

Resource Terms & Conditions

v2.5.1 April 2025

Definitions

Access Board: the Our Future Health board responsible for the Access Process.

Access Process: the process for requesting and being granted access to the Resource for the purposes of conducting research, such process to be confirmed to the Registered Researcher and Research Institution by Our Future Health in writing.

Accreditation: the process developed by Our Future Health to ensure a TRE has demonstrated sufficiently robust organisational, technical, security and administrative processes to be permitted to host a subset of the Our Future Health data to allow registered researchers to conduct an approved study. Accreditation is granted by an independent assessor to a specific TRE.

Accredited TRE: a TRE that has achieved accreditation via the Our Future Health accreditation process.

Applicable Law: any statute, statutory instrument, bye-law, order, directive, regulation, treaty, decree or law; rule, policy, code of practice, guidance or recommendation issued by any governmental, statutory or Regulatory Authority; and/or industry code of conduct or practice or guideline, research governance or ethical guidance or other requirements of Regulatory Authorities, in force from time to time which is or are legally binding on the relevant Party (including Data Protection Laws), and for the purposes of Schedule 2, including those identified in Annex 2, as amended or re-enacted from time to time.

Approved Study: any research project or study that has been approved by the Our Future Health Access Board in accordance with the Access Process.

Business Day: a day that is not a Saturday, Sunday or public or bank holiday in the United Kingdom.

Cohort Participant: an individual who agrees to join and is recruited to the Our Future Health project.

Commencement Date: the date of acceptance of these Terms & Conditions by the Parties.

Confidential Information: all information which: (a) is, at the time of disclosure, designated as confidential or proprietary; (b) is clearly confidential or proprietary from its nature and/or the circumstances in which it was imparted; (c) would be regarded as confidential or proprietary by a reasonable business person knowledgeable in the relevant field; or (d) gives value from being secret, including information relating to the terms of this Terms & Conditions and all other

information which relates to the business, strategies, trade secrets, products, programmes, financial affairs or other commercial affairs and any proprietary information of either Party, together with all copies of and all information extracted or derived from this information.

Core Cohort Data: any raw and processed data collected by and under the possession or control of Our Future Health that is derived from Cohort Participants and that is contained within the Resource, excluding Results Data and Findings.

Data Protection Laws: means all Applicable Laws, legally binding rules, policies, guidance, opinions, codes of practice or recommendations issued by any governmental, statutory or regulatory body and any legally binding industry codes of conduct or guideline, in each case relating to data protection, the processing of personal data, privacy and/or electronic communications in force from time to time in the UK.

Exclusivity Period: on a study-by-study basis (or interim analysis-by-interim analysis basis), the period of exclusivity for the relevant Results Data (during which time the Results Data are not required to be added to the Resource).

Fees: the fees paid or payable under this Agreement by the Research Institution to Our Future Health in consideration of the Research Institution being granted access to the Resource, as may be amended from time to time.

Findings: any Intellectual Property, know-how or other information arising out of or in connection with any Approved Study, excluding any Results Data, Core Cohort Data and/or Samples but including any data created, generated or derived from any analysis of such Results Data, Core Cohort Data and/or Samples.

Force Majeure Event: an event which is not reasonably foreseeable and is beyond the reasonable control of the relevant Party.

Good Industry Practice: in relation to any undertaking and any circumstances, the exercise of skill, care, diligence, prudence, foresight operating practice and judgement and the making of any expenditure that would reasonably be expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances.

Informed Consent: the consent provided digitally or through other documented means that is given by a Cohort Participant who agreed to join the Our Future Health project and who agreed to the inclusion of data about such Cohort Participant and their associated Samples within the Resource, and all necessary informed consents needed to authorise recontact of Cohort Participants to propose the opportunity to participate in Approved Studies,

Insolvent: a party is insolvent where it: gives notice or proposes or passes a resolution for, its winding up (save for the purpose of a solvent reconstruction or amalgamation); has a winding-up order made or a notice of striking off filed in respect of it; has an administration order or an application for an administration order made in respect of it; has a notice of appointment of an administrator or a notice of intention to appoint an administrator filed in respect of it at any court; proposes, makes or is subject to: a company voluntary arrangement; a composition with its creditors generally; an application to a court of competent jurisdiction for protection from its creditors generally; has a receiver or a provisional liquidator appointed over any of its assets, undertaking or income; or is subject to any event or proceeding, in any jurisdiction to which it is subject, that has an effect equivalent or similar to any of the foregoing events or proceedings

mentioned in this definition.

Intellectual Property or IP: all intellectual and industrial property rights of any kind whatsoever (whether registered or unregistered) including rights in inventions, patents, supplementary protection certificates, rights in know-how, rights to use and protect the confidentiality of confidential information (including trade secrets), registered trade marks, registered designs, unregistered design rights, unregistered trade marks, rights to prevent passing off or unfair competition and copyright (whether in drawings, plans, specifications, designs and computer software or otherwise), rights in data, database rights, topography rights, and applications for and rights to apply for and be granted any of the foregoing, including all applications for and rights to apply for and be granted renewals, extensions, continuations, divisions, reissues, re-examinations and substitutions, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist now or in the future in any part of the world.

International Data Transfer Agreement: the template IDTA A1.0 issued by the Information Commissioner's Office (ICO) and laid before the UK's Parliament in accordance with s119A of the Data Protection Act 2018 on 2 February 2022, as it is amended by the ICO from time to time.

Locking: on a study-by-study basis (or interim analysis-by-interim analysis basis), in relation to Results Data generated under, as applicable, a Stage 1 Study or a Stage 2 Study or another study under this Agreement (including an additional contribution study), or any portion thereof, an action or actions which prevents any further changes to the relevant dataset, and “**Locked**” shall be construed accordingly.

Materials: means such information or materials (including any trade mark, brand image, logo and other Intellectual Property but excluding any Resource Data, Results Data or Findings) exchanged between the Parties for the purpose of the relevant study or activity under these Terms & Conditions.

