
Part 1 : Front Sheet

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| Contract Reference | CON-321538-B5D8B (Version 2.02) |
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Introduction

- A NHS Digital (as defined in Clause 1.1, Part 1 below) has a statutory function to collect, analyse, publish and disseminate certain health and social care data and may in accordance with its statutory functions from time to time share and permit others to use that data.
- B Any party wishing to receive and use NHS Digital's data must first enter into this Contract and will, where the data is Personal Data, be a Controller of that Personal Data. This Contract is a framework agreement. It creates a framework of legally binding terms and conditions that will apply on each and every occasion NHS Digital agrees to share data with the Recipient (as defined in Clause 1.2, Part 1 below). NHS Digital will not share data with any party that has not entered into this Contract unless the party is a Processor acting on behalf of the Recipient, and NHS Digital has agreed to share the data with that Processor.
- C Entering into this Contract does not guarantee that NHS Digital will agree to share any data with the Recipient, on any particular occasion, or for any particular purpose. Sharing of data by NHS Digital is at the absolute discretion of NHS Digital and subject to such terms and conditions as NHS Digital may impose. The terms and conditions on which NHS Digital will permit the Recipient to receive and use data on a particular occasion and for a particular purpose will be set out in a separate Data Sharing Agreement entered into between NHS Digital and the Recipient. Each Data Sharing Agreement will be subject to the terms and conditions of this Contract and will identify the specific data in question and will set out any specific terms that will apply to the sharing and use of the data by the Recipient on that occasion and for that particular purpose.

1 Parties

This Contract is made between:

- 1.1 The **Health and Social Care Information Centre ("NHS Digital")**, a body corporate established pursuant to section 252 of the Health and Social Care Act 2012 whose address is The Leeds Government Hub, 7 & 8 Wellington Place, Leeds LS1 4AP; and
- 1.2 The party whose details are set out below (the "**Recipient**"):

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|--------------------------------------|---|
| Organisation Name: | University College London (UCL) |
| Company Number (if relevant): | U34 |
| Address: | Gower Street London WC1E 6BT England |
| Email Address: | |

2 Term of this Contract

- 2.1 The term of this Contract shall be:

| | | | |
|-----------------------|------------|------------|------------|
| Effective Date | 29/07/2021 | End | 29/07/2024 |
| Term: | 3 Year | | |

3 Status of this Contract

- 3.1 This Data Sharing Framework Contract comprises this Part 1 (Front Sheet), Part 2 (Terms and Conditions), the Schedules and any DSA entered into between the parties from time to time (collectively the "**Contract**"). It sets out the terms on which NHS Digital agrees to share the Data with the Recipient.
- 3.2 The purpose of this Contract is to:
 - 3.2.1 clarify the responsibilities and commitments of the parties in relation to the Data;
 - 3.2.2 impose confidentiality requirements on the Recipient;
 - 3.2.3 outline the data security principles and requirements with which the Recipient must comply;
 - 3.2.4 set out the audit rights of NHS Digital; and
 - 3.2.5 detail arrangements for termination or expiry of this Contract.
- 3.3 If there is a conflict or inconsistency between any provision contained in (i) Part 1 (Front Sheet), (ii) Part 2 (Terms and Conditions), (iii) the Schedules, (iv) the provisions of a DSA, (v) the Annexes of the DSA, and (vi) any Special Conditions, then:
 - 3.3.1 the provisions of the Special Conditions shall prevail, followed by,
 - 3.3.2 this Part 1, followed by,
 - 3.3.3 Part 2, followed by,
 - 3.3.4 the Schedules, followed by,
 - 3.3.5 the remainder of the terms of the DSA (other than the Annexes to the DSA), followed by,
 - 3.3.6 the other Annexes to the DSA.

- 3.4 The parties may, from time to time, wish to share Data under this Contract. A Data Sharing Agreement (“**DSA**”) will be entered into by the parties to document and agree the terms on which the relevant Data will be shared. A DSA will be entered into between the parties when the Recipient signs the relevant DSA. Signing of the DSA may be performed electronically on NHS Digital's online portal. Each DSA which is entered into between the parties will form part of this Contract and will be subject to the terms and conditions of this Contract (or any New Contract). In no circumstances will a DSA be entered into without the parties first entering into this Contract (or any New Contract).
- 3.5 Each DSA will detail:
- 3.5.1 the Data to be provided;
 - 3.5.2 the legal basis for sharing Data;
 - 3.5.3 the Purpose of the sharing and use of the Data;
 - 3.5.4 the expected benefits to health and/or social care by sharing the Data;
 - 3.5.5 the data transfer method;
 - 3.5.6 any Associated DSAs;
 - 3.5.7 any special terms and conditions for the use or reuse of the Data; and
 - 3.5.8 any Charges payable for the provision of the Data.
- 3.6 Where the Data to be shared in accordance with the terms of this Contract and a DSA is Personal Data, the parties acknowledge and agree that:
- 3.6.1 the sharing of such Personal Data will involve the transfer of Personal Data from NHS Digital as a Controller to the Recipient as a Controller; and
 - 3.6.2 the Recipient shall be either an independent Controller or, where specified in the relevant DSA, a Joint Controller with any other recipient who has entered into an Associated DSA.
- 3.7 Where agreed with NHS Digital under the terms of the relevant DSA, NHS Digital may transfer the Data directly to a third party Processor acting on behalf of the Recipient.
- 3.8 Where the Recipient has been authorised to use the Data Access Environment, (including an NHS Digital Trusted Research Environment (TRE)) to access the Data under the terms of the relevant DSA, the Recipient will comply with Schedule 5 of this Contract.

By signing this Part 1, the parties agree to be bound by the terms of this Contract.

| Signed for and on behalf of the Recipient: | |
|---|---|
| Organisation Name: | University College London (UCL) |
| Signature | f7499cc7-07f7-46c5-996f-f6d38754ec9d |
| Name: | Mark Emberton |
| Role: | Professor of Interventional Oncology, Honorary Consultant urologist UCLH NHS Trust and Dean of the UCL Faculty of Medical Science |
| Date: | 29/07/2021 |

| Signed for and on behalf of NHS Digital: | |
|---|---|
| Name: | Louise Dunn |
| Signature | C9FDA30A-29AE-4C97-C2EF-EFC8EBFDC52E |
| Role: | Principal Business and Operational Delivery Manager |
| Date: | 27/07/2021 |

Part 2: Terms and Conditions

1 Interpretation

- 1.1 Capitalised words and expressions used in this Contract shall bear the meanings given to them in Schedule 1. The rules of interpretation set out in Schedule 1 shall apply to this Contract.

2 NHS Digital responsibilities

- 2.1 NHS Digital will transfer the Data to the Recipient (or, if specified in the DSA, the Processor authorised by NHS Digital) using the data transfer method as set out in the relevant DSA. Where the transfer method is by way of NHS Digital granting the Recipient access to the Data Access Environment, (including an NHS Digital Trusted Research Environment) the Recipient will comply with Schedule 5 of this Contract.
- 2.2 NHS Digital will be a Controller, or will act on behalf of the Controller, for the Data prior to transfer of the Data insofar as the Data constitutes Personal Data.

3 Licence and Intellectual Property

- 3.1 NHS Digital grants to the Recipient a non-exclusive, non-transferable, suspendable (in whole or in part), revocable licence in the Territory for the duration of the Term of the relevant DSA solely for the Purpose and only in accordance with the terms of this Contract and the relevant DSA, to:
- 3.1.1 access, view, process, copy, and Manipulate (but not modify) the Data; and/or
 - 3.1.2 make the data accessible; and/or
 - 3.1.3 create only Manipulated Data and Derived Data; and/or
 - 3.1.4 store the Data.
- 3.2 The Recipient shall only be entitled to make the Data accessible under Clause 3.1.2, and to sub-license the rights granted to it under Clauses 3.1.1, 3.1.3 and 3.1.4 inclusive, to sub-licensees where:
- 3.2.1 NHS Digital has specifically authorised such sub-licensing in the relevant DSA;
 - 3.2.2 the Recipient complies at all times with the sub-licensing conditions set out in Annex A: section 10 of the relevant DSA, and Schedule 4 of this Contract; and
 - 3.2.3 the Recipient has entered into a written agreement with the sub-licensee for the sub-licensing of its rights under Clause 3.1 in relation to the Data in a form meeting the requirements of Clause 3.3 and Schedule 4 of this Contract ("**Sub-Licence**").
- 3.3 Any Sub-Licence must:
- 3.3.1 without prejudice to Clause 3.3.2, and subject to Clauses 3.3.3 to 3.3.8, contain provisions which are substantially the same as the terms set out in this Contract and the relevant DSA;
 - 3.3.2 include the Core Terms;
 - 3.3.3 not contain any provision which enables the sub-licensee to sub-license its rights;
 - 3.3.4 contain third party rights to permit and enable NHS Digital to have direct rights to audit (as set out in Clause 7) and to exercise remediation rights (as set out in Clause 8);
 - 3.3.5 ensure that sub-licensed rights relating to the Data suspend automatically at least on the suspension of the Contract and/or the relevant DSA;
 - 3.3.6 ensure that sub-licensed rights relating to the Data terminate automatically at least on termination or expiry of the Contract and/or the relevant DSA; and
 - 3.3.7 permit notification of such Sub-Licence to NHS Digital (by reporting in a form and frequency to be determined by NHS Digital from time to time), including the right for the Recipient to provide copies of the Sub-Licence to NHS Digital.
- 3.4 The Recipient shall notify NHS Digital of all Sub-Licences granted by the Recipient by reference to each relevant DSA. NHS Digital may specify the form, level of detail, and frequency of such reporting from time to time, and may require the Recipient to provide copies of the relevant Sub-Licences.

