copy of the Service User Health Record held by the Provider for any Service User for whom that Commissioner is responsible; and* + 1. notwithstanding SC23.1, if and as so reasonably requested by a Commissioner at any time following the expiry or termination of this Contract, promptly deliver to any third party provider of healthcare or social care services nominated by that Commissioner, or to the Commissioner itself, the Service User Health Record held by the Provider for any Service User for whom that Commissioner is responsible.
 | **All** |

1. **SC26 (Clinical Networks, National Audit Programmes and Approved Research Studies)**

8.1 With effect from 1 April 2018, delete the text of SC26.4 and replace with:

|  |  |
| --- | --- |
| If the Provider chooses to participate in any Commercial Contract Research Study which is submitted to the HRA for approval on or after 1 October 2018, the Provider must ensure that that participation will be in accordance with the National Directive on Commercial Contract Research Studies, at a price determined by NIHR for each Provider in accordance with the methodology prescribed in the Directive and under such other contractual terms and conditions as are set out in the Directive. | **All** |

8.2 With effect from 1 April 2018, add a new SC26.5 and 26.6 as follows:

|  |  |
| --- | --- |
| 26.5 The Provider must comply with HRA/NIHR Research Reporting Guidance, as applicable.26.6 The Parties must comply with NHS Treatment Costs Guidance, as applicable. | **All****All** |

1. **SC28 (Information Requirements)**
	1. With effect from 25 May 2018, delete the text of SC28.2.4 and replace with:

|  |  |
| --- | --- |
| 28.2.4 comply with Data Guidance issued by NHS England and NHS Digital and with Data Protection Legislation in relation to protection of patient identifiable data; |  |

* 1. With effect from 25 May 2018, delete the text of SC28.2.6 and replace with:

|  |  |
| --- | --- |
| 28.2.6 comply with the Data Guidance and Data Protection Legislation on the use and disclosure of personal confidential data for other than direct care purposes. |  |

1. **SC33 (incidents requiring reporting)**
	1. With effect from 25 May 2018, delete the text of SC33.5 and replace with:

|  |  |
| --- | --- |
| The Commissioners will have complete discretion (subject only to the Law) to use the information provided by the Provider under this SC33, Schedule 6C *(Incidents Requiring* Reporting *Procedure*) and Schedule 6A (*Reporting Requirements*) in any report which they make to any relevant Regulatory or Supervisory Body, any NHS Body, any office or agency of the Crown, or to any other appropriate regulatory or official body in connection with Serious Incidents, or in relation to the prevention of Serious Incidents, provided that in each case they notify the Provider of the information disclosed and the body to which they have disclosed it. | **All** |

1. **SC36 (Payment Terms)**
	1. With effect from 1 April 2018, delete the text of SC36.37A (2015/16 Contact: SC36.46A) and replace with the following (2015/16 Contract: with numbering and cross-referencing to be read as amended accordingly):

|  |  |
| --- | --- |
| 36.37A If the Provider has been granted access to the general element of the Provider Sustainability Fund, and has, as a condition of access:36.37A.1 agreed with the national teams of NHS Improvement and NHS England an overall financial control total and other associated conditions for the Contract Year 1 April 2018 to 31 March 2019; and36.37A.2 (where required by those bodies):36.37A2.1 agreed with those bodies and with the Commissioners specific performance trajectories to be achieved during the Contract Year 1 April 2018 to 31 March 2019 (as set out in an SDIP contained or referred to in Schedule 6D (*Service Development and Improvement Plans*)); and/or36.37A2.2 submitted to those bodies assurance statements setting out commitments on performance against specific Operational Standards and National Quality Requirements to be achieved during the Contract Year 1 April 2018 to 31 March 2019 which have been accepted by those bodies (as set out in an SDIP contained or referred to in Schedule 6D (*Service Development and Improvement Plans*)),no repayment will be required to be made, nor any deduction made, in relation to any breach of any threshold which occurs during that Contract Year for which such financial control totals and specific performance trajectories have been agreed and/or such assurance statements have been submitted and accepted in respect of any Operational Standard shown in bold italics in Schedule 4A (*Operational Standards*) or any National Quality Requirement shown in bold italics in Schedule 4B (*National Quality Requirements*).  | **All** |

* 1. With effect from 1 April 2018, add a new SC36.52 (2015/16 Contract: SC36.61) as follows:

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| --- | --- |
|  With effect from 1 October 2018, where, in the course of providing the Services, the Provider or any Sub-Contractor requires a sample taken from a Service User to be subject to a genomic laboratory test listed in the National Genomic Test Directory, that sample must be submitted to the appropriate Genomic Laboratory Hub commissioned by NHS England to arrange and/or perform the relevant test. Each submission of a sample must be made in accordance with the criteria for ordering tests set out in the National Genomic Test Directory. | **A+E, A, CR, CS, D, MH, MHSS, R** |

**general conditions**

1. **GC9 (Contract Management)**
	1. With effect from 1 April 2018, delete the text of GC9.26 and replace with:

|  |
| --- |
| **Provider Sustainability Fund**9.26 If the Provider has been granted access to the general element of the Provider Sustainability Fund, and has, as a condition of access:9.26.1 agreed with the national teams of NHS Improvement and NHS England an overall financial control total and other associated conditions for the Contract Year 1 April 2018 to 31 March 2019; and 9.26.2 (where required by those bodies):9.26.2.1 agreed with those bodies and with the Commissioners specific performance trajectories to be achieved during the Contract Year 1 April 2018 to 31 March 2019 (as set out in an SDIP contained or referred to in Schedule 6D (*Service Development and Improvement Plans*)); and/or9.26.2.2 submitted to those bodies assurance statements setting out commitments on performance against specific Operational Standards and National Quality Requirements to be achieved during the Contract Year 1 April 2018 to 31 March 2019 which have been accepted by those bodies (as set out in an SDIP contained or referred to in Schedule 6D (*Service Development and Improvement Plans*)),no Commissioner may withhold or retain payment under this GC9 (*Contract Management*) or otherwise in respect of any failure to agree a RAP, or to comply with any RAP, in relation to any breach of any threshold which occurs during that Contract Year for which such financial control totals and specific performance trajectories have been agreed and/or such assurance statements have been submitted and accepted in respect of any Operational Standard shown in bold italics in Schedule 4A (*Operational Standards*) or any National Quality Requirement shown in bold italics in Schedule 4B (*National Quality Requirements*), and/or any failure to comply with specific performance trajectories or assurances as referred to above. |

1. **GC12 Assignment and Sub-contracting**
	1. With effect from 25 May 2018, delete the text of GC12.14 and replace with:

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| --- |
| 12.14 Notwithstanding GC20 (*Confidential Information of the Parties*), a Commissioner which assigns, transfers, delegates or sub-contracts all or any of its rights or obligations under this Contract to any person may disclose to such person any information in its possession that relates to this Contract or its subject matter, the negotiations relating to it, or the Provider, provided always that this is in accordance with Data Protection Legislation and Data Guidance. |

1. **GC17 (TERMINATION)**
	1. With effect from 25 May 2018, add a new GC17.10.6 as follows, and renumber accordingly:

|  |
| --- |
| 17.10.6 the Provider has been issued with any enforcement or penalty notice under the DPA 2018, or the Provider or any member of Staff is found guilty or admits guilt in respect of an offence under the DPA 2018, in relation to any matter connected with this Contract or the Services; or |