NHS Data: the health or social care data specified in and that is provided by NHS England to Our Future Health under a DSA (as defined in Schedule 2) that is incorporated within the Resource and made available to the Research Institution and in each case which Our Future Health has identified as licensed by NHS England to Our Future Health under such DSA, including Manipulated Data (as defined in Schedule 2) unless otherwise specified.

Our Future Health Charity: the Our Future Health charity with company number 12212468, charity number 1189681 and registered address at 2 New Bailey, 6 Stanley Street, Greater Manchester M3 5GS.

Our Future Health: Our Future Health Trading Limited (registered number 12599493) whose registered office is at 2 New Bailey, 6 Stanley Street, Greater Manchester, United Kingdom, M3 5GS.

Our Future Health Trusted Research Environment (“TRE”): a TRE (including all tools and services) hosted by Our Future Health that will be available to a Research Institution's Registered Researchers in accordance with these Terms & Conditions and the Registered Researcher Terms & Conditions, and which hosts the Resource Data in a portable manner.

Party: Our Future Health or the Research Institution (or together, the “Parties”)

Personal Information: personal data as defined under the Data Protection Laws.

Policies: the policies of Our Future Health and the Our Future Health Charity, including those documents with these or similar names and equivalent function, including: Personal Data Protection Policy, Data Disclosure Policy, Airlock Policy, Publication Policy, Records Retention Policy, Information Security Policy, Sample Handling Policy, Whistleblowing Policy, Fraud, Theft, Bribery and Corruption Policy, Information Classification Handling Policy, Brand and Communications Guidelines, and the Our Future Health Ethics Framework, as made available to the Research Institution and their Registered Researcher(s) via the Our Future Health website and as may be updated from time to time.

Registered Researcher: any individual who has successfully completed the relevant registration process for Registered Researchers.

Registered Researcher Terms & Conditions: the terms and conditions agreed between the Registered Researcher and Our Future Health governing the researcher's use of the Resource.

Regulatory Authority: any governmental, statutory or regulatory body and any other competent authority or entity in any jurisdiction having responsibility for the regulation or governance of both or either of the parties and/or the activities which are comprised in all or part of the use of the Resource.

Relevant Personal Information: means any Resource Data and Samples that are Personal Information processed in relation to an Approved Study, which, as relevant, is set out in Schedule 1 or Part 1A.

Research Institution: Any institution or organisation electing to undertake research as part of an Approved Study under the Our Future Health project and which has agreed to these Terms & Conditions.

Research Registry: the publicly available register containing details of research studies that are using or have used the Our Future Health Resource.

Resource: the assets comprising the Core Cohort Data and/or associated Samples; the Our Future Health TRE; all Results Data from any Approved Study that is added to the Our Future Health TRE and that is available for use after expiry of the applicable Exclusivity Period; the Research Registry; and the authorisation process for enabling Registered Researchers to approach Cohort Participants for recruitment into an Approved Study.

Resource Data: the Core Cohort Data, and the copy of any Results Data added to the Resource.

Results Data: any primary individual level data created from analysis of Core Cohort Data, Samples, samples collected by a Research Institution and/or data added to the Resource as part of an Approved Study.

Samples: the biological samples collected from Cohort Participants who have provided Informed Consent during the lifetime of the Resource as specified in the Scientific Protocol (which shall include the blood specimen provided as part of recruitment, and other sample related items).

Scientific Protocol: the final scientific protocol made available to Research Institutions as may be updated from time to time by Our Future Health, which shall include providing for collection of Samples from all Cohort Participants. The Scientific Protocol shall be accessible to the Research Institution and their Registered Researchers via the Our Future Health website.

Small & Medium Enterprise: a company or other entity that has a headcount <250 staff and a turnover of ≤€50m and a balance sheet ≤ €43m.

Stage 1 Study: a study using the Resource, and which does not require further contact with and/or consent of Cohort Participants (in addition to the Informed Consent obtained when the Core Cohort Data was obtained).

Stage 2 Study: a study using the Resource which requires the recontact and the obtaining of additional study-specific consent and Informed Consent of Cohort Participants for recruitment into additional research studies which will either collect new data, samples or test interventions.

Term: the term of these Resource Terms & Conditions.

Terms & Conditions: these terms and conditions, as agreed between the Parties.

Trusted Research Environment or TRE: is an environment, that may be cloud-based, that allows Registered Researchers working on an Approved Study to conduct analysis on pseudonymised datasets in a secure manner, and where export of Results Data and Findings for that Approved Study are permitted but exports of Core Cohort Data or any other such individual level data is not permitted.

The terms **Controller, Data Protection Impact Assessment, Data Subject, Joint Controller, Personal Data, Personal Data Breach, Processor, Processing, Process, Sub-Processor** and **Supervisory Authority** shall be as defined under relevant Data Protection Laws.

1. The Resource

- 1.1 Subject to these Terms & Conditions, Our Future Health shall provide any Research Institution who has gained study approval via the Access Process with access to the Resource for the sole purpose of conducting an Approved Study. Where an individual researcher is conducting an Approved Study then such individual researcher shall be deemed to be a Research Institution for the purposes of these Terms & Conditions.
- 1.2 Access to the Resource shall be governed by the same Access Process for all Research Institutions. Access to certain data (e.g. NHS Data) may be conditional upon the Research Institution entering into additional terms and conditions where required either (i) by the relevant licence with Our Future Health; and/or (ii) where reasonably required in the opinion of Our Future Health.
- 1.3 The Research Institution will:
 - 1.3.1 provide a copy of any Results Data generated during the Term to Our Future Health for inclusion in the Resource by no later than the end of the applicable Exclusivity Period;
 - 1.3.2 at all times, comply with Data Protection Laws, all other Applicable Laws, all Our Future Health Policies (as updated from time to time), the Our Future Health Scientific Protocol and the Access Process, where required and applicable;
 - 1.3.3 at all times, use the Resource for the sole purpose of conducting the Approved Study, in accordance with these Terms & Conditions;
 - 1.3.4 comply with any and all training requirements, as confirmed by Our Future Health, including annual information governance training;
 - 1.3.5 obtain all relevant permissions for the Approved Study, such as necessary ethical and regulatory approvals;
 - 1.3.6 inform its Registered Researchers of its obligations concerning the use and disclosure of all data being accessed within the Resource, as set out in these Terms & Conditions;
 - 1.3.7 comply with all necessary security procedures and access protocols with respect to any data held within the Resource; and
 - 1.3.8 provide a report (in writing or in such other form as Our Future Health specifies) on the progress of all Approved Studies to Our Future Health, such report to be provided on a yearly basis by way of email to a notified contact at Our Future Health or via an upload to the Our Future Health platform. Where there is more than one Research Institution involved in the research, only the lead Research Institution will submit a report.
- 1.4 A Research Institution may only access NHS Data when a relevant Approved Study requiring NHS Data has been approved via the Access Process. Where a Research