- 3.5 The Recipient acknowledges and shall ensure, in respect of any Sub-Licence that:
- 3.5.1 NHS Digital may require the Recipient to provide a copy of any such Sub-Licence at any time;
 - 3.5.2 if NHS Digital becomes aware that any such Sub-Licence does not include the Core Terms and/or other mandatory terms stipulated in this Contract and/or the relevant DSA, this may result in the termination by NHS Digital of the relevant DSA and/or this Contract as per Paragraph 1 of Section C of Schedule 4;
 - 3.5.3 breach of any of the terms of any such Sub-Licence by the Recipient or the sub-licensee may result in the termination by NHS Digital of the relevant DSA and/or this Contract as per Paragraph 2 of Section C of Schedule 4; and
 - 3.5.4 the information provided to NHS Digital under Clause 3.4 in relation to such Sub-Licences may be shared publicly by NHS Digital at its own discretion including by disclosure on a Data Release Register.
- 3.6 The Recipient acknowledges that:
- 3.6.1 any and all Intellectual Property Rights in the Data are and shall remain at all times the property of NHS Digital or its licensors, as the case may be;
 - 3.6.2 it shall have no rights in or to the Data other than the right to use the Data in accordance with the express terms of this Contract and the relevant DSA; and
 - 3.6.3 NHS Digital has and/or its licensors have made and will continue to make substantial investment in obtaining, verifying, selecting, co-ordinating, developing, presenting and supplying the Data.
- 3.7 In consideration for the grant of the licence set out at Clause 3.1 and in accordance with Clause 3.12, the Recipient hereby assigns to NHS Digital absolutely with full title guarantee any and all Intellectual Property Rights (including but not limited to copyright and database rights) in any Manipulated Data from creation.
- 3.8 For the avoidance of doubt, in respect of the Intellectual Property Rights in the Manipulated Data assigned to NHS Digital by the Recipient under Clause 3.7:
- 3.8.1 The Recipient must ensure that any display of such Manipulated Data, wherever possible, cites the copyright of NHS Digital and/or any licensor of NHS Digital as appropriate as follows:

"Copyright © (year), NHS Digital. Re-used with the permission of the NHS Digital [and/or [name of licensor]]. All rights reserved."
 - 3.8.2 Whilst NHS Digital obtains ownership of Manipulated Data NHS Digital does not take ownership of any data of the Recipient or any third party that has been or will be obtained independently of NHS Digital Data Sharing Agreements.
 - 3.8.3 NHS Digital does not by virtue of Clause 3.7 have a right to use or take ownership of any data belonging to the Recipient or any third party which is Manipulated to create the Manipulated Data; and
 - 3.8.4 They shall be deemed to be included in the licence under Clause 3.7 from the date when such rights arise.
- 3.9 All Derived Data and any and all Intellectual Property Rights in Derived Data shall be owned exclusively by the Recipient. In consideration for the grant of the licence set out at Clause 3.1, the Recipient agrees to be bound by any terms set out in the Special Conditions regarding the making accessible (in hard-copy or electronic format), copying, processing, Manipulating, creating, storing and any other use of the Derived Data.
- 3.10 On demand by NHS Digital, the Recipient shall make a declaration (the form and content of which will be notified to the Recipient by NHS Digital at the relevant time) of any data created under the relevant DSA which it believes is Derived Data to NHS Digital. The Recipient will make available to NHS Digital, upon request, copies of any data declared to be Derived Data under this Clause 3.10.
- 3.11 Where the Recipient has made a declaration upon the request of NHS Digital under Clause 3.10, NHS Digital shall verify whether the data declared is Derived Data and inform the Recipient of the outcome of its verification. The Recipient hereby agrees that NHS Digital's verification is final and binding on whether data is classed as Derived Data or otherwise.

- 3.12 NHS Digital may call upon the Recipient at any time to execute such documents and perform such acts as may be required for the purpose of giving full effect to this Clause 3, in particular Clause 3.7. The Recipient shall, and shall use all reasonable endeavours to procure that any necessary third party shall, at its own cost, promptly execute such documents and perform such acts as may reasonably be required for the purpose of giving full effect to this Clause 3, in particular Clause 3.7.
- 3.13 In any display of the Data, wherever possible, the Recipient must cite the copyright of NHS Digital and/or any licensor of NHS Digital as appropriate as follows:
"Copyright © (year), NHS Digital. Re-used with the permission of NHS Digital [and/or [name of licensor]]. All rights reserved."

4 Recipient general responsibilities in relation to Data

- 4.1 The Recipient shall:
- 4.1.1 use the Data only in accordance with the Purpose;
 - 4.1.2 process the Data only in accordance with the terms of this Contract, the relevant DSA, and any Special Conditions;
 - 4.1.3 maintain good information governance standards and practices, meeting or exceeding the Data Security and Protection Toolkit (DSPT) required of its organisation type;
 - 4.1.4 not share the Data with any third party (other than any third party Processor permitted under the terms of the relevant DSA and only in relation to Data provided under that DSA) without the prior written consent of NHS Digital;
 - 4.1.5 ensure that Personnel processing the Data are suitably trained and made aware of their responsibilities in handling the Data;
 - 4.1.6 ensure that all Personnel, prior to accessing or using Data, are made fully aware of, and comply with the terms and conditions set out in this Contract and the relevant DSA;
 - 4.1.7 subject to any New Contract being entered into as set out in Clause 13.10 and subject to Clause 4.8, promptly and in any event within 28 days of the applicable date, the applicable date being the earlier of:
 - (a) the expiry or termination of this Contract; or
 - (b) the expiry or termination of the relevant DSA,permanently destroy or erase the Data and all Data licensed under the relevant DSA, together with all hard and soft copies of the same and provide NHS Digital with a Certification of Destruction. NHS Digital reserves the right to verify the deletion of the Data, including, without limitation by carrying out an audit in accordance with Clause 7, and the Recipient will cooperate with NHS Digital in relation to the same;
 - 4.1.8 immediately notify any Data Breach to NHS Digital as soon as the Recipient discovers such Data Breach; and:
 - (a) where the Recipient is obliged to complete the DSPT, the Recipient shall assess whether a "Serious Incident Requiring Investigation" (as defined in the DSPT) report needs to be made; or
 - (b) where the Recipient is not obliged to comply with the DSPT, the Recipient shall assess whether to notify the ICO of the Data Breach, in accordance with Applicable Law and the ICO's guidance on breach notification; and
 - 4.1.9 immediately notify NHS Digital if it no longer has a legal basis on which to process Data.
- 4.2 Unless specified in the Purpose, (or as otherwise authorised by an NHS Digital director in writing), the Recipient must not combine the Data with any other data held by the Recipient and must not attempt to identify any individual from the Data, or use or Manipulate the Data in any way that re-identifies any individual from the Data.
- 4.3 The Recipient shall when using and processing the Data comply with and have regard at all times to:
- 4.3.1 all Applicable Law;
 - 4.3.2 Good Industry Practice;
 - 4.3.3 Guidance; and
 - 4.3.4 the data security requirements set out in the DSA and Schedule 2.

- 4.4 In the event of any change in Applicable Law subsequent to the date of signature of this Contract, the Recipient shall take such steps (including, agreeing to additional obligations and/or executing additional documents) as may be requested by NHS Digital to ensure that the transfer to the Recipient, and the processing and use by the Recipient, of the Data complies with such amended Applicable Law.
- 4.5 Before undertaking any Publishing activity using the Data or any derived information, the Recipient must ensure it has complied with the terms of this Contract and the relevant DSA.
- 4.6 The Recipient must not contact any individual that could be identified from the Data, except where:
- 4.6.1 such contact is expressly permitted as part of the Purpose; and
- 4.6.2 either:
- (a) the individual concerned has already consented in writing to such contact; or
 - (b) there is legal authority for the Data to be used to contact the individual concerned without such consent.
- 4.7 Without prejudice to its rights under Clause 12 of this Contract, NHS Digital shall be entitled to suspend the supply of Data to the Recipient under this Contract and/or any DSA without incurring any liability to the Recipient if, in the reasonable opinion of NHS Digital, the Recipient may be in breach of any of its obligations under this Contract or any DSA.
- 4.8 The Recipient may retain the Data only to the extent it is required to do so by Applicable Law, including Research Law, and provided that:
- (a) the Recipient complies with the requirements of Clause 13.2 and NHS Digital agrees to enter into a new DSA which covers the retention of the Data;
 - (b) such retention is in compliance with Data Protection Law;
 - (c) such retention does not put NHS Digital in breach of Data Protection Law (recognising also that the Recipient is an Independent Controller); and
 - (d) the Recipient complies with Clause 4.1.7 as soon as it is no longer required to retain the Data.
- 5 Data protection**
- 5.1 To the extent that any of the Data constitutes Personal Data (or constitutes Anonymised Data, but then the Data becomes Personal Data in the hands of the Recipient), the Recipient shall hold and process such Data at all times:
- 5.1.1 as Controller of the Personal Data;
- 5.1.2 in accordance with Data Protection Law; and
- 5.1.3 using appropriate technical and organisational security measures against unauthorised or unlawful processing of Data and against accidental loss or destruction of, or damage to, the Data.
- 5.2 To the extent the Recipient processes Personal Data in connection with this Contract or any DSA, the Recipient agrees that, for the purposes of Data Protection Law, it processes such Personal Data either:
- 5.2.1 as an independent Controller in its own right: or
- 5.2.2 where specified in the relevant DSA, (i) as a Joint Controller or (ii) independent controllers, in each case with any other recipient who has entered into an Associated DSA.
- 5.3 Nothing in this Contract or in any DSA is intended to construe either party to this Contract as:
- 5.3.1 the Processor of the other party; or
- 5.3.2 a Joint Controller or independent controller with the other party.
- with respect to the Personal Data processed in connection with this Contract or any DSA.
- 5.4 Where the Data includes Personal Data, the Recipient shall:
- 5.4.1 store and process such Personal Data securely, and permanently destroy or erase it when it is no longer needed for the Purpose;