1. **GC21 (Patient Confidentiality, Data Protection, Freedom of Information and Transparency)**
	1. With effect from 25 May 2018, delete the text of GC21 and replace with:

|  |
| --- |
| **Information Governance – General Responsibilities**1. The Parties must comply with Data Protection Legislation, Data Guidance, the FOIA and the EIR, and must assist each other as necessary to enable each other to comply with these obligations.
2. The Provider must complete and publish an annual information governance assessment and must demonstrate satisfactory compliance as defined in the NHS Information Governance Toolkit (or any successor framework), as applicable to the Services and the Provider’s organisation type.
3. The Provider must:
	* 1. nominate an Information Governance Lead;
		2. nominate a Caldicott Guardian and Senior Information Risk Owner, each of whom must be a member of the Provider’s Governing Body;
		3. where required by Data Protection Legislation, nominate a Data Protection Officer;
		4. ensure that the Co-ordinating Commissioner is kept informed at all times of the identities and contact details of the Information Governance Lead, Data Protection Officer, Caldicott Guardian and the Senior Information Risk Owner; and
		5. ensure that NHS England and NHS Digital are kept informed at all times of the identities and contact details of the Information Governance Lead, Data Protection Officer, Caldicott Guardian and the Senior Information Risk Owner via the NHS Information Governance Toolkit (or any successor framework).
4. The Provider must adopt and implement the National Data Guardian’s Data Security Standards and must comply with further Guidance issued by the Department of Health, NHS England and/or NHS Digital pursuant to or in connection with the Standards. The Provider must be able to demonstrate its compliance with those Standards in accordance with the requirements and timescales set out in such Guidance, including requirements for enabling patient choice.
5. The Provider must, at least once in each Contract Year, audit its practices against quality statements regarding data sharing set out in NICE Clinical Guideline 138.
6. The Provider must ensure that its NHS Information Governance Toolkit (or any successor framework) submission is audited in accordance with Information Governance Audit Guidance where applicable. The Provider must inform the Co-ordinating Commissioner of the results of each audit and publish the audit report both within the NHS Information Governance Toolkit (or any successor framework) and on its website.
7. The Provider must report and publish any Data Breach and any Information Governance Breach in accordance with IG Guidance for Serious Incidents. If the Provider is required under Data Protection Legislation to notify the Information Commissioner or a Data Subject of a Personal Data Breach then as soon as reasonably practical and in any event on or before the first such notification is made the Provider must inform the Co-ordinating Commissioner of the Personal Data Breach. This GC21.7 does not require the Provider to provide the Co-ordinating Commissioner with information which identifies any individual affected by the Personal Data Breach where doing so would breach Data Protection Legislation.

**Data Protection**1. The Provider must have in place a communications strategy and implementation plan to ensure that Service Users are provided with, or have made readily available to them, Privacy Notices, and to disseminate nationally-produced patient information materials. Any failure by the Provider to inform Service Users as required by Data Protection Legislation or Data Guidance about the uses of Personal Data that may take place under this Contract cannot be relied on by the Provider as evidence that such use is unlawful and therefore not contractually required.
2. Whether or not a Party or Sub-Contractor is a Data Controller or Data Processor will be determined in accordance with Data Protection Legislation and the ICO Guidance on Data Controllers and Data Processors and any further Data Guidance from a Regulatory or Supervisory Body. The Parties acknowledge that a Party or Sub-Contractor may act as both a Data Controller and a Data Processor. The Parties have indicated in the Particulars whether they consider the Provider to be a Data Processor for the purposes of this Contract.
3. The Provider must ensure that all Personal Data processed by or on behalf of the Provider in the course of delivering the Services is processed in accordance with the relevant Parties’ obligations under Data Protection Legislation and Data Guidance.
4. In relation to Personal Data processed by the Provider in the course of delivering the Services, the Provider must publish, maintain and operate:
	* 1. policies relating to confidentiality, data protection and information disclosures that comply with the Law, the Caldicott Principles and Good Practice;
		2. policies that describe the personal responsibilities of Staff for handling Personal Data;
		3. a policy that supports the Provider’s obligations under the NHS Care Records Guarantee;
		4. agreed protocols to govern the sharing of Personal Data with partner organisations; and
		5. where appropriate, a system and a policy in relation to the recording of any telephone calls or other telehealth consultations in relation to the Services, including the retention and disposal of those recordings,

and apply those policies and protocols conscientiously.* 1. Where a Commissioner requires information for the purposes of quality management of care processes, the Provider must consider whether the Commissioner’s request can be met by providing anonymised or aggregated data which does not contain Personal Data. Where Personal Data must be shared in order to meet the requirements of the Commissioner, the Provider must:
		1. provide such information in pseudonymised form where possible; and in any event
		2. ensure that there is a legal basis for the sharing of Personal Data.
	2. Notwithstanding GC21.12, the Provider must (unless it can lawfully justify non-disclosure) disclose defined or specified confidential patient information to or at the request of the Co-ordinating Commissioner where support has been provided under the Section 251 Regulations, respecting any individual Service User’s objections and complying with other conditions of the relevant approval.

**The Provider as a Data Processor*** 1. Where the Provider, in the course of delivering the Services, acts as a Data Processor on behalf of a Commissioner, the provisions of Schedule 6F *(Provider Data Processing Agreement)* will apply.

**Responsibilities when engaging Sub-Contractors*** 1. Subject always to GC12 (*Assignment and Sub-Contracting*), if the Provider is to engage any Sub-Contractor to deliver any part of the Services (other than as a Data Processor) and the Sub-Contractor is to access personal or confidential information or interact with Service Users, the Provider must impose on its Sub-Contractor obligations that are no less onerous than the obligations imposed on the Provider by this GC21.
	2. Without prejudice to GC12 (*Assignment and Sub-Contracting*), if the Provider is to require any Sub-Contractor to act as a Data Processor on its behalf, the Provider must:
		1. require that Sub-Contractor to provide sufficient guarantees in respect of its technical and organisational security measures governing the data processing to be carried out, and take reasonable steps to ensure compliance with those measures;
		2. carry out and and record appropriate due diligence before the Sub-Contractor processes any Personal Data in order to demonstrate compliance with Data Protection Legislation; and
		3. as far as practicable include in the terms of the sub-contract terms equivalent to those set out in Schedule 6F *(Provider Data Processor Agreement)* and in any event ensure that the Sub-Contractor is engaged under the terms of a binding written agreement requiring the Sub-Contractor to:
			1. process Personal Data only in accordance with the Provider’s instructions as set out in the written agreement, including instructions regarding transfers of Personal Data outside the EU or to an international organisation unless such transfer is required by Law, in which case the Data Processor shall inform the Provider of that requirement before processing takes place, unless this is prohibited by law on the grounds of public interest;
			2. ensure that persons authorised to process the Personal Data on behalf of the Sub-Contractor have committed themselves to confidentiality or are under appropriate statutory obligations of confidentiality;
			3. comply at all times with obligations equivalent to those imposed on the Provider by virtue of the Seventh Data Protection Principle for so long as the DPA 1998 remains in force and after that time with those obligations set out at Article 32 of the GDPR and equivalent provisions implemented into Law by DPA 2018;
			4. impose obligations as set out in this clause GC21.16.3 on any Sub-processor appointed by the Sub-Contractor;
			5. taking into account the nature of the processing, assist the Provider by taking appropriate technical and organisational measures, insofar as this is possible, for the fulfilment of the Provider’s obligation to respond to requests for exercising rights granted to individuals by Data Protection Legislation;
			6. assist the Provider in ensuring compliance with the obligations set out at Article 32 to 36 of the GDPR and equivalent provisions implemented into Law, taking into account the nature of processing and the information available to the Sub-Contractor;
			7. at the choice of the Provider, delete or return all Personal Data to the Provider after the end of the provision of services relating to processing, and delete existing copies unless the Law requires storage of the Personal Data;
			8. create and maintain a record of all categories of data processing activities carried out under the Sub-Contract, containing:

21.16.3.8.1 the name and contact details of the Data Protection Officer (where required by Data Protection Legislation to have one);21.16.3.8.2 the categories of processing carried out on behalf of the Provider; 21.16.3.8.3 where applicable, transfers of Personal Data to a third country or an international organisation, including the identification of that third country or international organisation and, where relevant, the documentation of suitable safeguards; 21.16.3.8.4 a general description of the technical and organisation security measures taken to ensure the security and integrity of the Personal Data processed under this Contract;* + - 1. guarantee that it has technical and organisational measures in place that are sufficient to ensure that the processing complies with Data Protection Legislation and ensures that the rights of Data Subject are protected;
			2. allow rights of audit and inspection in respect of relevant data handling systems to the Provider or to the Co-ordinating Commissioner or to any person authorised by the Provider or by the Co-ordinating Commissioner to act on its behalf; and
			3. impose on its own Sub-Contractors (in the event the Sub-Contractor further sub-contracts any of its obligations under the Sub-Contract) obligations that are substantially equivalent to the obligations imposed on the Sub-Contractor by this GC21.16.3.
	1. The agreement required by GC21.16 must also set out:

21.17.1 the subject matter of the processing;21.17.2 the duration of the processing;21.17.3 the nature and purposes of the processing;21.17.4 the type of personal data processed;21.17.5 the categories of data subjects; and21.17.6 the plan for return and destruction of the data once processing is complete unless the Law requires that the data is preserved.**Freedom of Information and Transparency*** 1. The Provider acknowledges that the Commissioners are subject to the requirements of FOIA and EIR. The Provider must assist and co-operate with each Commissioner to enable it to comply with its disclosure obligations under FOIA and EIR. The Provider agrees:

21.18.1 that this Contract and any other recorded information held by the Provider on a Commissioner’s behalf for the purposes of this Contract are subject to the obligations and commitments of the Commissioner under FOIA and EIR; 21.18.2 that the decision on whether any exemption under FOIA or exception under EIR applies to any information is a decision solely for the Commissioner to whom a request for information is addressed; 21.18.3 that where the Provider receives a request for information relating to the Services provided under this Contract and the Provider itself is subject to FOIA or EIR, it will liaise with the relevant Commissioner as to the contents of any response before a response to a request is issued and will promptly (and in any event within 2 Operational Days) provide a copy of the request and any response to the relevant Commissioner; 21.18.4 that where the Provider receives a request for information and the Provider is not itself subject to FOIA or as applicable EIR, it will not respond to that request (unless directed to do so by the relevant Commissioner to whom the request relates) and will promptly (and in any event within 2 Operational Days) transfer the request to the relevant Commissioner; 21.18.5 that any Commissioner, acting in accordance with the codes of practice issued and revised from time to time under both section 45 of FOIA and regulation 16 of EIR, may disclose information concerning the Provider and this Contract either without consulting with the Provider, or following consultation with the Provider and having taken its views into account; and 21.18.6 to assist the Commissioners in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA or EIR) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of FOIA, and providing copies of all information requested by that Commissioner within 5 Operational Days of that request and without charge. 21.19 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of FOIA, or for which an exception applies under EIR, the content of this Contract is not Confidential Information. 21.20 Notwithstanding any other term of this Contract, the Provider consents to the publication of this Contract in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of FOIA or for which an exception applies under EIR. 21.21 In preparing a copy of this Contract for publication under GC21.20 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 will be at the Commissioners’ absolute discretion. 21.22 The Provider must assist and cooperate with the Commissioners to enable the Commissioners to publish this Contract.  |

1. **General Conditions: Definitions and Interpretation**
	1. With effect from the dates set out in Appendix 1, insert the new definitions set out in Part 1 of Appendix 1; amend the definitions set out in Part 2 of Appendix 1 as described in that Part 2; delete the definitions set out in Part 3 of Appendix 1, as applicable.
2. **Counterparts**
	1. This National Variation 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.
3. **Precedence of this National Variation Agreement**
	1. In the event of any inconsistency between the terms of this National Variation Agreement and the Contract, the terms of this National Variation Agreement shall take precedence.
4. **Continuing effect**
	1. Subject to the Variations, the Contract shall continue in full force and effect in all respects.
5. **Governing Law and Jurisdiction**
	1. This National Variation Agreement shall be subject to the provisions of GC39 of the Contract.

**IN WITNESS OF WHICH the Parties have signed this National Variation Agreement on the date(s) shown below**

|  |  |
| --- | --- |
| **SIGNED by**  | ………………………………………………….Signature |
| **[INSERT AUTHORISED** **SIGNATORY’S****NAME] for****and on behalf of** **[INSERT COMMISSIONER NAME]** | ………………………………………………….Title………………………………………………….Date |
| **[INSERT AS ABOVE FOR** **EACH COMMISSIONER]** |  |
| **SIGNED by**  | …………………………………………………Signature |
| **[INSERT AUTHORISED** **SIGNATORY’S****NAME] for****and on behalf of** **[INSERT PROVIDER NAME]** | ………………………………………………Title………………………………………………Date |

**Appendix 1: Definitions**

**Appendix 1 Part 1: New Defined Terms**

With effect from 1 April 2018, add the following definitions to the General Conditions (*Definitions and Interpretation*) in alphabetical sequence:

|  |
| --- |
| **Commercial Contract Research Study** a research project that is fully sponsored and fully funded by a commercial company |
| **Genomic Laboratory Hub** an organisation which holds a contract with NHS England to arrange and/or perform genomic laboratory services for a defined geographical population (details of each Genomic Laboratory Hub and the catchment it will serve will be published by NHS England from time to time, together with the sub-contracted organisations that are designated within the GLH to provide any of the services within the hub catchment area) |
| **Health Research Authority** the executive non-departmental public body sponsored by the Department of Health which protects and promotes the interests of patients and the public in health and social care research |
| **HRA/NIHR Research Reporting Guidance** the guidance published by the Health Research Authority and the National Institute for Health Research regarding publication by any Provider of data showing the progress of research studies in which that Provider is participating, available at <https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm> |
| **National Directive on Conducting Commercial Contract Research Studies** the mandatory requirements governing participation by NHS Trusts and NHS Foundation Trusts in Commercial Research Studies, published jointly by NHS England, the National Institute for Health Research and the Health Research Authority from time to time, including:1. a methodology for setting prices payable by research sponsors to Trusts for their participation; and
2. other contractual terms and conditions to apply to Trust participation
 |
| **National Genomic Test Directory** the document published from time to time by NHS England listing all of the commissioned and provided genomic tests. The Directory includes genetic testing for rare and more common inherited disorders where constitutional genomic testing directs clinical care, and for cancer covers somatic genomic testing where findings are actionable in clinical care or as part of conferring eligibility to clinical trials |
| **National Institute for Health Research** the organisation established by the Department of Health to transform research in the NHS |
| **Provider Sustainability Fund** the arrangement described in *Refreshing NHS Plans for 2018/19* (https://www.england.nhs.uk/wp-content/uploads/2018/02/planning-guidance-18-19.pdf) through which NHS Trusts and Foundation Trusts can access non-recurrent funding |