Institution accesses NHS Data, it shall, and shall procure that its Registered Researchers shall, comply with the obligations set out in Schedule 2, without prejudice to any other obligation in these Terms & Conditions or the Registered Researcher Terms & Conditions.

2. Registered Researchers

- 2.1 The Research Institution agrees to be held liable for any act and omission of its Registered Researchers and will be responsible for ensuring its Registered Researchers comply with all relevant obligations when using the Resource, including those set out in these Terms & Conditions and the Registered Researcher Terms & Conditions and any imposed by Applicable Law.
- 2.2 The Research Institution warrants that it and its Registered Researchers:
 - 2.2.1 have full capacity to perform the obligations set out within these Terms & Conditions, as applicable;
 - 2.2.2 have not been debarred or are subject to debarment or have otherwise been disqualified or suspended from performing scientific or clinical investigations or otherwise subjected to any restrictions or sanctions by the MHRA, EMA, FDA or any other governmental or Regulatory Authority or professional body with respect to the performance of scientific or clinical investigations;
 - 2.2.3 are not aware of any conflict which would impact their use of the Resource;
 - 2.2.4 have complied with and will continue to comply with the Access Process; and
 - 2.2.5 have verified their identity in accordance with the Access Process.
- 2.3 To the extent in the future that any Registered Researcher is debarred, or becomes subject to debarment, or is otherwise disqualified or suspended from performing scientific or clinical investigations or is otherwise subjected to any restrictions or sanctions by the MHRA, EMA, FDA or any other governmental or Regulatory Authority or professional body with respect to the performance of scientific or clinical investigations, the Research Institution will notify Our Future Health promptly. In accordance with this clause 2.3, Our Future Health has the right to remove access rights to the Resource from any such Registered Researcher.

3. Exclusivity

- 3.1 The Research Institution shall have an Exclusivity Period as approved by the Access Board as part of the Access Process. The criteria and process for extension to the Exclusivity Period will be defined in the Access Process and will be equally applicable to all Research Institutions.
- 3.2 Access to the Resource will only be provided to the Research Institution (and the Registered Researchers listed in an Approved Study) for the duration of the Approved Study.

4. Fees and Payment

- 4.1 In consideration of being granted access to the Resource (subject to earlier termination in accordance with these Terms & Conditions) the Research Institution shall pay Our Future Health the Fees, in accordance with this clause 4.
- 4.2 Without prejudice to clause 4.3:
 - 4.2.1 Our Future Health shall send the Research Institution an invoice for the initial Fees once the relevant study has been approved, where access to the Resource will not be granted until the related invoice has been paid; and
 - 4.2.2 where the Research Institution is conducting a multi-year study, Our Future Health shall also send the Research Institution annual invoices within thirty (30) days of the anniversary of the Research Institution being granted access to the Resource.
- 4.3 All Fees will be paid by the Research Institution within thirty (30) days of receipt of the relevant invoice, unless alternative payment terms have been agreed in writing between the Parties. In the event the Research Institution fails to do so, without prejudice to Our Future Health's other rights under these Terms & Conditions, it reserves the right to:
 - 4.3.1 withhold access to the Resource;
 - 4.3.2 terminate access to the Resource; and/ or
 - 4.3.3 charge the Research Institution late payment interest on that sum at 2% per annum over the base lending rate as set by the Bank of England's Monetary Committee from time to time from the due date until the date of payment (whether before or after any judgment), such interest to accrue on a daily basis.
- 4.4 The Research Institution will make all payments due under these Terms & Conditions to Our Future Health in Great British Pounds Sterling.
- 4.5 Any sum payable under these Terms & Conditions is exclusive of VAT (and any other similar or equivalent taxes, duties, fees and levies imposed by any government or other authority) which is payable, where applicable, in addition to that sum in the manner and at the rate prescribed by Applicable Law, subject to receipt by the paying party of a valid, accurate, complete and audit worthy VAT invoice.
- 4.6 The Research Institution shall promptly and without undue delay notify Our Future Health's Access Team through email at access@ourfuturehealth.org.uk of any changes to the funding of their study. In the case of SMEs, this shall include but is not limited to any changes which may impact and cause the Research Institution to no longer meet the definition of an SME through any means. Our Future Health reserves the right to revisit the Fees accordingly.