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- 5.4.2 not Publish such Personal Data without the prior written consent of NHS Digital. Such consent may (at NHS Digital's sole discretion) be conditional upon such Personal Data being de-identified to a standard suitable for subsequent release in compliance with the Anonymisation Standard for Publishing Health and Social Care Data (ISB 1523) and the ICO Anonymisation: managing data protection risk code of practice;
 - 5.4.3 not disseminate such Personal Data, or a subset of such Personal Data, to any third party other than a Processor approved under the relevant DSA (and only in relation to Data provided under that DSA) without prior written consent from NHS Digital;
 - 5.4.4 take reasonable steps to ensure the reliability of each of its Personnel who have access to such Personal Data;
 - 5.4.5 inform NHS Digital immediately if it receives any communication from the ICO which relates to such Personal Data, unless explicitly prohibited from doing so by the ICO;
 - 5.4.6 ensure access to such Personal Data by Personnel is managed, auditable and restricted to those needing to process such Personal Data;
 - 5.4.7 only be entitled to appoint a Processor to process such Personal Data on behalf of the Recipient where permitted under the terms of the relevant DSA (and only in relation to Data provided under that DSA) or with the prior written consent of NHS Digital and shall remain fully responsible to NHS Digital under the terms of this Contract and the relevant DSA for the actions of its Processors; and
 - 5.4.8 not transfer to or process such Personal Data outside the European Economic Area except with the express prior written consent of NHS Digital and only in circumstances when such transfer is permitted under, and complies with the requirements of, Data Protection Law and Applicable Law.
- 6 Confidentiality**
- 6.1 The Recipient must:
 - 6.1.1 keep the Data confidential, and shall not disclose it to any third party save where expressly permitted to do so in accordance with the terms of this Contract and the relevant DSA; and
 - 6.1.2 use the Data only in so far as is necessary to perform its obligations and exercise its rights under this Contract and the relevant DSA.
 - 6.2 The restrictions on disclosure and use contained in this Clause 6 shall not apply to the Data to the extent that it:
 - 6.2.1 is or was already in the possession of or becomes available to the Recipient in either case free of any obligation of confidentiality;
 - 6.2.2 is required to be disclosed by the Recipient by Applicable Law, or Parliamentary obligation, or the rules of any stock exchange or governmental or regulatory authority having the force of law;
 - 6.2.3 is required to be disclosed to the Recipient's professional advisers; or
 - 6.2.4 at the time of receipt by the Recipient, is in the public domain or after such receipt comes into the public domain other than as a result of breach by the Recipient of this Clause 6.
 - 6.3 The Recipient shall be responsible for any unauthorised disclosure or use of the Data made by any of its Personnel and shall take all reasonable precautions to prevent such unauthorised disclosure or use.
 - 6.4 If the Recipient is obliged to respond to requests under the Freedom of Information Act 2000 ("**FOIA**") and a request is received regarding the Data, the Recipient must consult with NHS Digital prior to any release of the Data and shall take into account NHS Digital's views before responding to any request. Notwithstanding this Clause 6.4, NHS Digital acknowledges and the Recipient accepts that the Recipient is responsible in its absolute discretion for determining whether information regarding the Data is exempt from disclosure under FOIA.
 - 6.5 Without prejudice to any other rights or remedies that NHS Digital may have, the Recipient acknowledges and agrees that damages alone would not be an adequate remedy for any breach of confidentiality and that accordingly, NHS Digital would be entitled to the remedies of injunctions, specific performance or other equitable relief for any threatened or actual breach of confidentiality by the Recipient.

7 Audit and specific rights

- 7.1 NHS Digital (and any auditors of or other advisers to NHS Digital) shall be entitled at any time during the Contract Term and for a period of 12 (twelve) months after the termination or expiry of this Contract, to audit the Recipient's compliance with the requirements of this Contract.
- 7.2 NHS Digital (and any auditors of or other advisers to NHS Digital) shall be entitled to audit the Recipient's use of the Data which may include the auditing of the hosting and IT infrastructure, security, processes and procedures. The rights of NHS Digital (and any auditors of or other advisers to NHS Digital) under this Clause 7 to audit the Recipient's use of the Data includes the right for NHS Digital (and any auditors of or other advisers to NHS Digital) to audit the use of the Data by any person to whom the Recipient has transferred or given access to the Data whether as a sub-licensee, sub-contractor, Processor or otherwise (each being a "**Third Party Contractor**"). The Recipient must include such provisions as are necessary to give NHS Digital (and any auditors of or other advisers to NHS Digital) that right in any sub-contract or Sub-Licence or other agreement or arrangement under which the Recipient permits such Third Party Contractor to have access to the Data and must use its best endeavours to procure that NHS Digital (and any auditors of or other advisers to NHS Digital) shall have access to the sites used by any such person to access the Data as if that person were the Recipient.
- 7.3 Subject to Clause 7.4, NHS Digital will give the Recipient or Third Party Contractor not less than 10 (ten) Working Days' notice of any proposed audit and will not carry out more than 2 (two) audits within any 12 (twelve) month period.
- 7.4 If NHS Digital, acting reasonably, has any concerns that:
- 7.4.1 the terms of this Contract and/or any DSA are not being adhered to by the Recipient and/or any Third Party Contractor; or
 - 7.4.2 the terms of any Associated DSA are not being adhered to by the relevant recipient under that Associated DSA,
- NHS Digital (and any auditors of or other advisers to NHS Digital) shall be entitled to carry out one or more audits on the Recipient and/or the Third Party Contractor, including making unannounced visits and carrying out spot checks of the Recipient's sites and Third Party Contractor's Sites. There shall be no restriction on the number of audits NHS Digital (and any auditors of or other advisers to NHS Digital) may carry out under this Clause 7.4, and the restriction on the number of audits that NHS Digital (and any auditors of or other advisers to NHS Digital) may carry out within a 12 (twelve) month period shall not apply to any audits carried out under this Clause 7.4.
- 7.5 The Recipient shall, for the purpose of any audit carried out under this Clause 7, provide or procure the access to the Recipient's and relevant Third Party Contractor's sites, systems, procedures, documents and staff as may be necessary or desirable in connection with the audit and shall permit or procure that NHS Digital (and any auditors of or other advisers to NHS Digital) are permitted to take copies of relevant documents and data pursuant to such audit.
- 7.6 The Recipient shall provide and shall procure that its Third Party Contractor provides such information as NHS Digital (and any auditors of or other advisers to NHS Digital) reasonably requests in order to verify the Recipient's compliance with the terms of this Contract and/or any DSA.
- 7.7 The cost of any audit carried out under this Clause 7 shall be borne by NHS Digital unless, in NHS Digital's reasonable opinion, the audit reveals that the Recipient or Third Party Contractor either has not complied, or is not complying, with any of the Recipient's obligations under this Contract, or any DSA, in which case the Recipient shall promptly reimburse NHS Digital for all reasonable costs of the audit and the full cost of any investigation which NHS Digital may commence prior to an audit taking place.
- 7.8 Subject to Clauses 7.9, 7.10, 7.11 and 7.12, NHS Digital agrees not to disclose to any third party any confidential information relating to the Recipient received or obtained by NHS Digital (i) under Clause 3.9 with respect to the Recipient's Derived Data, and (ii) in the course of carrying out any audit under this Clause 7.
- 7.9 The restrictions on disclosure and use of the Recipient's confidential information contained in Clause 7.8 shall not apply to information to the extent that it is or was:
- 7.9.1 already in the possession of or becomes available to NHS Digital in either case free of any obligation of confidentiality;
 - 7.9.2 required to be disclosed by NHS Digital by law, regulation or pursuant to an order of a regulatory or supervisory body, or by any other competent authority, or to a professional adviser; or

- 7.9.3 at the time of receipt by NHS Digital, is in the public domain or after such receipt comes into the public domain other than as a result of breach by NHS Digital of this Clause 7.
- 7.10 NHS Digital shall be entitled to share confidential information received or obtained by NHS Digital in the course of carrying out any audit under this Clause 7 with government organisations in accordance with its performance of its functions including NHS England, the Department of Health and Social Care, Government Legal Department, National Audit Office and any auditors or advisors to NHS Digital.
- 7.11 NHS Digital shall be entitled to Publish the auditor's findings and any audit report.
- 7.12 NHS Digital is obliged to respond to requests under FOIA. NHS Digital must consult with the Recipient prior to any release of confidential information received under this Clause 7 and shall take into account the Recipient's views before responding to any request. Notwithstanding this Clause 7.12, Recipient acknowledges and accepts that NHS Digital is responsible in its absolute discretion for determining whether the information is exempt from disclosure under FOIA.

8 Remediation process

- 8.1 Without limitation to Clause 7, Clause 13.6 and NHS Digital's other rights and remedies under this Contract, where: (i) the Recipient is in breach of this Contract or any DSA; or (ii) there is a breach of any Associated DSA; or (iii) (in NHS Digital's reasonable opinion) there has been or is likely to be a breach of any Associated DSA, NHS Digital may:
- 8.1.1 suspend provision of all or part of the Data to the Recipient until the breach or suspected breach is resolved to NHS Digital's reasonable satisfaction;
- 8.1.2 suspend the licence(s) granted to the Recipient under Clause 3.1 in relation to all or part of the Data until the breach or suspected breach is resolved to NHS Digital's reasonable satisfaction; and/or
- 8.1.3 (a) destroy or erase all or part of the Data received by the Recipient in accordance with Applicable Law, and Guidance, and produce a Certificate of Destruction; and/or
(b) produce, or cooperate with any recipient who is a party to an Associated DSA to produce, a remediation plan detailing how the Recipient (and, if applicable, any recipient who is a party to an Associated DSA) will resolve the breach or suspected breach to NHS Digital's reasonable satisfaction, together with a project plan.
- 8.2 Without prejudice to NHS Digital's rights and remedies under this Contract (including under Clause 12) where in NHS Digital's reasonable opinion the Recipient has not complied, or is not complying, with any of the Recipient's obligations under this Contract, or any DSA, the Recipient shall be liable to promptly reimburse NHS Digital for its reasonable costs and expenses incurred in connection with such breach. For the avoidance of doubt, such reasonable costs may include costs associated with any additional NHS Digital activity due to any resulting ICO investigation and any additional media and communication activity and costs.

9 Warranties

- 9.1 The Recipient warrants that:
- 9.1.1 it has the full right and authority to enter into this Contract; and
- 9.1.2 it shall use the Data in accordance with all Applicable Laws.
- 9.2 The Data is provided to the Recipient by NHS Digital on an 'as is' basis and NHS Digital does not warrant the accuracy or completeness of the Data, nor that the Data does not infringe the Intellectual Property Rights of any third party, nor does it undertake that the Data will meet the requirements of, or be fit for any purpose of, the Recipient.

10 Charges

- 10.1 In consideration of the provision of the Data by NHS Digital, the Recipient agrees to pay the Charges as set out in the relevant DSA.
- 10.2 The Charges set out in the relevant DSA are payable by the Recipient thirty (30) days from the date of receipt by the Recipient of an invoice for any Charges from NHS Digital (the "**Due Date**").