With effect from 25 May 2018, add the following definitions to the General Conditions (*Definitions and Interpretation*) in alphabetical sequence:

|  |
| --- |
| **Data Guidance** any applicable guidance, guidelines, direction or determination, framework, code of practice, standard or requirement regarding information governance, confidentiality, privacy or compliance with Data Protection Legislation (whether specifically mentioned in this Contract or not) to the extent published and publicly available or their existence or contents have been notified to the Provider by the Co-ordinating Commissioner and/or any relevant Regulatory or Supervisory Body. This includes but is not limited to guidance issued by NHS Digital, the National Data Guardian for Health & Care, the Department of Health, NHS England, the Health Research Authority, Public Health England, the European Data Protection Board and the Information Commissioner |
| **Data Loss Event** any event that results, or may result, in unauthorised processing of Personal Data held by the Provider under this Contract or Personal Data for which the Provider has responsibility under this Contract including without limitation actual or potential loss, destruction, corruption or inaccessibility of Personal Data, including any Personal Data Breach |
| **Data Processing Services** the data processing services described in the Annex to Schedule 6F |
| **Data Protection Impact Assessment** an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data |
| **Data Protection Legislation** (i) the DPA 1998 (ii) the GDPR, the LED and any applicable national Laws implementing them as amended from time to time (iii) the DPA 2018 (iv) all applicable Law concerning privacy, confidentiality or the processing of personal data including but not limited to the Human Rights Act 1998, the Health and Social Care (Safety and Quality) Act 2015, the common law duty of confidentiality and the Privacy and Electronic Communications (EC Directive) Regulations |
| **Data Protection Officer** has the meaning given to it in Data Protection Legislation |
| **Data Subject** has the meaning given to it in Data Protection Legislation |
| **Data Subject Access Request** a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to Data Protection Legislation to access their Personal Data |
| **DPA 1998** the Data Protection Act 1998 |
| **DPA 2018** the Data Protection Act 2018 |
| **European Data Protection Board** has the meaning given to it in Data Protection Legislation |
| **GDPR** the General Data Protection Regulation *(Regulation (EU) 2016/679)* |
| **LED** Law Enforcement Directive *(Directive (EU) 2016/680)* |
| **Personal Data Breach** has the meaning given to it in the Data Protection Legislation |
| **Privacy Notice** the information that must be provided to a Data Subject under whichever of the following Laws is in force at the relevant time:(i) paragraph 2(3) of Part II of Schedule 1 DPA 1998(ii) Article 13 and Article 14 of the GDPR; or(iii) DPA 2018 |
| **Processor Data** is any data processed by the Provider in connection with the Data Processing Services |
| **Protective Measures** appropriate technical and organisational measures which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of such measures |
| **Sub-processor** any Sub-Contractor appointed by a Data Processor to process Personal Data on behalf of the Commissioners pursuant to this Contract |

**Appendix 1 Part 2: Variations to Defined Terms**

With effect from 1 April 2018, delete the definitions given to the following defined terms and replace with the amended definitions as follows or where applicable vary the defined term as described below (and, where the defined term itself is amended, any use in the Contract of the original term is to be read as the amended term):

| **Term:** | **Amended definition or amendment to defined term** |
| --- | --- |
| **Commercial Contract Research Study** | a research project that is fully sponsored and fully funded by a commercial company |
| **e-Invoicing Guidance** | guidance relating to the application and use of the NHS Shared Business Services e-Invoicing Platform, available at: https://networkgrowth.s3.amazonaws.com/Tradeshift%20Supplier%20Training%20Guide.pdf |
| **HEE Quality Framework** | the Health Education England Quality Framework, available at: https://hee.nhs.uk/our-work/quality |
| **HRA/NIHR Research Reporting Guidance** | the guidance published by the Health Research Authority and the National Institute for Health Research regarding publication by any Provider of data showing the progress of research studies in which that Provider is participating, available at <https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm> |
| **National Clinical Audit and Patient Outcomes Programme** | a set of centrally commissioned national clinical audits that measure Provider performance against national quality standards or evidence-based best practice, and allows comparisons to be made between provider organisations to improve the quality and outcomes of care https://www.hqip.org.uk/national-programmes/#.WuoR4U9lJMw |
| **National Directive on Commercial Contract Research Studies** | the mandatory requirements governing participation by Providers in Commercial Research Studies, published jointly by NHS England, the National Institute for Health Research and the Health Research Authority from time to time, including1. a methodology for setting prices payable by research sponsors to Providers for their participation; and
2. other contractual terms and conditions to apply to Provider participation
 |
| **National Institute for Health Research** | the organisation established by the Department of Health to transform research in the NHS |
| **National Service Specifications** | the Service Specifications published by NHS England for prescribed specialised services, available via:<https://www.england.nhs.uk/commissioning/spec-services/npc-crg/> |
| **Never Events Policy Framework** | the *Never Events Policy Framework*, available at: <https://improvement.nhs.uk/resources/never-events-policy-and-framework/> |
| **NHS Choice Framework** | the framework providing information about patients’ rights to choice in the NHS: <https://www.gov.uk/government/publications/the-nhs-choice-framework/the-nhs-choice-framework-what-choices-are-available-to-me-in-the-nhs> |
| **NHS Clinical Classifications Service** | the NHS resource responsible for the delivery of national clinical classifications standards and guidance for the NHS clinical coding profession: https://isd.digital.nhs.uk/trud3/user/guest/group/61/home |
| **NHS Identity Guidelines** | NHS Identity policy and guidelines, available at https://www.england.nhs.uk/nhsidentity/, and any other Guidance issued from time to time in relation to the NHS Identity |
| **Overseas Visitor Charging Guidance** | any guidance issued from time to time by the Secretary of State or by NHS England on the making and recovery of charges under the Overseas Visitor Charging Regulations, including that available via:<https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/666031/UPDATED_Guidance_to_Charging_Regulations_post_23_October.pdf>and<https://www.england.nhs.uk/publication/improving-systems-for-cost-recovery-for-overseas-visitors/> |
| **Proposer** | a Party making a Variation Proposal |
| **Safeguarding Guidance** | *Working Together to Safeguard Children - A guide to inter-agency working to safeguard and promote the welfare of children – statutory guidance*<https://www.gov.uk/government/publications/working-together-to-safeguard-children--2>*Care and Support Statutory Guidance issued under the Care Act*<https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/315993/Care-Act-Guidance.pdf> |
| **Safeguarding Training Guidance** | guidance in relation to safeguarding published by the Department for Education, including *Safeguarding children and young people: roles and competencies for health care staff*, available at:<https://www.rcpch.ac.uk/resources/safeguarding-children-young-people-roles-competences-healthcare-staff> |
| **SCCI** | the Standardisation Committee for Care Information, the body with delegated responsibility for appropriate information standards for the health and social care system (or that body’s predecessor):https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions |
| **Seven Day Service Hospital Priority Clinical Standards** | standards 2, 5, 6 and 8 of the standards for seven day services, available via: https://improvement.nhs.uk/resources/seven-day-services/ |
| **Standard DBS Position** | any position listed in the Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975 (as amended) and in relation to which a Standard DBS Check is permitted: https://www.gov.uk/government/publications/dbs-check-eligible-positions-guidance |
| **Urgent Care Data Sharing Agreement** | an agreement providing for the sharing of certain clinical data between commissioners and providers of urgent and emergency care services in accordance with *Data Sharing Requirements to support Development of Urgent and Emergency Care Dashboards – Guidance for Data Providers* available at <https://www.england.nhs.uk/nhs-standard-contract/> |
| **Variation Agreement** | an agreement in writing in the form available at: <https://www.england.nhs.uk/nhs-standard-contract/> |