5. Intellectual Property

- 5.1 Our Future Health hereby grants (including by way of sublicensing where any necessary rights are owned by the Our Future Health Charity and/or contributors to the Resource) the Research Institution a worldwide, royalty-free, fully paid-up, non-exclusive licence to access and use those elements of the Resource that are relevant to an Approved study being conducted by the Research Institution in accordance with these Terms & Conditions.
- 5.2 All rights, title and interest in and to the Results Data (and any Intellectual Property subsisting in the same) created by or on behalf of the Research Institution through use of the Resource shall be solely owned by that Research Institution.
- 5.3 The Research Institution hereby grants to Our Future Health (or will procure the grant of in the case of its affiliates and/or contracted third parties generating Results Data) a non exclusive, perpetual, irrevocable, worldwide, fully paid up, royalty free, transferable, sublicensable licence to use (after the applicable Exclusivity Period only) the Results Data as part of the Resource and to make such Results Data available to other Registered Researchers using the Resource and to Our Future Health's and the Our Future Health Charity's employees and service providers using the Resource.
- 5.4 All rights, title and interest in and to any Findings (and any Intellectual Property subsisting in the same) shall be solely owned by the Research Institution. No right or license in relation to any Findings or any Intellectual Property subsisting in the same or based thereon is granted by the Research Institution under these Terms & Conditions. If and to the extent a Research Institution opts to submit any Findings (and/or any Intellectual Property subsisting in the same) to Our Future Health for inclusion in the Resource, the Research Institution will be required to enter into a license with Our Future Health on the same terms as those set out in clause 5.3.
- 5.5 Each Party's respective Materials shall at all times remain to be their own property. Unless expressly authorized to do so under these Terms & Conditions, the Parties acknowledge and agree that they are not permitted to use the other Party's Materials without obtaining the other Party's prior written consent.
- 5.6 Without prejudice to the generality of clause 5.5, the Parties acknowledge and agree that they are not permitted to use the other Party's Materials for marketing purposes without obtaining the other Party's prior written consent.
- 5.7 On termination or expiry of the Terms & Conditions:
 - 5.7.1 the Parties shall cease using each other's Materials; and
 - 5.7.2 the terms in this clause 5 shall survive and continue in full effect.

6. Data Management

- 6.1 Any Samples collected by a Research Institution's Registered Researchers as part of an Approved Study will be under the custodianship of and controlled and (only to the extent permitted by and subject to Applicable Law) owned by, the Research Institution (for clarity, such Samples shall not be provided to Our Future Health unless the Research Institution and Our Future Health agree otherwise).

7. Data Protection

- 7.1 The Parties acknowledge and agree that:
- 7.1.1 they will each act as independent controllers regarding the Relevant Personal Information with respect to all activities undertaken or required in performance of these Terms & Conditions, provided that the Research Institution shall only use the Relevant Personal Information for the purposes of the Approved Study; and
 - 7.1.2 they will at all times process the Relevant Personal Information in accordance with their respective obligations under the Data Protection Laws, implementing appropriate technical and organisational measures to ensure an appropriate level of security to protect the Relevant Personal Information.
- 7.2 Should the role of either Party, as set out in clause 7.1.1, need to be modified for the purpose of any individual study, the Parties shall agree to such modification in writing.
- 7.3 In respect of the Relevant Personal Information, Our Future Health shall ensure that:
- 7.3.1 it has satisfied a lawful ground under the Data Protection Laws permitting:
 - 7.3.1.1 Our Future Health to transfer the Relevant Personal Information to the Research Institution for the Research Institution to use it for the purpose of the study or activity in relation to which such data is shared under these Terms & Conditions; and
 - 7.3.1.2 the Research Institution to use the Relevant Personal Information for the purposes of the study or activity in relation to which such data is shared under these Terms & Conditions and solely within the approval granted by the Access Board.
 - 7.3.2 it has delivered to the Data Subjects such information as is required to comply with its obligations under Data Protection Laws. Our Future Health will be responsible for including in that initial fair processing notice all such reasonable information as is provided to Our Future Health by each Research Institution to comply with its respective fair processing obligations under Data Protection Laws (and the parties acknowledge that this information may include a link to a second layer Research Institution fair processing notice). For the avoidance of doubt, Our Future Health will have no ongoing responsibility to each Research Institution to update or amend that initially provided information in respect of

Stage 1 Studies. In respect of Stage 2 Studies, each Party will be responsible for the provision of its own fair notice obligations under Data Protection Laws; and

- 7.3.3 it has implemented reasonable measures to ensure the Relevant Personal Information is accurate and up to date.
- 7.4 If either Party receives any communication from a Supervisory Authority which relates directly or indirectly to:
 - 7.4.1 processing of Relevant Personal Information undertaken by the other Party; or
 - 7.4.2 a potential failure to comply with Data Protection Laws in relation to the processing of the Relevant Personal Information by the other Party the relevant Party shall, to the extent permitted by Applicable Laws, promptly notify the other Party. Both Parties commit to provide reasonable cooperation and assistance to the other Party in relation to the same, provided that such Party shall not be required to incur material costs or expenses in providing such co operation and assistance.
- 7.5 Each Party shall ensure that the Relevant Personal Information shall be kept confidential and held securely in accordance with these Terms & Conditions and:
 - 7.5.1 is not disclosed to any of its staff unless those persons: (i) have undergone appropriate training in data protection; and (ii) are legally or contractually bound to hold the information in confidence;
 - 7.5.2 is processed only for the purpose of the relevant study or activity under these Terms & Conditions, or as otherwise agreed in writing between the Parties;
 - 7.5.3 is transferred outside the Our Future Health TRE or Accredited TRE (and not between the two) to third parties not authorised under these Terms & Conditions only where secure and is either:
 - 7.5.3.1 within the approval from the Access Board (or to a necessary sub processor who is supporting the delivery of the research within that approval) and where the third party recipient is:
 - 7.5.3.1.1 made subject to appropriate confidentiality obligations; and
 - 7.5.3.1.2 required to comply with its obligations under Data Protection Laws in respect of its processing of the Relevant Personal Information; or
 - 7.5.3.2 legally required under Applicable Law and subject to notification (such notification to include evidence of the relevant legal requirement) to Our Future Health no later than twenty-eight (28) working days in advance, save where such notification would itself be a breach of its legal requirements under Applicable Laws, and subject always to the

accreditation process as it applies to the Research Institution and Access Process; and

7.5.3.3 is subject to appropriate technical and organisational measures (including, but not limited to, encryption and password protection), when transferring and/or processing Relevant Personal Information, to preserve the confidentiality, integrity, availability and resilience of the Relevant Personal Information and prevent any unlawful Processing or disclosure or damage, taking into account the state of the art, the costs of implementation, the nature, scope, context and purposes of Processing as well as the risk of varying likelihood and severity for the rights and freedoms of the Data Subjects.