- 10.3 All Charges (or appropriate portions thereof) shall be paid by the Recipient to NHS Digital to its nominated bank account by the Due Date(s), in cleared funds, without withholding, set-off or deduction, and time for payment is of the essence.
- 10.4 All Charges payable shall be paid in pounds (£) sterling and are exclusive of VAT, which shall be paid in addition at the appropriate rate, where VAT applies.
- 10.5 Where the Recipient fails to make payment, NHS Digital shall be entitled (but shall not be obliged) to charge the Recipient interest on all sums overdue at the statutory interest rate as set by the LPCDA (from time to time in force) calculated on a daily basis from the relevant Due Date until payment is made in full by the Recipient.
- 10.6 In addition to its right to charge interest on late payment as set out in Clause 10.6, and without prejudice to its other rights under this Contract or any applicable DSA, where the Recipient fails to make payment within a further fourteen (14) days from the first date that any sums are overdue, NHS Digital shall be entitled (but shall not be obliged) to do any, or a combination of, the following on written notice to the Recipient:
- 10.6.1 to immediately suspend provision of Data under any of the DSAs; and/or
 - 10.6.2 to terminate either immediately or by the time specified in the notice, the applicable DSA; and/or
 - 10.6.3 to terminate either immediately or by the time specified in the notice, all other DSAs that are entered into under this Contract; and/or
 - 10.6.4 to immediately suspend any existing applications.

11 Liability

- 11.1 This Clause 11 sets out:
- 11.1.1 the types of loss for which NHS Digital shall not in any circumstances be liable to the Recipient under or in connection with this Contract or any DSA;
 - 11.1.2 the maximum liability that NHS Digital shall have to the Recipient under or in connection with this Contract or any DSA; and
 - 11.1.3 the types of liability that are not limited by anything in this Contract.
- 11.2 Except as set out in Clause 11.4, NHS Digital shall in no circumstances be liable to the Recipient for:
- 11.2.1 any loss of profits, revenue, opportunity, contracts, sales, turnover, anticipated savings, goodwill, reputation, business opportunity, production, or loss to or corruption of data (regardless of whether any of these losses or damages are direct, indirect or consequential); and
 - 11.2.2 any indirect or consequential loss or damage whatsoever (including where such loss or damage is of the type specified in Clause 11.2.1).
- 11.3 Except as set out in Clause 11.4, NHS Digital's total aggregate liability for any and all claims arising under or in connection with each DSA regardless of form of action and whether in contract, tort (including negligence and breach of statutory duty) or otherwise is limited to the greater of:
- 11.3.1 the total Charges paid by the Recipient to NHS Digital under that DSA under which the event or events giving rise to the liability occurred; or
 - 11.3.2 £1,000 (one thousand pounds).
- 11.4 Nothing in this Contract shall limit either party's liability to the other for:
- 11.4.1 death or personal injury resulting from the negligence of its employees, agents or subcontractors;
 - 11.4.2 fraud or fraudulent misrepresentation; or
 - 11.4.3 any other liability that cannot be excluded or limited as a matter of law.
- 11.5 Other than any warranties expressly set out in this Contract, all warranties, conditions or other terms, whether express or implied by statute, common law, trade usage or otherwise are excluded except to the extent the exclusion is prohibited by law.

12 Indemnity

- 12.1 The Recipient shall indemnify NHS Digital in full for any liabilities, losses, demands, claims, damages, amounts agreed in settlement, costs and expenses incurred which arise from or in connection with:
- 12.1.1 any loss of the Data by the Recipient;
 - 12.1.2 unauthorised or unlawful use of the Data beyond the Purpose(s) by the Recipient;
 - 12.1.3 any breach of this Contract by the Recipient, whether arising in negligence, contract or otherwise; and
 - 12.1.4 any monetary penalty notice imposed on NHS Digital by the Information Commissioner under Data Protection Law as a result of the Recipient's breach of this Contract.
- 13 **Term and termination**
- 13.1 This Contract shall, subject to prior termination in accordance with this Clause 13, continue for the Contract Term. Each DSA shall, subject to prior termination in accordance with this Clause 13, become effective on the relevant effective date and shall continue for the Term as set out and defined in the relevant DSA.
- 13.2 If the Recipient wishes to retain the Data beyond the end of the Term of any DSA:
- 13.2.1 it must have submitted an application to NHS Digital not less than two months prior to the expiry of the Term of the relevant DSA either (a) as a standard application, or (b) detailing the legal obligation to retain the Data, what Data is subject to the legal obligation of retention, and the reason why the stated legal obligation supersedes the right of the impacted data subject(s) to have their Personal Data deleted;
 - 13.2.2 NHS Digital will consider such application and will determine, acting reasonably, whether it can agree to the retention of the Data and whether to enter into a new DSA in relation to this, and in doing so may require such additional information from the Recipient as it considers necessary to make such determination;
 - 13.2.3 where NHS Digital does agree to the retention of the Data and to enter into a new DSA in relation to this, such new DSA must be executed by the parties to replace the relevant DSA prior to the expiry of the Term of the relevant DSA; and
 - 13.2.4 the Recipient will be required to ensure that this Contract (or a replacement to this Contract) is in place for the duration of the DSA(s). Under no circumstances shall the Recipient retain the Data without an extant DSA and Contract (or New Contract) in place which relates to that Data.
- 13.3 NHS Digital may terminate this Contract and/or any DSA by giving to the Recipient not less than one month's prior written notice.
- 13.4 NHS Digital may terminate any DSA immediately on written notice to the Recipient if any Associated DSA is terminated (for any reason).
- 13.5 On or at any time after the occurrence of an event specified in Clauses 10.7 or 13.6, NHS Digital shall be entitled to terminate this Contract and/or any DSA, with immediate effect by written notice to the Recipient.
- 13.6 NHS Digital may terminate this Contract and/or any DSA if:
- 13.6.1 the Recipient is in material breach of this Contract and/or any DSA and that breach cannot be remedied;
 - 13.6.2 the Recipient is in material breach of this Contract and/or any DSA which can be remedied but the Recipient fails to do so within 30 days starting on the day after receipt of written notice from NHS Digital;
 - 13.6.3 in respect of Data which constitutes Personal Data, the Recipient no longer has the legal basis to process this Data;
 - 13.6.4 the Recipient stops payment of its debts or is unable to pay its debts as they fall due;
 - 13.6.5 the Recipient is dissolved;

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- 13.6.6 the Recipient becomes or is declared insolvent or a resolution is passed for the winding up of the Recipient, or the Recipient convenes a meeting of its creditors or makes or proposes to make any arrangement or composition with its creditors or a liquidator, an administrative receiver, a receiver, manager, trustee or administrator or analogous officer is appointed in respect of all or any part of its property, undertaking or assets, or the Recipient becomes subject to any bankruptcy procedure or analogous insolvency procedure in any jurisdiction, or any person files a notice of intention to appoint an administrator or a notice of appointment of an administrator or applies to court for an administration order in respect of the Recipient;
- 13.6.7 it becomes unlawful for the Recipient to perform all or any of its obligations under this Contract and/or any DSA;
- 13.6.8 there is a change in Applicable Law which materially affects NHS Digital's powers to provide Data to the Recipient; or
- 13.6.9 the Recipient (being a natural person) shall die or become mentally incapacitated.
- 13.7 Without prejudice to NHS Digital's rights under Clauses 13.3 and 13.5:
- 13.7.1 where the Recipient commits any breach of this Contract and/or any DSA; or
- 13.7.2 an event specified in Clause 13.6 occurs; or
- 13.7.3 if there is a breach of any Associated DSA; or
- 13.7.4 (in NHS Digital's reasonable opinion) there has been or is likely to be a breach of any Associated DSA,
- NHS Digital shall be entitled to suspend this Contract and/or any DSA (which shall include the suspension of any licence granted to the Recipient under Clause 3.1) without incurring any liability to the Recipient, with immediate effect by written notice to the Recipient.
- 13.8 The Recipient may terminate this Contract or any DSA at any time by notifying NHS Digital in writing.
- 13.9 Termination and, subject to Clause 13.10, expiry of this Contract will automatically terminate all DSAs that are entered into under this Contract.
- 13.10 If the Recipient wishes to renew this Contract beyond the expiry of the Contract Term, it must contact NHS Digital not less than three months prior to the expiry of the Contract Term to put in place a new data sharing framework contract which shall when executed by the parties replace this Contract (the "**New Contract**"). Where a New Contract is agreed, any DSA which continues beyond the preceding Contract Term, will be subject to the terms and conditions of the New Contract with effect from the expiry of the preceding Contract Term.
- 14 Consequences of termination**
- 14.1 Save where a New Contract is entered into in accordance with Clause 13.10, on or before the effective date of termination or expiry of this Contract the Recipient must ensure that all Data is securely and permanently destroyed or erased. On or before the effective date of termination or expiry of any DSA, the Recipient must ensure that all Data licensed under that DSA is securely and permanently destroyed or erased, save where agreed in a replacement DSA for the Data to be retained.
- 14.2 On completion of the activity in Clause 14.1, the Recipient shall promptly, and in any event within 28 days of the date of termination or expiry of this Contract, or any DSA, provide confirmation of the secure and permanent destruction to NHS Digital in the form of a Certificate of Destruction.
- 14.3 Any provision of this Contract that expressly or by implication is intended come into or continue in force on or after termination or expiry of this Contract (including Clauses 6, 7, 8, 9, 10, 11, 12, 13, 16, 17, 18 and 19) shall remain in full force and effect.
- 15 Assignment**
- 15.1 The Recipient shall not assign, novate, transfer, charge, dispose of or deal in any other manner with this Contract and/or any DSA, or any of its rights or beneficial interests under it, or purport to do any of the same, nor sub-contract any or all of its obligations under this Contract, without the prior written consent of NHS Digital.