With effect from 25 May 2018, delete the definitions given to the following defined terms and replace with the amended definitions as follows or where applicable vary the defined term as described below (and, where the defined term itself is amended, any use in the Contract of the original term is to be read as the amended term):

|  |  |
| --- | --- |
| **Term:** | **Amended definition or amendment to defined term** |
| **Data Controller** | has the meaning given to it in the Data Protection Legislation |
| **Indirect Losses** | 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 but, for the avoidance of doubt, excluding any costs incurred in remedying any breach of Data Protection Legislation |
| **Personal Data** | has the meaning given to it in the Data Protection Legislation |
| **Regulatory or Supervisory Body** | any statutory or other body having authority to issue guidance, standards or recommendations with which the relevant Party and/or Staff must comply or to which it or they must have regard, including:1. CQC;
2. NHS Improvement;
3. NHS England;
4. the Department of Health;
5. NICE;
6. Healthwatch England and Local Healthwatch;
7. Public Health England;
8. the General Pharmaceutical Council;
9. the Healthcare Safety Investigation Branch;
10. the Information Commissioner; and
11. the European Data Protection Board
 |
| **Seventh Data Protection Principle** | the seventh principle set out in paragraphs 9-12 of Part II of Schedule 1 to the DPA 1998<http://www.legislation.gov.uk/ukpga/1998/29/schedule/1/part/II/crossheading/the-seventh-principle> |

**Appendix 1 Part 3: Deleted Defined Terms**

With effect from 1 April 2018, delete the definition given to the following defined term:

|  |
| --- |
| **Sustainability and Transformation Fund** the arrangement described in *Delivering the Forward View: NHS planning guidance 2016/17 – 2020/21* (<https://www.england.nhs.uk/ourwork/futurenhs/deliver-forward-view/>) through which NHS Trusts and Foundation Trusts can access non-recurrent funding |

With effect from 25 May 2018, delete the definition given to the following defined term:

|  |
| --- |
| **DPA** the Data Protection Act 1998 |

**Appendix 2:**

**Operational Standards and National Quality Requirements**

**Schedule 4 Part A: Operational Standards**

| **Ref** | **Operational Standards** | **Threshold** | **Method of Measurement** | **Consequence of breach** | **Timing of application of consequence** | **Application** |
| --- | --- | --- | --- | --- | --- | --- |
|  | **RTT waiting times for non-urgent consultant-led treatment** |  |  |  |  |  |
| ***E.B.3*** | ***Percentage of Service Users on incomplete RTT pathways (yet to start treatment) waiting no more than 18 weeks from Referral\**** | ***Operating standard of 92% at specialty level (as reported on Unify)*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users waiting more than 18 weeks at the end of the month exceeds the tolerance permitted by the threshold, £300 in respect of each such Service User above that threshold*** | ***Monthly*** | ***Services to which 18 Weeks applies*** |
|  | **Diagnostic test waiting times** |  |  |  |  |  |
| ***E.B.4*** | ***Percentage of Service Users waiting 6 weeks or more from Referral for a diagnostic test\**** | ***Operating standard of no more than 1%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users waiting 6 weeks or more at the end of the month exceeds the tolerance permitted by the threshold, £200 in respect of each such Service User above that threshold*** | ***Monthly*** | ***A******CS******CR******D*** |
|  | **A&E waits** |  |  |  |  |  |
| ***E.B.5*** | ***Percentage of A & E attendances where the Service User was admitted, transferred or discharged within 4 hours of their arrival at an A&E department\**** | ***Operating standard of 95%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users in the month not admitted, transferred or discharged within 4 hours exceeds the tolerance permitted by the threshold, £120 in respect of each such Service User above that threshold. To the extent that the number of such Service Users exceeds 15% of A&E attendances in the relevant month, no further consequence will be applied in respect of the month*** | ***Monthly*** | ***A+E******U*** |
|  | **Cancer waits - 2 week wait** |  |  |  |  |  |
| ***E.B.6*** | ***Percentage of Service Users referred urgently with suspected cancer by a GP waiting no more than two weeks for first outpatient appointment\**** | ***Operating standard of 93%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users who have waited more than two weeks during the Quarter exceeds the tolerance permitted by the threshold, £200 in respect of each such Service User above that threshold***  | ***Quarterly*** | ***A******CR******R*** |
| ***E.B.7*** | ***Percentage of Service Users referred urgently with breast symptoms (where cancer was not initially suspected) waiting no more than two weeks for first outpatient appointment\**** | ***Operating standard of 93%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users who have waited more than two weeks during the Quarter exceeds the tolerance permitted by the threshold, £200 in respect of each such Service User above that threshold*** | ***Quarterly*** | ***A******CR******R*** |
|  | **Cancer waits – 31 days** |  |  |  |  |  |
| ***E.B.8*** | ***Percentage of Service Users waiting no more than one month (31 days) from diagnosis to first definitive treatment for all cancers\**** | ***Operating standard of 96%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users who have waited more than 31 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold*** | ***Quarterly*** | ***A******CR******R*** |
| ***E.B.9*** | ***Percentage of Service Users waiting no more than 31 days for subsequent treatment where that treatment is surgery\**** | ***Operating standard of 94%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users who have waited more than 31 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold*** | ***Quarterly*** | ***A******CR******R*** |
| ***E.B.10*** | ***Percentage of Service Users waiting no more than 31 days for subsequent treatment where that treatment is an anti-cancer drug regimen\**** | ***Operating standard of 98%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users who have waited more than 31 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold*** | ***Quarterly*** | ***A******CR******R*** |
| ***E.B.11*** | ***Percentage of Service Users waiting no more than 31 days for subsequent treatment where the treatment is a course of radiotherapy\**** | ***Operating standard of 94%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users who have waited more than 31 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold*** | ***Quarterly*** | ***A******CR******R*** |
|  | **Cancer waits – 62 days** |  |  |  |  |  |
| ***E.B.12*** | ***Percentage of Service Users waiting no more than two months (62 days) from urgent GP referral to first definitive treatment for cancer\**** | ***Operating standard of 85%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users who have waited more than 62 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold*** | ***Quarterly*** | ***A******CR******R*** |
| ***E.B.13*** | ***Percentage of Service Users waiting no more than 62 days from referral from an NHS screening service to first definitive treatment for all cancers\**** | ***Operating standard of 90%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of Service Users in the Quarter who have waited more than 62 days during the Quarter exceeds the tolerance permitted by the threshold, £1,000 in respect of each such Service User above that threshold*** | ***Quarterly*** | ***A******CR******R*** |
|  | **Ambulance Service Response Times** |  |  |  |  |  |
|  | ***(With effect from 1 April 2018) Category 1 (life-threatening) calls – percentage of calls resulting in a response arriving within 15 minutes \*\**** | ***Operating standard that 90th centile is no greater than 15 minutes*** | ***Review of Service Quality Performance Reports*** | ***Issue of a Contract Performance Notice and subsequent process in accordance with GC9*** | ***Quarterly*** | ***AM*** |
|  | ***(With effect from 1 April 2018) Category 1 (life-threatening) calls – mean time taken for a response to arrive \*\**** | ***Mean is no greater than 7 minutes*** | ***Review of Service Quality Performance Reports*** | ***Issue of a Contract Performance Notice and subsequent process in accordance with GC9*** | ***Quarterly*** | ***AM*** |
|  | ***(With effect from 1 April 2018) Category 2 (emergency) calls – percentage of calls resulting in an appropriate response arriving within 40 minutes \*\**** | ***Operating standard that 90th centile is no greater than 40 minutes*** | ***Review of Service Quality Performance Reports*** | ***Issue of a Contract Performance Notice and subsequent process in accordance with GC9*** | ***Quarterly*** | ***AM*** |
|  | ***(With effect from 1 April 2018) Category 2 (emergency) calls – mean time taken for an appropriate response to arrive \*\**** | ***Mean is no greater than 18 minutes*** | ***Review of Service Quality Performance Reports*** | ***Issue of a Contract Performance Notice and subsequent process in accordance with GC9*** | ***Quarterly*** | ***AM*** |
|  | ***(With effect from 1 April 2018) Category 3 (urgent) calls – percentage of calls resulting in an appropriate response arriving within 120 minutes \*\**** | ***Operating standard that 90th centile is no greater than 120 minutes*** | ***Review of Service Quality Performance Reports*** | ***Issue of a Contract Performance Notice and subsequent process in accordance with GC9*** | ***Quarterly*** | ***AM*** |
|  | ***(With effect from 1 April 2018) Category 4 (non-urgent “assess, treat, transport” calls only) – percentage of calls resulting in an appropriate response arriving within 180 minutes \*\**** | ***Operating standard that 90th centile is no greater than 180 minutes*** | ***Review of Service Quality Performance Reports*** | ***Issue of a Contract Performance Notice and subsequent process in accordance with GC9*** | ***Quarterly*** | ***AM*** |
|  | **Mixed sex accommodation breaches** |  |  |  |  |  |
| E.B.S.1 | Mixed sex accommodation breach\* | >0 | Review of Service Quality Performance Reports | £250 per day per Service User affected | Monthly | ACRMH |
|  | **Cancelled operations** |  |  |  |  |  |
| E.B.S.2  | All Service Users who have operations cancelled, on or after the day of admission (including the day of surgery), for non-clinical reasons to be offered another binding date within 28 days, or the Service User’s treatment to be funded at the time and hospital of the Service User’s choice\* | Number of Service Users who are not offered another binding date within 28 days >0 | Review of Service Quality Performance Reports | Non-payment of costs associated with cancellation and non- payment or reimbursement (as applicable) of re-scheduled episode of care | Monthly | ACR |
|  | **Mental health** |  |  |  |  |  |
| ***E.B.S.3***  | ***Care Programme Approach (CPA): The percentage of Service Users under adult mental illness specialties on CPA who were followed up within 7 days of discharge from psychiatric in-patient care\**** | ***Operating standard of 95%*** | ***Review of Service Quality Performance Reports***  | ***Where the number of Service Users in the Quarter not followed up within 7 days exceeds the tolerance permitted by the threshold, £200 in respect of each such Service User above that threshold*** | ***Quarterly*** | ***MH******MHSS*** |