- 7.6 If an individual makes a request to either Party to exercise any of their rights under Data Protection Laws in respect of Relevant Personal Information, the receiving Party shall respond to that request in accordance with Data Protection Laws. To the extent the request concerns processing of Relevant Personal Information undertaken by the other Party, the receiving Party shall: (i) promptly and without undue delay forward the request to the other Party; and (ii) cooperate and provide reasonable assistance in relation to that request to enable the other Party to respond in accordance with Data Protection Laws, provided that such Party shall not be required to incur material costs or expenses in providing such co operation and assistance.
- 7.7 Upon becoming aware of a Personal Data Breach affecting Relevant Personal Information, each Party shall notify the other Party promptly and without undue delay, and provide the other Party with a reasonable description of the Personal Data Breach promptly as such information becomes available. The Parties agree to provide reasonable assistance as is necessary to each other to facilitate the handling of any Personal Data Breach in an expeditious and compliant manner.
- 7.8 In the event the country from which the Research Institution (including through its Registered Researchers) is accessing or otherwise Processing Relevant Personal Information is subject to change, the Research Institution shall notify Our Future Health of this prior to any such access or Processing taking place. In such circumstances, the Parties shall cooperate in good faith to ensure appropriate arrangements are in place in respect of the Research Institution's access or Processing, which may include agreeing to the preparing and execution of any required International Data Transfer Agreement or other applicable appropriate safeguard in accordance with the Data Protection Laws.
- 7.9 Both Our Future Health and the Research Institution hereby agree to the preparation and execution of any required 'International Data Transfer Agreement' or other applicable appropriate safeguard(s) in accordance with the Data Protection Laws where either Party, acting as a data exporter, proposes to transfer Relevant Personal Information to the other, or to any third party acting as data importer that is located in a country that does not provide an adequate level of data protection according with the adequacy decisions of the United Kingdom. Each Party will enter into any such International Data Transfer Agreement or appropriate safeguard on behalf of itself.

- 7.10 To the extent there is any conflict between any term of the relevant appropriate safeguard or International Data Transfer Agreement and any other part of these Terms & Conditions, the terms of the relevant appropriate safeguard or International Data Transfer Agreement shall prevail.
- 7.11 On termination or expiry of the Terms & Conditions, any terms in this clause 7 shall survive and continue in full effect.

8. Confidentiality

8.1 Subject to the other provisions of this clause 8:

8.1.1 at any time during the Term and after the date of termination, all Confidential Information disclosed by or on behalf of a Party (the “Discloser”) to, or which is otherwise learned or obtained by or on behalf of the other Party (the “Recipient”) shall be maintained in confidence and otherwise safeguarded by the Recipient in the same manner and with the same protection as such Recipient maintains its own confidential information;

8.1.2 the Recipient may disclose Confidential Information of the Discloser to:

8.1.2.1 employees, officers, agents, contractors, workers, consultants and advisers of the Recipient and its affiliates and permitted sub licensees; and

8.1.2.2 to the Recipient’s attorneys, independent accountants, financial advisors or Intellectual Property advisors for the sole purpose of enabling such attorneys, independent accountants, financial advisors or Intellectual Property advisors to advise such party, in each case to the extent reasonably necessary for the purposes of these Terms & Conditions provided that such persons enter into confidentiality undertakings, or are otherwise bound by written confidentiality obligations, no less stringent than those contained in these Terms & Conditions; and

8.1.3 the Recipient may only use the Discloser’s Confidential Information for the purposes of exercising its rights or performing its obligations under or in connection with these Terms & Conditions.

8.2 The obligations in clause 8.1 shall not apply to the extent that the Recipient can demonstrate that such Confidential Information of the Discloser:

8.2.1 was generally available to the public and in the public domain before its receipt by the Recipient, or thereafter becomes available to the public and enters the public domain through no fault of the Recipient;

8.2.2 is known by the Recipient at the time of its receipt without an obligation of confidentiality, and not through a prior disclosure by or on behalf of the Discloser, as documented by the Recipient’s business records;

- 8.2.3 is subsequently disclosed to the Recipient by a third party who may lawfully do so and such third party is not under an obligation of confidentiality to the Discloser;
 - 8.2.4 is developed by the Recipient independently and without use of, or reference to, any of the Discloser's Confidential Information received by the Recipient, as evidenced by the Recipient's written business records; or
 - 8.2.5 is approved in writing by the Discloser for release by the Recipient.
- 8.3 Notwithstanding the foregoing, the Parties acknowledge and agree that Core Cohort Data may only be accessed by Registered Researchers and may not be disclosed as contemplated by clause 8.1.2 above.
- 8.4 Notwithstanding the obligations set forth in clause 8.1, a Party may disclose the other Party's Confidential Information to the extent such disclosure is required by Applicable Law. Confidential Information that is disclosed pursuant to this clause 8.4 shall remain otherwise subject to the confidentiality and non-use provisions of this clause 8 and the Recipient disclosing Confidential Information pursuant to Applicable Law or court order shall take all steps reasonably necessary to ensure the continued confidential treatment of such Confidential Information.
- 8.5 On termination or expiry of the Terms & Conditions, the terms in this clause 8 shall survive and continue in full effect.