- 15.2 NHS Digital may assign, transfer, charge, dispose of or deal in any manner with its rights and obligations under this Contract and/or any DSA. Where it does so, NHS Digital shall notify the Recipient of such change in writing.
- 16 Notices**
- 16.1 Except where any provision of this Contract states otherwise, all notices and communications sent pursuant to this Contract shall be in writing and shall be deemed to have been duly given:
- 16.1.1 when delivered, if delivered by hand; or
 - 16.1.2 on the second Working Day after mailing, first class postage pre-paid; or
 - 16.1.3 when delivered by email, when the recipient, by an email sent to the email address for the sender, or by a notice delivered by another method in accordance with this clause, acknowledges having received that email, (with an automatic “read receipt” also constituting acknowledgment of an email for purposes of this clause).
- 16.2 Notices shall be addressed to the addresses provided in Part 1 of this Contract or to such other address as the parties may notify in writing from time to time. Each party shall notify the other party in accordance with this Clause 16 if the address specified in Part 1 of this Contract is no longer an appropriate address for the service of notices and communications.
- 17 Publicity**
- 17.1 NHS Digital shall be entitled to Publish the terms of this Contract, any DSA and the results of any audit.
- 18 Miscellaneous**
- 18.1 Nothing in this Contract or any arrangement contemplated by it shall constitute either party a partner, agent, fiduciary or employee of the other party.
- 18.2 NHS Digital may notify the Recipient in writing from time to time of any update(s) that shall apply to this Contract and/or any DSA. Where specified by NHS Digital, such updates shall be effective from the date specified in such notification.
- 18.3 Without prejudice to Clause 18.2, no amendment or variation of the terms of this Contract or any DSA shall be effective unless made or confirmed in writing, and signed by the parties to this Contract.
- 18.4 If any provision of this Contract shall be found by any court or body or authority of competent jurisdiction to be invalid or unenforceable, such provision shall be severed from the remainder of this Contract which shall remain in full force and effect to the extent permitted by law.
- 18.5 The rights and remedies provided by this Contract are cumulative and (unless otherwise provided in this Contract) are not exclusive of any rights or remedies provided by law.
- 18.6 This Contract does not create, confer or purport to create or confer any benefit or right enforceable by any person not a party to it (except that a person who is a permitted successor to or assignee of the rights of a party to this Contract shall be deemed to be a party to this Contract).
- 18.7 NHS Digital shall not be liable to the Recipient for any delays in performance, non-performance or breach of any of its obligations under this Contract and/or any DSA caused by matters beyond its reasonable control. Such matters shall include (without limitation) industrial disputes, acts of God, insurrection or civil disorder, war or military operations, national or local emergency, acts of government or acts or omissions of third parties.
- 19 Governing law and jurisdiction**
- 19.1 This Contract and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with English law.
- 19.2 Each party irrevocably agrees that, for the sole benefit of NHS Digital and subject to Clause 19.3, the courts of England and Wales shall have exclusive jurisdiction to hear and determine any suit, action or proceedings, and to settle any disputes or claims (including non-contractual disputes or claims) which may arise out of or in connection with this Contract and/or any DSA, its subject matter or formation.

- 19.3 Nothing in this Clause 19 shall limit the right of NHS Digital to take proceedings against the Recipient in any other court of competent jurisdiction, nor shall the taking of proceedings in any one or more jurisdictions preclude the taking of proceedings in any other jurisdictions, whether concurrently or not, to the extent permitted by the law of such other jurisdiction.
- 20 **Entire agreement**
- 20.1 This Contract constitutes the entire agreement and understanding of the parties and supersedes any previous agreement between the parties relating to the subject matter of this Contract, but without prejudice to the rights and liabilities of the parties accrued before the date of this Contract.
- 20.2 Except in respect of any fraudulent misrepresentation made by a party, the parties acknowledge that they have not relied on any representations, writings, negotiations or understandings, whether express or implied, (other than as set out in this Contract) in entering into this Contract.
- 20.3 Nothing in this Clause 20 shall operate to limit or exclude any liability for fraud.

SCHEDULE 1 Interpretation

1 In this Contract the following expressions have the following meanings:

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| "Anonymised Data" | Data in a form that does not identify individuals and where identification through its combination with other data is not likely to take place; |
| "Applicable Law" | all laws, regulations, orders, directions or determinations that are applicable to the obligations of the Recipient under this Contract and/or any DSA, including by way of example but not limited to those identified in Schedule 3, as amended or re-enacted from time to time; |
| "Associated DSA" | any data sharing agreement between NHS Digital and a third party recipient which is expressly stated in the relevant DSA under this Contract to be an "Associated DSA"; |
| "Certificate of Destruction" | a certificate signed by an authorized representative of the Recipient, or specialist third party engaged to securely destroy the Data, which assures NHS Digital that the Data and all hard and soft copies thereof held by the Recipient have been securely and permanently destroyed in accordance with Applicable Law and Guidance (including the NHS Digital Destruction and Disposal of Sensitive Data Good Practice Guidelines), and " Certification of Destruction " shall be interpreted as the provision of such certificate; |
| "Charges" | the charges payable, if any, for the provision of the Data as set out in the relevant DSA(s), and the cost of audit(s) where applicable; |
| "Contract Term" | has the meaning given in Clause 2.1 of Part 1; |
| "Controller" | a controller as defined in Data Protection Law; |
| "Core Terms" | means those terms identified in: <ul style="list-style-type: none"> • Section A of Schedule 4 of this Contract; and • Section B of Schedule 4 of this Contract and Annex A of the relevant DSA; and • any other terms notified to the Recipient by NHS Digital in writing from time to time; |
| "Data" | the health or social care data specified in and that is provided by NHS Digital to the Recipient under a DSA; and such term shall also be deemed to include Manipulated Data unless otherwise specified; |
| "Data Access Environment" or "DAE" | the hosted environment to which the Recipient may be granted access by NHS Digital which provides secure access to the Data and reduces the need for it to leave NHS Digital. The Data Access Environment (DAE) contains a range of built-in tools to interrogate, analyse and visualise data for a more complete picture of health and care for research and planning |
| "DAE Data Loss Event" | any event that results, or may result, in unauthorised access to Personal Data held by NHS Digital in the DAE, and/or actual or potential loss and/or destruction of Personal Data in breach of Schedule 5, including any Personal Data Breach; |
| "DARS Application" | the application submitted by a Recipient to NHS Digital's Data Access Request Service (DARS) used to request access to Data; |
| "Data Breach" | a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to Data; |

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| "Data Protection Law" | the Data Protection Act 2018 and all other applicable laws and regulations from time to time in force relating to data protection, privacy and the processing of personal data, including GDPR, together with all guidance and codes of practice issued or adopted by a regulator (or group of regulators) with jurisdiction over the data processing arrangements contemplated in this Contract, as amended or re-enacted from time to time; |
| "Derived Data" | any Data (wholly or in part) that is Manipulated to such a degree that it: <ul style="list-style-type: none"> (a) cannot be identified as originating or deriving from the Data and cannot be reverse-engineered such that it can be so identified; and (b) is not capable of use as a substitute for the Data; and (c) has not at any time been verified by NHS Digital as not fulfilling the criteria (a) and (b) above |
| "DSA" | has the meaning given in Clause 3.4 of Part 1; |
| "DSPT" | The Data Security and Protection Toolkit is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's 10 data security standards. All organisations that have access to NHS patient data and systems must use this toolkit to provide assurance that they are practising good data security and that personal information is handled correctly. The DSPT can be accessed from https://www.dsptoolkit.nhs.uk/ |
| "End User Access Agreement" | the agreement (together with the documents and links referred to in it) setting out the terms and conditions on which a Recipient and authorised Personnel may use the DAE (as updated from time to time by NHS Digital); |
| "FOIA" | has the meaning given in Clause 6.4 of Part 2; |
| "GDPR" | the European General Data Protection Regulation, namely Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC on and from the date upon which the Regulation applies (as set out in Article 99); |
| "Good Industry Practice" | the degree of skill, care, prudence, foresight and operating practice which would reasonably and ordinarily be expected from time to time of a skilled and experienced person engaged in the same or similar type of undertaking or carrying out the same or similar type of activities as the Recipient; |
| "Guidance" | any applicable guidance or standards including codes of practice, standards and guidance issued by the Information Commissioner, the National Data Guardian, the Department of Health and Social Care, NHS England, the Standardisation Committee for Care Information and NHS Digital, including by way of example but not limited to those identified in Schedule 3 of this Contract; |
| "Information Asset Owner" | a senior member of staff who is the nominated owner for one or more identified information assets within the Recipient; |
| "Information Asset Register" | a list of personal and non-personal information assets held by the Recipient; |
| "Intellectual Property Rights" or "IPR" | all intellectual property rights including copyright, database rights, trade marks and trade names, patents, topography rights, design rights, trade secrets, know-how and all rights of a similar nature or having similar effect which subsist anywhere in the world, whether or not any of them are registered and applications for registrations of any of them; |
| "Joint Controller" | two or more Controllers who jointly determine the purposes and means of processing personal data; |
| "LPCDA" | the Late Payment of Commercial Debts (Interest) Act 1998 (as amended by The Late Payment of Commercial Debt Regulations 2002 (SI 1674) and the Late Payment of Commercial Debt Regulations 2013); |

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| "Manipulate" | means: <ul style="list-style-type: none"> • combine (wholly or in part) with other data or information; or • aggregate (wholly or in part) with other data or information; or • adapt (wholly or in part); (and " Manipulating " and " Manipulated " shall be construed accordingly) |
| "Manipulated Data" | any Data that has been Manipulated, unless and until it qualifies as Derived Data (to be determined at the sole discretion of NHS Digital); |
| "New Contract" | has the meaning given in Clause 13.10 of Part 2; |
| "NHS Digital Content" | means the material in the Data Access Environment, which may include login details and associated information, website and portal designs, commercial data, information, text, standards, images, interactive services, reports, and any other works or materials, but excludes the Data; |
| "Personal Data" | personal data as defined in Data Protection Law; |
| "Personal Data Breach" | has the meaning given in Data Protection Law; |
| "Personnel" | all employees, agents and contractors of the Recipient who may have access to the Data; |
| "process" and "processing" | have the meaning set out in Data Protection Law; |
| "Processor" | a processor as defined in Data Protection Law; |
| "Publish(ing)" | to make available to third parties in any form, including the production of hard copy materials, soft and/or electronic copies, e-mails and posting online; |
| "Purpose(s)" | the purpose(s) for which the Recipient is permitted to use the Data, as set out in the relevant DSA; |
| "Recipient" | the party named in Clause 1.2 of Part 1 of this Contract who will be a Controller of any Personal Data to be shared under and in accordance with this Contract and any DSA; |
| "Research Law" | any Applicable Law which is specifically concerned with the use of clinical research data and which mandates the retention of such data by the Recipient, including by way of example but not limited to those identified in Schedule 3. For the avoidance of doubt, it does not include any contractual obligation of the Recipient. |
| "Special Conditions" | the special conditions for processing the Data as set out in the relevant DSA; |
| "Sub-Licence" | any written agreement entered into between the Recipient and a sub- licensee as referred to in Clause 3.2.3 of Part 2; |
| "Territory" | the territory specified in the relevant DSA; |
| "Term" | the term for which the Recipient is permitted to use the relevant Data as defined in the relevant DSA; |
| "Third Party Contractor" | has the meaning given in Clause 7.2 of Part 2; |
| "Working Day" | a day, other than a Saturday, Sunday or public holiday in England, when banks in London are open for business. |

2 In this Contract:

- 2.1 any gender includes any other gender and the singular includes the plural and vice versa;
- 2.2 references to persons include bodies corporate, unincorporated associations, governments, states, partnerships and trusts (in each case, whether or not having separate legal personality);
- 2.3 the Schedules form part of this Contract and the expression "this Contract" includes the Schedules;
- 2.4 any reference to a statutory provision includes a reference to any modification, consolidation, replacement or re-enactment of the provision from time to time in force and all subordinate instruments, orders or regulations made under it; and

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- 2.5 any words following or associated with the terms including, include, in particular, for example, by way of example, or any similar expression, shall be construed as illustrative and shall not limit the sense of the words, description, definition, phrase or term preceding or associated with those terms.