In respect of those Operational Standards shown in ***bold italics***, the provisions of SC36.37A apply.

\* as further described in *Joint Technical Definitions for Performance and Activity 2017/18-2018/19,* available at: <https://www.england.nhs.uk/wp-content/uploads/2015/12/joint-technical-definitions-performance-activity.pdf>

\*\* as further described in *Ambulance System Indicators*, available at <https://www.england.nhs.uk/statistics/wp-content/uploads/sites/2/2013/04/20170926-Ambulance-System-Indicators.docx>

**Appendix 2:**

**Operational Standards and National Quality Requirements**

**Schedule 4 Part B: National Quality Requirements**

|  | **National Quality Requirement** | **Threshold** | **Method of Measurement**  | **Consequence of breach** | **Timing of application of consequence** | **Application** |
| --- | --- | --- | --- | --- | --- | --- |
| E.A.S.4 | Zero tolerance methicillin-resistant *Staphylococcus aureus*\* | >0 | Review of Service Quality Performance Reports | £10,000 in respect of each incidence in the relevant month | Monthly | A |
| E.A.S.5 | Minimise rates of Clostridium difficile\* | [Insert baseline threshold identified for Provider: see Schedule 4F] | Review of Service Quality Performance Reports | As set out in Schedule 4F, in accordance with applicable Guidance | Annual | A |
| ***E.B.S.4*** | ***Zero tolerance RTT waits over 52 weeks for incomplete pathways\**** | ***>0*** | ***Review of Service Quality Performance Reports*** | ***£5,000 per Service User with an incomplete RTT pathway waiting over 52 weeks at the end of the relevant month*** | ***Monthly*** | ***Services to which 18 Weeks applies*** |
| ***E.B.S.7a*** | ***All handovers between ambulance and A&E must take place within 15 minutes with none waiting more than 30 minutes\**** | ***>0*** | ***Review of Service Quality Performance Reports*** | ***£200 per Service User waiting over 30 minutes in the relevant month*** | ***Monthly*** | ***A+E*** |
| ***E.B.S.7b*** | ***All handovers between ambulance and A&E must take place within 15 minutes with none waiting more than 60 minutes\**** | ***>0***  | ***Review of Service Quality Performance Reports*** | ***£1,000 per Service User waiting over 60 minutes (in total, not aggregated with E.B.S.7a consequence) in the relevant month*** | ***Monthly*** | ***A+E*** |
| ***E.B.S.8a*** | ***Following handover between ambulance and A & E, ambulance crew should be ready to accept new calls within 15 minutes and no longer than 30 minutes\**** | ***>0*** | ***Review of Service Quality Performance Reports*** | ***£20 per event where > 30 minutes in the relevant month*** | ***Monthly*** | ***AM*** |
| ***E.B.S.8b*** | ***Following handover between ambulance and A&E, ambulance crew should be ready to accept new calls within 15 minutes and no longer than 60 minutes\**** | ***>0*** | ***Review of Service Quality Performance Reports*** | ***£100 per event where > 60 minutes (in total, not aggregated with E.B.S.8a consequence) in the relevant month*** | ***Monthly*** | ***AM*** |
| ***E.B.S.5*** | ***Trolley waits in A&E not longer than 12 hours\**** | ***>0*** | ***Review of Service Quality Performance Reports*** | ***£1,000 per incidence in the relevant month*** | ***Monthly*** | ***A+E*** |
| E.B.S.6 | No urgent operation should be cancelled for a second time\* | >0 | Review of Service Quality Performance Reports | £5,000 per incidence in the relevant month | Monthly | ACR |
|  | ***VTE risk assessment: all inpatient Service Users undergoing risk assessment for VTE, as defined in Contract Technical Guidance*** | ***95%*** | ***Review of Service Quality Performance Reports*** | ***Issue of Contract Performance Notice and subsequent process in accordance with GC9*** | ***Quarterly*** | ***A*** |
|  | Duty of candour | Each failure to notify the Relevant Person of a suspected or actual Notifiable Safety Incident in accordance with Regulation 20 of the 2014 Regulations | Review of Service Quality Performance Reports | Recovery of the cost of the episode of care, or £10,000 if the cost of the episode of care is unknown or indeterminate | Monthly | All |
|  | ***Completion of a valid NHS Number field in mental health and acute commissioning data sets submitted via SUS, as defined in Contract Technical Guidance*** | ***99%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of breaches in the month exceeds the tolerance permitted by the threshold, £10 in respect of each excess breach above that threshold*** | ***Monthly*** | ***A******MH******MHSS*** |
|  | ***Completion of a valid NHS Number field in A&E commissioning data sets submitted via SUS, as defined in Contract Technical Guidance*** | ***95%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of breaches in the month exceeds the tolerance permitted by the threshold, £10 in respect of each excess breach above that threshold*** | ***Monthly*** | ***A&E*** |
|  | ***Completion of Mental Health Services Data Set ethnicity coding for all Service Users, as defined in Contract Technical Guidance*** | ***Operating standard of 90%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of breaches in the month exceeds the tolerance permitted by the threshold, £10 in respect of each excess breach above that threshold*** | ***Monthly*** | ***MH******MHSS*** |
|  | ***Completion of IAPT Minimum Data Set outcome data for all appropriate Service Users, as defined in Contract Technical Guidance*** | ***Operating standard of 90%*** | ***Review of Service Quality Performance Reports*** | ***Where the number of breaches in the month exceeds the tolerance permitted by the threshold, £10 in respect of each excess breach above that threshold*** | ***Monthly*** | ***MH******MHSS*** |
| ***E.H.4*** | ***Early Intervention in Psychosis programmes: the percentage of Service Users experiencing a first episode of psychosis or ARMS (at risk mental state) who wait less than two weeks to start a NICE-recommended package of care\**** | ***For the period 1 April 2017 to 31 March 2018, operating standard of 50%. From 1 April 2018, operating standard of 53%*** | ***Review of Service Quality Performance Reports*** | ***Issue of Contract Performance Notice and subsequent process in accordance with GC9***  | ***Quarterly*** | ***MH******MHSS*** |
| ***E.H.1*** | ***Improving Access to Psychological Therapies (IAPT) programmes: the percentage of Service Users referred to an IAPT programme who wait six weeks or less from referral to entering a course of IAPT treatment\**** | ***Operating standard of 75%*** | ***Review of Service Quality Performance Reports*** | ***Issue of Contract Performance Notice and subsequent process in accordance with GC9*** | ***Quarterly*** | ***MH******MHSS*** |
| ***E.H.2*** | ***Improving Access to Psychological Therapies (IAPT) programmes: the percentage of Service Users referred to an IAPT programme who wait 18 weeks or less from referral to entering a course of IAPT treatment\**** | ***Operating standard of 95%*** | ***Review of Service Quality Performance Reports*** | ***Issue of Contract Performance Notice and subsequent process in accordance with GC9*** | ***Quarterly*** | ***MH******MHSS*** |
|  | ***Full implementation of an effective e-Prescribing system for chemotherapy across all relevant clinical teams within the Provider (other than those dealing with children, teenagers and young adults) across all tumour sites*** | ***Failure to achieve full implementation as described under Service Specification B15/S/a Cancer: Chemotherapy (Adult) by 31 March 2017*** | ***Review of Service Quality Performance Reports*** | ***5% of the Actual Monthly Value for the Services provided under Service Specification B15/S/a (Cancer: Chemotherapy (Adult) per month, until full implementation is achieved*** | ***Monthly*** | ***Where both Specialised Services and Cancer apply*** |
|  | ***Full implementation of an effective e-Prescribing system for chemotherapy across all relevant clinical teams within the Provider dealing with children, teenagers and young adults across all tumour sites*** | ***Failure to achieve full implementation as described under Service Specification B15/S/b Cancer: Chemotherapy (Children, Teenagers and Young Adults) by 30 September 2017*** | ***Review of Service Quality Performance Reports*** | ***5% of the Actual Monthly Value for the Services provided under Service Specification B15/S/b Cancer: Chemotherapy (Children, Teenagers and Young Adults) per month, until full implementation is achieved*** | ***Monthly*** | ***Where both Specialised Services and Cancer apply*** |

In respect of the National Quality Requirements shown in ***bold italics*** the provisions of SC36.37A apply.

\* as further described in *Joint Technical Definitions for Performance and Activity 2017/18-2018/19,* available at: <https://www.england.nhs.uk/wp-content/uploads/2015/12/joint-technical-definitions-performance-activity.pdf>

**Appendix 3:**

**SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS**

**F. Provider Data Processing Agreement**

NOTE: This Schedule 6F applies only where the Provider is appointed to act as a Data Processor under this Contract