9. Warranties, Liability and Indemnity

- 9.1 Our Future Health shall indemnify the Research Institution from and against any losses, liabilities, costs, damages and expenses incurred arising out of or resulting from any third party claim, proceeding or investigation in connection with Our Future Health's breach of Applicable Law, except to the extent arising or resulting from any Research Institution or Research Institution's Registered Researchers' negligence, gross negligence or wilful misconduct or breach of these Terms & Conditions.
- 9.2 The Research Institution shall indemnify Our Future Health from and against any loss, damages, reasonable costs and expenses incurred by any of them arising out of or resulting from any third-party claim in connection with the Research Institution's breach of Applicable Law, except to the extent arising or resulting from Our Future Health's negligence, gross negligence or wilful misconduct or breach of these Terms & Conditions.
- 9.3 For any Approved Study involving multiple Research Institutions, the liability of each of the Research Institutions for their obligations under these Terms & Conditions shall be several and extend only to any loss or damage arising out of their own breaches.
- 9.4 The Research Institution represents, warrants and undertakes that it will:
- 9.4.1 obtain all necessary consents, licenses and authorisations required from any applicable Regulatory Authorities for it to conduct its Approved Study (as

applicable) and comply with Applicable Law in conducting such Approved Studies; and

9.4.2 it has full and sufficient rights to grant the license granted under clause 5.3.

9.5 Subject to clause 9.6, neither Party shall be liable to the other Party for:

9.5.1 any special, consequential, incidental or indirect damages; and/or

9.5.2 any loss of profit, loss of use or loss of opportunity (in each case whether of a direct, indirect or consequential nature) howsoever arising from or relating to these Terms & Conditions, regardless of any notice of the possibility of such damages. This clause 9.5 does not apply to clause 9.1 and clause 9.2.

9.6 Nothing in these Terms & Conditions shall exclude or limit the liability of either Party:

9.6.1 for death or personal injury resulting from its negligence or the negligence of a person for whom it is vicariously liable (negligence being as defined in Section 1(1) Unfair Contract Terms Act 1977);

9.6.2 for its fraud or fraudulent misrepresentation or fraud or fraudulent misrepresentation by a person for whom it is vicariously liable; or

9.6.3 for any matter for which it is not permitted by law to exclude or limit, or to attempt to exclude or limit, its liability.

9.7 Subject to clauses 9.1, 9.2 and 9.6, the maximum aggregate liability of either Party under or in connection with these Terms & Conditions shall be £1,000,000 (one million pounds sterling).

10. Term and Termination

10.1 These Terms & Conditions will commence on the Commencement Date and shall remain in full force and effect for the term of the Approved Study unless terminated earlier in accordance with the terms of this clause 10.

10.2 Without affecting any other right or remedy available to it, either Party may terminate these Terms & Conditions immediately by serving written notice to the other Party if any of the following circumstances arise:

10.2.1 the other Party commits a material breach of the Terms & Conditions which cannot be remedied, or commits a material breach of the Terms & Conditions which can be remedied but fails to remedy that breach within twenty (20) Business Days of receipt of a notice setting out the breach;

10.2.2 the other Party becomes Insolvent; or

10.2.3 the other Party is unable to perform its obligations in whole or in any material part for a period of more than forty (40) Business Days due to a Force Majeure

Event and has not submitted a plan to mitigate such Force Majeure Event within such forty (40) Business Day period.

- 10.3 Our Future Health reserves the right to revoke the license granted at clause 5.1 if there has been a demonstrated misuse of Samples or Resource Data by the Research Institution or the Research Institution's Registered Researcher(s). For the purposes of this clause 10.3, "misuse" shall mean failure by the Research Institution or the Research Institution's Registered Researcher(s) to comply with the relevant terms of these Terms & Conditions, Approved Study, Access Process, Applicable Laws or the Scientific Protocol.
- 10.4 If Our Future Health considers that there has been a misuse of Samples or Resource Data by the Research Institution or the Research Institution's Registered Researcher(s), it shall immediately notify the Research Institution and provide its reasons for this view and proposed remedial actions. If the Research Institution does not respond within ten (10) Business Days or does not provide sufficient explanation as to why there has not been misuse, Our Future Health may terminate the Terms & Conditions.

11. Consequences of Expiry or Termination

- 11.1 Notwithstanding clause 11.4, where an Approved Study is a Stage 1 Study, the expiry or termination of these Terms & Conditions for any reason will result in the termination of the Approved Study, and the Research Institution will return any Resource Data to Our Future Health.
- 11.2 Notwithstanding clause 11.4, where an Approved Study is a Stage 2 Study, the expiry of these Terms & Conditions will result in the termination of the Approved Study, and the Research Institution will return any Resource Data to Our Future Health.
- 11.3 Notwithstanding clause 11.4, where an Approved Study is a Stage 2 Study, the termination of these Terms & Conditions for any reason will result in suspension of access to the Resource for the Research Institution and its Registered Researcher(s) for a period of 12 weeks during which time the Research Institution will submit a plan of action for remediation. During this period, Our Future Health may, at its sole discretion, block any invitations to Stage 2 Study Cohort Participants.
- 11.4 Upon the termination or expiry of these Terms & Conditions for any reason:
- 11.4.1 the following provisions of these Terms & Conditions will continue in force: clauses 4 (solely as to payments that were payable and due prior to notice of termination or expiry), 5.2, 7, 8, 9, 11 and 14.9, together with any other provisions which expressly or impliedly continue to have effect after expiry or termination of these Terms & Conditions. Exclusivity in relation to Results Data shall continue for the relevant Exclusivity Period in accordance with clause 3.1 notwithstanding termination or expiry of these Terms & Conditions;
- 11.4.2 all other rights (including the Research Institution and Registered Researcher's access to and use of the Resource) and obligations will immediately cease, without prejudice to any rights, obligations, claims (including claims for

damages for breach) and liabilities which have accrued prior to the termination or expiry of the Terms & Conditions; and

11.4.3 Our Future Health will be entitled to block the Research Institution and Registered Researcher from any further right of access to or use of the Resource.

12. Audit

12.1 Our Future Health shall have the right to conduct an audit of the records held by the Research Institution in respect of any activities contemplated under these Terms & Conditions, either by itself or through its agents where:

12.1.1 an audit is imposed on Our Future Health by a regulatory body; and/or

12.1.2 Our Future Health has reasonable grounds for believing that the Research Institution has not complied with its obligations under these Terms & Conditions and/or Applicable Law.