SCHEDULE 2 Data Security Requirements

Section A

1. Without prejudice to the Recipient's other obligations in respect of information security, the Recipient shall:
 - 1.1 having regard to the state of technological development, provide a level of security (including appropriate technical and organisational measures) appropriate to:
 - 1.1.1 the harm that might result from unauthorised or unlawful processing of Data or accidental loss, destruction or damage of such Data; and
 - 1.1.2 the nature of the Data;
 - 1.2 take reasonable steps to ensure the reliability of the Recipient's Personnel who have access to the Data which shall include:
 - 1.2.1 ensuring all such Personnel understand the confidential nature of the Data and the issues which arise if proper care is not taken in the processing of the Data;
 - 1.2.2 ensuring all such Personnel are properly trained in data protection appropriate to their role, and to ensure that all such Personnel have completed such training prior to their use of the Data. Where requested to do so the Recipient shall provide examples of training materials used, together with methodologies used to demonstrate that Personnel have understood the training. Training shall be repeated at regular intervals to take account of developments in law on good data protection practice and in any event on an annual basis; and
 - 1.2.3 ensuring all such Personnel are properly vetted, both during the initial recruitment process and throughout their engagement in their processing of the Data, including through the use of procedures to identify changes in personal circumstances which may affect an individual's ability to process the Data in accordance with the terms of this Contract;
 - 1.3 provide NHS Digital with such information, assistance and co-operation as NHS Digital may require from time to time to establish NHS Digital's and/or the Recipient's compliance with the Data Protection Law; and
 - 1.4 inform NHS Digital as soon as reasonably practicable of any particular risk to the security of the Data of which it becomes aware, and of the categories of Data and individuals which may be affected.
- 2 The Recipient shall promptly, and in any event not later than reasonably required in order to enable NHS Digital to fulfil its duties under the Data Protection Law provide such information as NHS Digital requires relating to the identity of any third parties to whom the Data has been disclosed by the Recipient to the extent NHS Digital requires this information to comply with its duties under the Data Protection Law.
- 3 The Recipient shall implement and maintain security and risk assessment standards, facilities, controls and procedures appropriate to the nature of the Data held by it and the harm that would be caused by its loss or disclosure, including:
 - 3.1 to maintain a comprehensive and up-to-date data protection policy, (and the Recipient shall ensure that all its Personnel who have access to the Data shall comply with the obligations upon them contained in the data protection policy);
 - 3.2 to maintain an up to date Information Asset Register, which identifies the Information Asset Owner for Data supplied under the relevant DSA.
- 4 The Recipient shall ensure:
 - 4.1 that it has properly configured access rights for its Personnel including a well-defined joiners and leavers process to ensure access rights to the Data are properly managed;
 - 4.2 that it has proper controls in place to make sure that complex alphanumeric passwords are required for access to the Data and that training is provided in relation to the need to keep such passwords secure;

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- 4.3 it has in place procedures to identify wrongful use of Data, including the monitoring of wrongful access to Data;
 - 4.4 that suitable and effective authentication processes are established and used to protect Data;
 - 4.5 that Data is backed up on a regular basis and that all back up data is subject to such vigorous security procedures as are necessary in order to protect data integrity, such security measures being commensurate to the nature of the data. The Recipient shall take particular care when transporting backup data and other personal information and shall ensure such backup data and other personal information is transported in a safe and secure manner;
 - 4.6 that Data transferred electronically is encrypted using only the Advanced Encryption Standard (AES) – 256 bits specification;
 - 4.7 that Data stored on laptops or other portable media is encrypted and that the Recipient maintains an accurate, up to date asset register, including all such portable media used to process the Data;
 - 4.8 that Personnel are not able to access the Data from home or via their own electronic device other than through a secure electronic network and that Data may not be stored in such devices;
 - 4.9 that suitable physical security measures are established commensurate to the harm that could result from the unlawful disclosure of the Data. Such physical security measures shall be as identified in the Recipient's data protection policy;
 - 4.10 without prejudice to the Recipient's obligations to NHS Digital in relation to the disposal of Data, all Data which is disposed of must be disposed of in accordance with Applicable Law and Guidance (including the NHS Digital Destruction and Disposal of Sensitive Data Good Practice Guidelines), (and provided it does not conflict with the foregoing, in accordance with the Recipient's policy for the disposal of Data identified in the data protection policy, including the disposal of assets containing Personal Data, a copy of which policy shall be provided, on request, to NHS Digital; and
 - 4.11 that the Recipient establishes and maintains adequate data security compliance policies and audits its use of Personal Data in compliance with its data security policies on a regular basis and in any event annually.
- 5 The Recipient shall nominate in writing an individual to take responsibility and be accountable for compliance with Data Protection Law, and shall provide to NHS Digital the name of that individual.

Section B

- 1 It is the Department of Health's policy that all organisations which process NHS patient information must provide security assurance through annual completion and publication of the DSPT
- 2 To provide assurance that good information governance practices are being maintained, the Recipient must demonstrate, and will allow NHS Digital to audit, that it:
 - A: meets or exceeds the **DSPT** standards required by NHS Digital for their organisation type Organisation Code:
 - If A does not apply, B and/or C, as NHS Digital may require and specify in the relevant DSA:
 - B: is Certified against international security standard **ISO 27001**
 - AND/OR
 - C: Has other security assurance in place which, without prejudice to any other elements of such assurance, meets the requirements of paragraph 4 below.
- 3 In cases where the Recipient has not completed an DSPT assessment to NHS Digital's satisfaction and where the Recipient is not ISO 27001 certified, in addition to the information provided in the relevant DSA detailing the security assurance it has in place, the Recipient must ensure that it meets the requirements set out in paragraph 4 of this section B of Schedule 2, which NHS Digital reserves the right to audit in accordance with Clause 7 of Part 2 of this Contract.
- 4 Where the Recipient has provided information in the relevant DSA about what other security assurance it has in place, and without prejudice to the Recipient's other obligations under this Contract, the Recipient shall:
 - 4.1 process Personal Data only for the provision of health care or adult social care, or the promotion of health, and only for purposes described in this Contract and the relevant DSA, and which are consistent with the purposes recorded in the Recipient's data protection registration with the Information Commissioner's Office;
 - 4.2 request and process the minimum data necessary (e.g. using age range rather than age if sufficient);
 - 4.3 deploy secure processes, procedures, practice and technology for storage and access, commensurate with the Personal Data being processed;
 - 4.4 ensure the rights of individuals are met, such as satisfying subject access requests received, ensuring data accuracy and correcting errors, and handling objections and complaints;
 - 4.5 permanently destroy/delete or erase the Data once it is no longer required for the purpose for which it was collected and confirm destruction to NHS Digital;
 - 4.6 ensures all Personnel with access to Personal Data provide a written undertaking that they understand and will act in accordance with the Data Protection Law, will not share passwords, and will protect the confidentiality of the Personal Data;
 - 4.7 report immediately to NHS Digital any security incidents relating to the Data, and any instances of breach of any of the terms of this Contract; and
 - 4.8 comply with any specific legislation in relation to the Data (such as the Statistics and Registration Services Act 2007).

SCHEDULE 3

Applicable Law and Guidance

Applicable Law with which the Recipient must comply under this Contract includes, but is not limited to the following:

Applicable Law

- The Copyright, Designs and Patents Act 1988
- The Human Rights Act 1998
- The Computer Misuse Act 1990
- The Electronic Communications Act 2000
- The Freedom of Information Act 2000
- The Freedom of Information (Scotland) Act 2002
- The Regulation of Investigatory Powers Act 2000
- Health Service (Control of Patient Information Regulations) 2002 and any notice issued by the Secretary of State for Health under these regulations
- The Environmental Information Regulations 2004
- Section 251 of the NHS Act 2006 (originally enacted under Section 60 of the Health and Social Care Act 2001) together with any approvals granted under regulations made pursuant to section 251 of the NHS Act 2006
- The Statistics and Registration Services Act 2007
- The Health and Social Care Act 2012
- The Care Act 2014
- The European General Data Protection Regulation, namely Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC
- The Data Protection Act 2018
- Health and Social Care (National Data Guardian) Act 2018

The Recipient shall comply with all applicable guidance and codes of practice issued or adopted by a regulator (or group of regulators) with jurisdiction over the data processing arrangements contemplated in this Contract, including but not limited to:

Guidance

- Anonymisation Standard for Publishing Health and Social Care Data (ISB, 1523).
- Anonymisation: managing data protection risk code of practice (ICO, 2012).
- A guide to confidentiality in health and social care (HSCIC 2013).
- ISO/IEC 27001:2013 (published by the [International Organization for Standardization](#) (ISO) and the [International Electrotechnical Commission](#) (IEC)).
- The Caldicott Committee Report on the Review of Patient-Identifiable Information 1997.
- NHS Digital Destruction and Disposal of Sensitive Data Good Practice Guidelines Version: 3.0 Date: March 2015.
- The Caldicott Information Governance Review: Information: To share or not to share? The Information Governance Review (March 2013) also known as Caldicott 2
- NHS Digital Code of Practice on confidential information (HSCIC, 2014).
- Confidentiality: NHS Code of Practice 2003.
- The NHS Care Record Guarantee 2011 (Version 5).

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- Information Security Management: NHS Code of Practice (2007).
 - IGA: Records Management Code of Practice for Health and Social Care 2016.
 - ONS Review of Dissemination of Health Statistics: Confidentiality Guidance 2006.
 - The ONS Disclosure control guidance for birth and death statistics 2014.
 - The Code of Practice for Official Statistics.
 - The Social Care Record Guarantee 2009.
 - Such guidance as may be issued by the ICO in relation to the European General Data Protection Regulation, namely Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

Research Law

Research Law includes, but is not limited to the following:

- The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended from time to time).
- EU Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (as amended from time to time), to the extent such directive applies to the Recipient.
- From the date it comes into application, the EU Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use (as amended from time to time), to the extent such regulation is directly applicable to the Recipient.
- International Conference on Harmonisation (ICH) guidelines on Good Clinical Practice as amended from time to time.