1. **SCOPE**
	1. The Co-ordinating Commissioner appoints the Provider as a Data Processor to perform the Data Processing Services.
	2. When delivering the Data Processing Services, the Provider must, in addition to its other obligations under this Contract, comply with the provisions of this Schedule 6F.
	3. This Schedule 6F applies for so long as the Provider acts as a Data Processor in connection with this Contract.
2. **DATA PROTECTION**
	1. The Parties acknowledge that for the purposes of Data Protection Legislation in relation to the Data Processing Services the Co-ordinating Commissioner is the Data Controller and the Provider is the Data Processor. The Provider must process the Processor Data only to the extent necessary to perform the Data Processing Services and only in accordance with written instructions set out in this Schedule, including instructions regarding transfers of Personal Data outside the EU or to an international organisation unless such transfer is required by Law, in which case the Provider must inform the Co-ordinating Commissioner of that requirement before processing takes place, unless this is prohibited by Law on the grounds of public interest.
	2. The Provider must notify the Co-ordinating Commissioner immediately if it considers that carrying out any of the Co-ordinating Commissioner’s instructions would infringe Data Protection Legislation.
	3. The Provider must provide all reasonable assistance to the Co-ordinating Commissioner in the preparation of any Data Protection Impact Assessment prior to commencing any processing. Such assistance may, at the discretion of the Co-ordinating Commissioner, include:
		1. a systematic description of the envisaged processing operations and the purpose of the processing;
		2. an assessment of the necessity and proportionality of the processing operations in relation to the Data Processing Services;
		3. an assessment of the risks to the rights and freedoms of Data Subjects; and
		4. the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.
	4. The Provider must, in relation to any Personal Data processed in connection with its obligations under this Schedule 6F:
		1. process that Personal Data only in accordance with Annex A, unless the Provider is required to do otherwise by Law. If it is so required the Provider must promptly notify the Co-ordinating Commissioner before processing the Personal Data unless prohibited by Law;
		2. ensure that it has in place Protective Measures, which have been reviewed and approved by the Co-ordinating Commissioner as appropriate to protect against a Data Loss Event having taken account of the:
			1. nature of the data to be protected;
			2. harm that might result from a Data Loss Event;
			3. state of technological development; and
			4. cost of implementing any measures;
		3. ensure that:
			1. when delivering the Data Processing Services the Provider Staff only process Personal Data in accordance with this Schedule 6F (and in particular Annex A);
			2. it takes all reasonable steps to ensure the reliability and integrity of any Provider Staff who have access to the Personal Data and ensure that they:
				1. are aware of and comply with the Provider’s duties under this paragraph;
				2. are subject to appropriate confidentiality undertakings with the Provider and any Sub-processor;
				3. are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third party unless directed in writing to do so by the Co-ordinating Commissioner or as otherwise permitted by this Contract;
				4. have undergone adequate training in the use, care, protection and handling of Personal Data; and
				5. are aware of and trained in the policies and procedures identified in GC21.11 (*Patient Confidentiality, Data Protection, Freedom of Information and Transparency*).
		4. not transfer Personal Data outside of the EU unless the prior written consent of the Co-ordinating Commissioner has been obtained and the following conditions are fulfilled:
			1. the Co-ordinating Commissioner or the Provider has provided appropriate safeguards in relation to the transfer as determined by the Co-ordinating Commissioner;
			2. the Data Subject has enforceable rights and effective legal remedies;
			3. the Provider complies with its obligations under Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Co-ordinating Commissioner in meeting its obligations); and
			4. the Provider complies with any reasonable instructions notified to it in advance by the Co-ordinating Commissioner with respect to the processing of the Personal Data;
		5. at the written direction of the Co-ordinating Commissioner, delete or return Personal Data (and any copies of it) to the Co-ordinating Commissioner on termination of the Data Processing Services and certify to the Co-ordinating Commissioner that it has done so within five Operational Days of any such instructions being issued, unless the Provider is required by Law to retain the Personal Data;
		6. if the Provider is required by any Law or Regulatory or Supervisory Body to retain any Processor Data that it would otherwise be required to destroy under this paragraph 2.4, notify the Co-ordinating Commissioner in writing of that retention giving details of the Processor Data that it must retain and the reasons for its retention; and
		7. co-operate fully with the Co-ordinating Commissioner during any handover arising from the cessation of any part of the Data Processing Services, and if the Co-ordinating Commissioner directs the Provider to migrate Processor Data to the Co-ordinating Commissioner or to a third party, provide all reasonable assistance with ensuring safe migration including ensuring the integrity of Processor Data and the nomination of a named point of contact for the Co-ordinating Commissioner.
	5. Subject to paragraph 2.6, the Provider must notify the Co-ordinating Commissioner immediately if, in relation any Personal Data processed in connection with its obligations under this Schedue 6F, it:
		1. receives a Data Subject Access Request (or purported Data Subject Access Request);
		2. receives a request to rectify, block or erase any Personal Data;
		3. receives any other request, complaint or communication relating to obligations under Data Protection Legislation owed by the Provider or any Commissioner;
		4. receives any communication from the Information Commissioner or any other Regulatory or Supervisory Body (including any communication concerned with the systems on which Personal Data is processed under this Schedule 6F);
		5. receives a request from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law;
		6. becomes aware of or reasonably suspects a Data Loss Event; or