12.2 Audits shall be conducted at a time mutually convenient to both parties.

13. Force Majeure

13.1 A Party will not be in breach of these Terms & Conditions or otherwise liable to the other Party for any failure to perform or delay in performing its obligations under these Terms & Conditions to the extent that such failure or delay is due to a Force Majeure Event.

13.2 If a Force Majeure Event occurs, the Party affected shall:

13.2.1 as soon as reasonably practicable after becoming aware of the Force Majeure Event give the other Party written notice of the occurrence, anticipated duration and impact of the Force Majeure Event;

13.2.2 use all commercially reasonable efforts, without being required to incur additional expenditure, to mitigate the effects of the Force Majeure Event, and to continue to perform the affected obligations notwithstanding the occurrence of the Force Majeure Event and to ensure that the Force Majeure Event comes to an end; and

13.2.3 continue to perform all of its obligations under these Terms & Conditions the performance of which are not affected by the Force Majeure Event.

13.3 A Party will not be in breach of these Terms & Conditions or otherwise liable to the other Party for any failure to perform or delay in performing its obligations under these Terms & Conditions to the extent that this is due to a Force Majeure Event affecting the other Party.

14. General

14.1 **Assignment.** Save as expressly provided under these Terms & Conditions, neither Party

will be entitled to assign, transfer, delegate, charge, hold on trust for any person or deal in any other manner with any of its rights or obligations under these Terms & Conditions except with the prior written consent of the other Party (not to be unreasonably withheld or delayed). Any attempted assignment, transfer or delegation shall be null and void.

- 14.2 **Amendment.** Our Future Health may notify updates and changes to these Terms & Conditions at any time by giving notice to the Research Institution. The Research Institution's continued receipt of information constitutes acceptance of the updated/changed terms unless the Research Institution notifies Our Future Health that it does not wish to accept such terms within 30 days of the notice of updates/changes being given, in which case, these Terms & Conditions shall terminate on Our Future Health's receipt of such notice from the Research Institution.
- 14.3 **Severability.** If any term of these Terms & Conditions is found by any court or body or authority of competent jurisdiction to be illegal, unlawful, void, or unenforceable, such term will be deemed to be severed from these Terms & Conditions and this will not affect the remainder of these Terms & Conditions which will continue in full force and effect.
- 14.4 **Notices.** Any notices under these Terms & Conditions shall be: (i) in writing; (ii) sent to the email addresses referenced in the sign-up process for these Terms & Conditions; and (iii) deemed delivered 24 hours after despatch.
- 14.5 **Misrepresentation.** Neither Party has entered into these Terms & Conditions in reliance upon, and it will have no remedy in respect of, any misrepresentation, representation or statement (whether made by the other Party or any other person and whether made to the other Party or any other person) which is not expressly set out in these Terms & Conditions and nothing in this clause 14.5 will be interpreted or construed as limiting or excluding the liability of either Party for fraud or fraudulent misrepresentation.
- 14.6 **Variation.** Save as otherwise expressly provided in these Terms & Conditions, no variation to these Terms & Conditions will be effective unless it is in writing and signed by a duly authorised representative on behalf of each of the parties.
- 14.7 **Waiver.** A delay in exercising or failure to exercise a right or remedy under or in connection with these Terms & Conditions will not constitute a waiver of, or prevent or restrict future exercise of, that or any other right or remedy, nor will the single or partial exercise of a right or remedy prevent or restrict the further exercise of that or any other right or remedy. A waiver of any right, remedy, breach or default will only be valid if it is in writing and signed by the Party giving it, and in the circumstances and for the purpose for which it was given and will not constitute a waiver of any other right, remedy, breach or default.
- 14.8 **Governing Law and Jurisdiction.** These Terms & Conditions and any dispute or claim arising out of or in connection with them or their subject matter or formation (including non-contractual disputes or claims) will be governed by and will be construed in accordance with the law of England and Wales, and the Parties submit to the non-exclusive jurisdiction of the English Courts.

- 14.9 **Third Party Beneficiaries.** Save as expressly provided under these Terms & Conditions, no person other than a Party to these Terms & Conditions, their respective successors and permitted assigns, shall have any rights to enforce any term of these Terms & Conditions.
- 14.10 **Partnership.** Nothing in these Terms & Conditions is intended to, or shall be deemed to, establish any partnership or **agency** between the Parties or authorises either Party to make or enter into any commitments for or on behalf of the other Party. Each Party confirms it is acting on its own behalf and not for the benefit of any other person.

Signed for and on behalf of the Research Institution

Name

Research institution name

Job title

Email address

Signature *A signature request will be sent after submission*

Date

Schedule 1

Description of Processing

Where the Research Institution is processing Relevant Personal Information under these Terms and Conditions, the Parties agree that the detail of the subject matter, duration, nature and purpose of the processing, the type of Relevant Personal Information and the categories of individuals whose data is processed in relation to this processing activity are as set out below.

Duration, nature and purpose of processing	
Duration of processing	Unless stated otherwise in these Terms & Conditions or agreed in writing between the parties, Relevant Personal Information will be processed for the term of these Terms & Conditions and any such additional period stated in these Terms & Conditions.
Nature and purpose of processing	For the purpose of the Research Institution participating in an activity under these Terms & Conditions.
Relevant Personal Information	
Individuals may include:	Employees and contingent workers, Cohort Participants, research subjects.
Categories of Relevant Personal Information may include:	Personal biographical information (e.g. age, gender and nationality), health information, lifestyle information, educational attainment, government ID numbers, information on personal interactions with Our Future Health.
Special categories of Relevant Personal Information may include:	Ethnicity or race, medical or health information, religious or philosophical beliefs or affiliations, sexual orientation or sex life, genetic information, biometric data, biological samples.