SCHEDULE 4 Sub-licensing conditions

Section A

- 1 Where NHS Digital consents to the Recipient sub-licensing the Data to third parties, the Recipient shall ensure that each written agreement with the sub-licensee includes (or include wording to the effect of and no less strict than) the following terms:
 - 1.1 NHS Digital shall benefit from and can enforce the terms of the Sub-Licence directly in accordance with the Contracts (Rights of Third Parties) Act 1999 (without the involvement or consent of the Recipient) against the sub-licensee.
 - 1.2 NHS Digital shall have the right at any time and at its own discretion to perform an audit of any sub-licensee, provided that the sub-licensee is given seven (7) days' notice where permissible and practicable;
 - 1.3 NHS Digital shall have the right to suspend, in whole or in part, the Sub-Licence(s) in relation to all or part of the Data where:
 - 1.3.1 the licence granted under Clause 3.1 of the Contract is suspended in whole or in part; or
 - 1.3.2 the sub-licensee has not complied, or is not complying with any of its obligations under the Sub-Licence, until the breach is resolved to NHS Digital's reasonable satisfaction;
 - 1.4 The sub-licensee shall be bound by the same terms regarding the use of its Derived Data as the Recipient in respect of its Derived Data as stipulated in Clauses 3.9 to 3.12 of the Contract and Special Conditions of the relevant DSA, including replication of Clauses 3.9 to 3.12 of the Contract, save for amending all references to the "sub-licensee" in place of the "Recipient";
 - 1.5 The sub-licensee shall have no rights in or to the Data other than the right to use the Data in accordance with the express terms of the Sub-Licence, which shall not exceed the licence permitted under the DSA;
 - 1.6 The sub-licensee shall prospectively assign any and all future Intellectual Property Rights in any Manipulated Data to NHS Digital from creation and shall execute, or procure the execution of, any document, or shall perform, or procure the performance of, any acts as may be required to give this effect.
 - 1.7 Replication of Clauses 4.1, 4.2 and 4.3 of the Contract, amending all references to the "Recipient" with "sub-licensee", and amending all references to the "DSA" to "sub-licence agreement", and removing the wording "subject to any New Contract being entered into as set out in Clause 13.10 and subject to Clause 4.8" in Clause 4.1.7;
 - 1.8 Replication of Clause 5 of the Contract, save for amending to the "sub-licensee" in place of the "Recipient";
 - 1.9 Replication of Clauses 6.1 and 6.3 of the Contract, save for amending to the "sub-licensee" in place of the "Recipient";
 - 1.10 Obligations no less onerous on the sub-licensee than are on the Recipient under this Contract in respect of: FOIA requirements in Clause 6.4;
 - 1.11 Obligations no less onerous on the sub-licensee than are on the Recipient under this Contract in respect of: SCHEDULE 2 (Data Security Requirements);
 - 1.12 On termination or expiry of the relevant Sub-Licence, the sub-licensee must ensure that all Data is securely and permanently destroyed or erased (together with all hard and soft copies of the same) promptly and in any event within 28 days of the date of termination or expiry of the Sub-Licence, providing confirmation of the secure and permanent destruction to NHS Digital and the Recipient in the form of a Certificate of Destruction; and
 - 1.13 The sub-licensee shall not have the right to assign, novate, transfer, charge, dispose of or deal in any other manner with the Sub-Licence, or any of its rights or beneficial interests under it, or purport to do the same, nor sub-contract any or all of its obligations under the Sub-Licence without the prior written consent of both NHS Digital and the Recipient.

Section B

- 1 Where NHS Digital consents to the Recipient sub-licensing the Data to third parties, the DSA must stipulate the following terms:
 - 1.1 the duration of the Sub-Licence (which shall not in any event extend beyond the term of the relevant DSA);
 - 1.2 specification of the Data that may be sub-licensed;
 - 1.3 the scope of the purpose of the Sub-Licence (which shall not in any event extend beyond the scope of the purpose stated within the relevant DSA);
 - 1.4 the identity and/or category of any third parties to whom the Data may be sub-licensed;
 - 1.5 any additional conditions on which NHS Digital may revoke the Recipient's right to sub-license the Data.
- 2 NHS Digital may impose further Special Conditions in the DSA on sub-licensing that must be met by the Recipient and/or the sub-licensee as appropriate, prior to any sharing of Data, which will be set out in the "Special Conditions" section of Annex A: section 10 or elsewhere in the DSA, and which may include:
 - 2.1 the identity and/or category of any third parties to whom the Data may not be sub-licensed;
 - 2.2 any requirements to anonymise or pseudonymise the Data prior to onward sharing;
 - 2.3 a requirement for the Recipient to comply with any instructions issued by NHS Digital in respect of the Data;
 - 2.4 any specific exclusions to the scope of the Sub-Licence; and
 - 2.5 any audit rights that NHS Digital may require to ensure compliance with these Sub-Licence conditions.

Section C

- 1 Any Sub-Licence or arrangement entered into between any Recipient and sub-licensee which is:
 - 1.1 not permitted by the relevant DSA; and/or
 - 1.2 does not include the Core Terms stipulated in this Contract and/or the relevant DSA,shall constitute a material breach of this Contract, and entitles NHS Digital to suspend or terminate the relevant DSA and/or this Contract in accordance with Clause 13 (Term and termination) of this Contract.
- 2 Any breach of any of the sub-licensing conditions set out in this Schedule 4 by the Recipient or the sub-licensee shall constitute a material breach of this Contract and entitles NHS Digital to terminate the relevant DSA and/or this Contract in accordance with Clause 13 (Term and termination) of this Contract.
- 3 Any event which permits NHS Digital to suspend or terminate this Contract and/or the relevant DSA as stipulated in this Contract shall also permit NHS Digital to require the Recipient to immediately suspend or terminate any Sub-Licence or arrangement with any sub-licensee(s).

SCHEDULE 5 Data Access Environment

The provisions of this Schedule 5 will apply if NHS Digital permits the Recipient to use the Data Access Environment or Trusted Research Environment (TRE) pursuant to a DSA.

1 Access to the DAE

- 1.1 The Recipient acknowledges that the DAE and any analytical or modelling tools which may be made available through it are operated by third party providers to NHS Digital. Accordingly, the Recipient agrees that it shall comply with the third party terms as referred to in the End User Access Agreement, and as made available when logging into the DAE (or alternatively available from NHS Digital upon request). The third party terms may be added to as additional functionality is added, and also may be updated from time to time by the relevant third party provider.
- 1.2 NHS Digital shall provide access details (including relevant user name and passwords) for the Personnel who the Recipient wishes to have access to the DAE under a DSA (as indicated in the DARS Application relevant to the DSA or otherwise requested in writing by the Recipient) and to whom NHS Digital agrees to give access. Such access details may not be transferred or shared between Personnel, and the Recipient shall not allow any Personnel other than those approved to access the DAE. Recipient must promptly update NHS Digital if the Personnel who require access to the DAE changes. The Recipient is responsible for ensuring that it promptly notifies NHS Digital of those Personnel that leave the organisation, and therefore should have their access to the DAE terminated. The Recipient shall give NHS Digital a minimum of 2 working days advance notice where possible. If such notice is not possible, the Recipient shall ensure that they also call the NHS Digital team.
- 1.3 The Recipient agrees that the terms of the End User Access Agreement shall apply in respect of the DAE, and shall also procure that any Personnel who access the DAE under or in connection with a DSA agree to and comply with the End User Access Agreement.
- 1.4 The Recipient may not download any Data, Manipulated Data or Derived Data from the DAE unless the location to which the relevant download is to be made has been approved in the DSA. The processing of any such downloaded Data, Manipulated Data or Derived Data shall be subject to the provisions of the Contract as if it had been provided directly by NHS Digital rather than downloaded through the DAE.
- 1.5 The Recipient may not, and will procure that any Personnel do not, upload any content of any type to the DAE unless that content has been approved of by NHS Digital in the DSA. No content may be uploaded which is not owned by the Recipient, or that which the Recipient is not authorised to upload and use. Recipient is responsible at all times for retaining back-up copies of any material uploaded to the DAE.
- 1.6 At the expiration or termination of the applicable DSA (or, if earlier, the Recipient's right to access the DAE), at NHS Digital's sole discretion and without notice to the Recipient, NHS Digital shall erase any content uploaded into the DAE by the Recipient or its Personnel.
- 1.7 The costs and charges associated with using the DAE to access the Data, if any, will be set out in the relevant DSA(s), and will be payable by the Recipient as a part of the Charges.

2 Availability and performance of the DAE

- 2.1 Target service levels in relation to the availability and/or functionality of the DAE, if any, will be set out in the relevant DSA(s).