		7. becomes aware of or reasonably suspects that it has in any way caused the Co-ordinating Commissioner or other Commissioner to breach Data Protection Legislation.
	6. The Provider’s obligation to notify under paragraph 2.5 includes the provision of further information to the Co-ordinating Commissioner in phases, as details become available.
	7. The Provider must provide whatever co-operation the Co-ordinating Commissioner reasonably requires to remedy any issue notified to the Co-ordinating Commissioner under paragraphs 2.5 and 2.6 as soon as reasonably practicable.
	8. Taking into account the nature of the processing, the Provider must provide the Co-ordinating Commissioner with full assistance in relation to either Party's obligations under Data Protection Legislation and any complaint, communication or request made under paragraph 2.5 (and insofar as possible within the timescales reasonably required by the Co-ordinating Commissioner) including by promptly providing:
		1. the Co-ordinating Commissioner with full details and copies of the complaint, communication or request;
		2. such assistance as is reasonably requested by the Co-ordinating Commissioner to enable the Co-ordinating Commissioner to comply with a Data Subject Access Request within the relevant timescales set out in Data Protection Legislation;
		3. assistance as requested by the Co-ordinating Commissioner following any Data Loss Event;
		4. assistance as requested by the Co-ordinating Commissioner with respect to any request from the Information Commissioner’s Office, or any consultation by the Co-ordinating Commissioner with the Information Commissioner's Office.
	9. Without prejudice to the generality of GC15 *(Governance, Transaction Records and Audit),* the Provider must allow for audits of its delivery of the Data Processing Services by the Co-ordinating Commissioner or the Co-ordinating Commissioner’s designated auditor.
	10. For the avoidance of doubt the provisions of GC12 *(Assignment and Sub-contracting)* apply to the delivery of any Data Processing Services.
	11. Without prejudice to GC12, before allowing any Sub-processor to process any Personal Data related to this Schedule 6F, the Provider must:
		1. notify the Co-ordinating Commissioner in writing of the intended Sub-processor and processing;
		2. obtain the written consent of the Co-ordinating Commissioner;
		3. carry out appropriate due diligence of the Sub-processor and ensure this is documented;
		4. enter into a binding written agreement with the Sub-processor which as far as practicable includes equivalent terms to those set out in this Schedule 6F and in any event includes the requirements set out at GC21.16.3; and
		5. provide the Co-ordinating Commissioner with such information regarding the Sub-processor as the Co-ordinating Commissioner may reasonably require.
	12. The Provider must create and maintain a record of all categories of data processing activities carried out under this Schedule 6F, containing:
		1. the categories of processing carried out under this Schedule 6F;
		2. where applicable, transfers of Personal Data to a third country or an international organisation, including the identification of that third country or international organisation and, where relevant, the documentation of suitable safeguards;
		3. a general description of the Protective Measures taken to ensure the security and integrity of the Personal Data processed under this Schedule 6F; and
		4. a log recording the processing of the Processor Data by or on behalf of the Provider comprising, as a minimum, details of the Processor Data concerned, how the Processor Data was processed, when the Processor Data was processed and the identity of any individual carrying out the processing.
	13. The Provider warrants and undertakes that it will deliver the Data Processing Services in accordance with all Data Protection Legislation and this Contract and in particular that it has in place Protective Measures that are sufficient to ensure that the delivery of the Data Processing Services complies with Data Protection Legislation and ensures that the rights of Data Subjects are protected.
	14. The Provider must comply at all times with obligations equivalent to those imposed on the Co-ordinating Commissioner by virtue of Seventh Data Protection Principle for so long as the DPA 1998 remains in force and after that time with those set out at Article 32 of the GDPR and equivalent provisions implemented into Law.
	15. The Provider must assist the Commissioners in ensuring compliance with the obligations set out at Article 32 to 36 of the GDPR and equivalent provisions implemented into Law, taking into account the nature of processing and the information available to the Provider.
	16. The Provider must take prompt and proper remedial action regarding any Data Loss Event.
	17. The Provider must assist the Co-ordinating Commissioner by taking appropriate technical and organisational measures, insofar as this is possible, for the fulfilment of the Commissioners’ obligation to respond to requests for exercising rights granted to individuals by Data Protection Legislation.

**Annex A**

**Data Processing Services**

**Processing, Personal Data and Data Subjects**

1. The Provider must comply with any further written instructions with respect to processing by the Co-ordinating Commissioner.
2. Any such further instructions shall be incorporated into this Annex.

| **Description**  | **Details** |
| --- | --- |
| Subject matter of the processing | *[This should be a high level, short description of what the processing is about i.e. its subject matter]* |
| Duration of the processing | *[Clearly set out the duration of the processing including dates]* |
| Nature and purposes of the processing | *[Please be as specific as possible, but make sure that you cover all intended purposes. The nature of the processing means any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of data (whether or not by automated means) etc. The purpose might include: employment processing, statutory obligation, recruitment assessment etc]* |
| Type of Personal Data  | *[Examples here include: name, address, date of birth, NI number, telephone number, pay, images, biometric data etc]* |
| Categories of Data Subject | *[Examples include: Staff (including volunteers, agents, and temporary workers), Co-ordinating Commissioners/ clients, suppliers, patients, students / pupils, members of the public, users of a particular website etc]* |
| Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data | *[Describe how long the data will be retained for, how it be returned or destroyed]* |