- 2.2 The DAE, all Data, and any third party information, products, and services found or used on the DAE, are provided 'as is', without any endorsement and without warranty of any kind whether express or implied, including but not limited to the implied warranties of completeness, satisfactory quality, fitness for a particular purpose, non-infringement, compatibility, security and accuracy. NHS Digital is not liable for any errors or omissions and is not responsible for any impact those errors or omissions may have on the Recipient. The Recipient is responsible for alerting NHS Digital if at any time it does not have the legal authority to retain or process the Data, and NHS Digital will then remove the Recipient's access to the Data within the DAE
- 2.3 If the need arises, NHS Digital reserves the right to throttle, amend, delete, suspend or withdraw all or any part of the DAE without notice and NHS Digital will not be liable if for any reason the DAE or any parts of it are unavailable at any time.
- 2.4 NHS Digital does not warrant that the functions of the DAE will be uninterrupted or error free, that defects will be corrected, or that the DAE or the servers that make it available will be free of viruses or represent the full functionality, accuracy, or reliability of the Data.
- 2.5 NHS Digital will not be liable for any loss or damage caused by a virus which may infect any computer equipment, computer programs, data or other proprietary material used to access the DAE, or in relation to the use of any Data, or from any third party website linked to from the DAE or the End User Access Agreement.
- 2.6 In no event will NHS Digital be liable for any loss or damage including, without limitation, indirect or consequential loss or damage, or any loss or damages whatsoever arising from use or loss of use of, data or profits arising out of or in connection with defects, viruses, or system failures, associated with the use of the DAE, or reliance on any displayed content, business interruption, or any errors or omissions.
- 2.7 NHS Digital may make changes to the End User Access Agreement, and the content and features of the DAE, the terms and conditions applicable to any third party tool, product, or service used to manage, analyse, or model any part of the DAE or Data, and any other policies or links applicable to the Recipient's or any Personnel's use of the DAE, at any time and for any reason without providing notice of those changes. The Recipient recognises that it may be necessary on occasion for NHS Digital to change or replace Data available in the DAE. Recipients directly impacted by that change or refresh will be notified by NHS Digital by email. Scheduled changes or refreshes may occur without notification if set out in schedules included in the DSA. Nonstandard or non-scheduled changes or refreshes impacting multiple recipients will be announced within the DAE.
- 2.8 NHS Digital aims to make the DAE accessible to as many people as possible (subject to controls). The DAE is designed to work with and uses standards which should work on the majority of browsers in common use. NHS Digital however offers no warranty for the DAE working in any particular browser or configuration. There may be inconsistencies in the presentation of pages if an older or deprecated version of a browser is used to access the DAE, or the DAE may not work at all. Information on accessibility can be found at <https://digital.nhs.uk/about-nhs-digital/accessibility-help>
- 2.9 The Recipient may not, and will procure that any Personnel will not, upload, or attempt to upload, any content to the DAE unless expressly permitted by the DSA.
- 2.10 NHS Digital does not assume any responsibility for the content or reliability of any external websites which may be linked to from within the DAE or the End User Access Agreement and NHS Digital does not endorse those websites or the views expressed within those websites. NHS Digital does not guarantee that any links will always work and that the DAE or any linked websites will always be available, and NHS Digital will not be liable for any loss or damage that may arise from use of linked websites.
- 2.11 NHS Digital will not be liable or responsible for any loss or damage arising from action or inaction resulting on the Recipient's reliance on the Data, content, or materials displayed on the DAE, or any actions or advice taken, or any other information or services that are obtained by the Recipient using the DAE.

3 Termination of access to the DAE

- 3.1 In addition to NHS Digital's rights under paragraph 2.3 of this Schedule 5, all rights to access the DAE will terminate automatically on the termination or expiry of the DSA, and NHS Digital may terminate or suspend access to the DAE (or any part) without liability to the Recipient, where it is required to do so under any applicable third party terms (including, without limitation, on the termination or expiry of any relevant agreement with its third party providers).

4 Additional Security Requirements

- 4.1 Without prejudice to the Recipient's security related obligations under the Contract, the Recipient shall ensure that any Personnel who access the DAE only do so within an environment which does not increase the risk of any unauthorised access to or visibility of the Data. This shall include, without limitation:
- 4.1.1 not accessing the DAE in public or otherwise on any device in circumstances in which the Data may be visible by any individuals not authorised through the DARS Application process;
 - 4.1.2 not accessing the DAE on any device which is not encrypted in accordance with the security standards set out in this Contract; and
 - 4.1.3 not accessing the DAE through public networks.
- 4.2 The DAE may only be used for lawful purposes, and the Recipient or Personnel may not access without authority, interfere with, damage or disrupt: (i) any part of the DAE or any of the Data; (ii) any equipment or network on which the DAE is stored; (iii) any software or services used in the provision of the DAE; or (iv) any equipment or network or software owned or used by any third party.
- 4.3 The DAE may not be used: (i) in any way that breaches any applicable local, national, or international law or regulation; (ii) in any way that breaches the Contract or the End User Access Agreement; (iii) unlawfully, fraudulently, maliciously, or in any way that is harmful to NHS Digital or other users, or has any unlawful, fraudulent, malicious, or harmful purpose or effect; (iv) to send, knowingly receive, upload, download, use or re-use any material which does not comply with the Contract or the End User Access Agreement; (v) to transmit, or procure the sending of, any unsolicited or unauthorised advertising or promotional material or any other form of similar solicitation (spam); (vi) to knowingly send or transmit any data that contains viruses; (vii) in any way which would change the DAE or infringe on Intellectual Property Rights in relation to using the DAE; (viii) in any way which attempts to unencrypt or otherwise intercept any transmission of Data to or from the DAE or any applicable third parties; and (ix) in any way which could disable or compromise the security of the DAE, or that belonging to any third party, or interferes with the use of the DAE by other parties.

5 Intellectual Property Rights in the DAE

- 5.1 For the avoidance of doubt, the provisions of the Contract apply to the Intellectual Property Rights in the Data within the DAE.
- 5.2 Save as set out in paragraph 5.1 of this Schedule 5, and unless otherwise indicated, NHS Digital is the owner or the licensee of all Intellectual Property Rights in the DAE and the NHS Digital Content, and any of the tools provided or used in the management, analysis, and modelling of Data, and is the owner of all Intellectual Property Rights of any nature arising out of or in connection with the use of the DAE (including the appearance and branding of the DAE). Those works are protected by copyright laws and treaties around the world. All such rights are reserved.
- 5.3 NHS Digital grants the Recipient a non-exclusive, revocable, and limited right to use the DAE for the term of the DSA solely in accordance with this Schedule and the End User Access Agreement. No other rights or licences are granted in respect of the DAE.
- 5.4 At no time does the Recipient or any Personnel have permission to use the NHS Digital name or branding in any way.

6 Data Processing

- 6.1 For the avoidance of doubt, in relation to the Data, the data sharing provisions are as set out in the Contract.

- 6.2 Without prejudice to the provisions set out in Clause 5 of Part 2 of the Data Sharing Framework Contract and solely in respect of: (1) the hosting provision and operation of the DAE only, and (2) in relation to data uploaded by the Recipient, NHS Digital acts as a processor on behalf of the Recipient (as controller).
- 6.3 The Personal Data processing activities contemplated by this paragraph 6 of this Schedule 5 are as follows:

| | |
|--|--|
| Subject matter, nature and purpose of the processing of Personal Data | The provision of a secure hosted environment on which health and social care related data made available by NHS Digital under the Contract can be accessed, analysed and Manipulated by the Recipient. |
| Duration of the processing of Personal Data | For the duration of the Recipient's access to the DAE under this Schedule 5. |
| Type of Personal Data processed | The Personal Data identified in the relevant DARS Application. |
| Categories of data subjects of the Personal Data processed | The data subjects identified in the relevant DARS Application. |

- 6.4 In its role as processor in the provision of the DAE and subject to paragraph 6.7 of this Schedule 5, NHS Digital shall:
- 6.4.1 process the Personal Data only on the documented instructions of the Recipient (which the parties agree are comprised of this Schedule 5 together with the provision of instructions via configuration or analysis tools made available through the DAE). NHS Digital shall notify the Recipient immediately if, in NHS Digital's opinion, an instruction from the Recipient breaches a requirement of Data Protection Law. Notwithstanding the foregoing, the Recipient acknowledges that, taking into account the automated nature of the DAE and processing, NHS Digital is not in a position to determine whether the Recipient's instructions via configuration of, or use of analysis tools made available through, the DAE infringe Data Protection Law;
 - 6.4.2 provide all reasonable assistance to the Recipient to prepare any data protection impact assessment before commencing any processing;
 - 6.4.3 have in place appropriate technical and organisational measures (which may include, by way of example, pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of such measures adopted by it) which have been reviewed and approved by the Recipient as appropriate, to guard against a DAE Data Loss Event, which take into account the nature of the data, the harm that might result, the state of technology and the cost of implementing the measures;
 - 6.4.4 ensure that persons authorised to process the Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;
 - 6.4.5 not transfer Personal Data outside of the European Economic Area unless NHS Digital has provided appropriate safeguards in relation to the transfer and data subjects have enforceable rights and effective legal remedies;
 - 6.4.6 delete or (to the extent only that the Recipient has any ongoing permission to retain any Data under the DSA) return the Recipient's Personal Data (including copies) if requested in writing by the Recipient on termination or expiry of access to the DAE, unless required to retain the Personal Data by Union or Member State law;
 - 6.4.7 notify the Recipient without undue delay if it receives any communication from a third party relating to the parties' obligations under the Data Protection Law in respect of this Schedule 5, or it becomes aware of a DAE Data Loss Event, and will provide the Recipient with all reasonable assistance in relation to the Recipient's obligations under Data Protection Law;
 - 6.4.8 maintain records and information to demonstrate its compliance with this Schedule 5;
 - 6.4.9 respect the conditions referred to in paragraphs 6.5 and 6.6 of this Schedule 5 for engaging another processor; and

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- 6.4.10 subject to paragraph 6.8 of this Schedule 5, make available to the Recipient all information necessary to demonstrate compliance with this paragraph 6.4 of this Schedule 5 and allow for and contribute to audits, including inspections, conducted by the Recipient or another auditor mandated by the Recipient.
- 6.5 Where NHS Digital engages another processor for carrying out specific processing activities on its behalf, NHS Digital shall enter into an agreement with the subprocessor on terms that provide at least the same level of protection for the Personal Data as this paragraph and meet the requirements of Data Protection Law. Where that other processor fails to fulfil its data protection obligations, NHS Digital shall remain fully liable to the Recipient for the performance of that other processor's obligations.
- 6.6 The Recipient consents to NHS Digital engaging subprocessors for the processing of Personal Data in accordance with this paragraph 6 of this Schedule 5. A list of NHS Digital's current subprocessors is set out when logged in to the DAE. Such list may be updated by NHS Digital (or a relevant third party provider) from time to time. If the Recipient does not approve of a new subprocessor, then the Recipient may terminate its use of the DAE (or, where feasible, relevant part of it) on written notice to NHS Digital.
- 6.7 Where subprocessing is being carried out by a third party service provider, the Recipient agrees that the performance of NHS Digital's obligations in this paragraph 6 of this Schedule 5 shall be subject to the terms and conditions applicable to that processing as are identified in the End User Access Agreement or as otherwise are applicable to NHS Digital.
- 6.8 The Recipient acknowledges that any audits or inspections under paragraph 6.4.10 of this Schedule 5 in respect of any element of the DAE provided by a third-party service provider will be limited to the provision of information and documentation and will not include the right to audit that third party service provider's physical infrastructure.
- 6.9 The provisions of this Schedule 5 do not restrict any statutory rights a competent data protection authority (such as the Information Commissioner's Office in the UK) may have under applicable law to perform audits based on a valid and binding order.