Schedule 2

NHSE Sub Licensing Flow Down Terms

Applicable to studies using NHSE linked health data

These terms represent the relevant obligations that Our Future Health is required to flow down to those authorised to access NHS Data in whole or part (regardless of whether as a Controller and/or a Processor) and will apply to all processing of NHS Data (and as otherwise set out below). Such parties who are provided access to and authorised to process NHS Data are referred to herein as the “**Sub Licensee**”.

NHS England may impose further Special Conditions on sub licensing that must be met by Our Future Health and/or the Sub Licensee, prior to any sharing of (additional) NHS Data, which will be communicated by Our Future Health to the Sub Licensee from time to time.

Unless stated otherwise, the terms in this Schedule 2 shall apply to NHS Data, Manipulated Data and Derived Data (all as further defined below) only. To the extent only of any conflict or inconsistency between this Schedule 2 and any other provision of this Agreement, in respect of NHS Data, Manipulated Data and Derived Data, this Schedule 2 will prevail in respect of such NHS Data, Manipulated Data and Derived Data only.

Definitions

Anonymised Data: NHS Data in a form that does not identify individuals and where identification through its combination with other data is not likely to take place;

Associated DSA: any data sharing agreement between NHS England and a third-party recipient which is expressly stated in the relevant DSA under this Sub-Licence to be an Associated DSA;

Certificate of Destruction: a certificate signed by an authorised representative of the Sub Licensee, or specialist third party engaged to securely destroy the NHS Data, which assures NHS England that the NHS Data and all hard and soft copies thereof held by the Sub Licensee have been securely and permanently destroyed in accordance with Applicable Law and Guidance (including the NHS England Destruction and Disposal of Sensitive Data Good Practice Guidelines), and “Certification of Destruction” shall be interpreted as the provision of such certificate;

Data: the health or social care data specified in and that is provided by NHS England to the Recipient under a DSA; and such term shall also be deemed to include Manipulated Data unless otherwise specified;

Data Breach: a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to NHS Data;

Derived Data: any Data (wholly or in part) that is Manipulated to such a degree that it: (a) cannot be identified as originating or deriving from the Data and cannot be reverse engineered such that it can be so identified; (b) is not capable of use as a substitute for the Data; and (c) has not at any time been verified by NHS England as not fulfilling the criteria (a) and (b) above;

DSA: a data sharing agreement entered into by Our Future Health and NHS England to document and agree the terms on which the relevant NHS Data will be shared, including the Associated DSA referred to in Schedule 5;

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 practicing good data security, and that personal information is handled correctly. The DSPT can be accessed from <https://www.dsptoolkit.nhs.uk/>;

FOIA: the Freedom of Information Act 2000;

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, the Standardisation Committee for Care Information and NHS England, including those identified in Annex 2;

Information Asset Owner: a senior member of staff who is the nominated owner for one or more identified information assets within the Sub Licensee;

Information Asset Register: a list of personal and non-personal information assets held by the Sub Licensee;

NHS England: the non-departmental public body whose address is The Leeds Government Hub, 7 & 8 Wellington Place, Leeds LS1 4AP;

NHSE Contract: the agreements, including framework agreements and data sharing agreements, between Our Future Health and NHS England relating to the NHS Data;

Manipulate: a) combine (wholly or in part) with other data or information; or b) aggregate (wholly or in part) with other data or information; or c) adapt (wholly or in part). "Manipulating" and "Manipulated" shall be construed accordingly;

Manipulated Data: any NHS Data that has been Manipulated, unless and until it qualifies as Derived Data (to be determined at the sole discretion of NHS England);

Personnel: all employees, agents and contractors of the Recipient who may have access to the Data;

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 Sub Licensee is permitted to use the NHS Data, as set out in the relevant DSA and as set out in Annex 3;

Recipient: the party who will be a Controller of any Personal Data to be shared under and in accordance with this Contract and any DSA;

Relevant Territory: means the territory applicable to the licence for the NHS Data as set out in Annex 3 and the approval provided via the Access Process;

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 Sub Licensee, including those identified in Annex 2. For the avoidance of doubt, it does not include any contractual obligation of the Sub Licensee;

Sub Licence: the terms and conditions in respect of the sub licensing of Our Future Health's rights in respect of the processing of NHS Data, including the terms set out in this Schedule 2;

Special Conditions: the special conditions for processing the NHS Data as set out in the relevant DSA;

Term: the term for which the Sub Licensee is permitted to use the relevant NHS Data as defined in the relevant DSA and as set out in Annex 3;

Third Party Contractor: a sub contractor, Processor or otherwise; and

Working Day: a day, other than a Saturday, Sunday or public holiday in England, when banks in London are open for business.

1. Relationship with NHS England

- 1.1 Our Future Health is the recipient of the NHS Data from NHS England and will act as the primary contact point with NHS England in relation to the NHS Data. Our Future Health is and shall be entitled to notify NHS England of the existence of and information relating to this Sub Licence, and to provide copies of this Sub Licence to NHS England.
- 1.2 Where any provision in this Sub-Licence is expressed to be exercisable by NHS England, it may be exercised by Our Future Health on behalf of NHS England.
- 1.3 Where notice of any matter is to be provided by the Sub Licensee to NHS England, the Sub Licensee will, at the same time, also provide a copy of such notice to Our Future Health.
- 1.4 Where the Sub-Licence expressly states that consent of NHS England is required, the Sub Licensee shall submit any request for such consent to Our Future Health, who will liaise with NHS England in connection with the request.
- 1.5 NHS England 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.

2. The NHS Data

- 2.1 The NHS Data is provided by NHS England to Our Future Health, and Our Future Health provides access to the NHS Data, within the Our Future Health TRE, to the Sub-Licensee, on an 'as is' basis and neither NHS England nor Our Future Health warrants the accuracy or completeness of the NHS Data, nor that the NHS Data does not infringe the Intellectual Property of any third party, nor does it undertake that the NHS Data will meet the requirements of, or be fit for any purpose of, the Sub-Licensee.
- 2.2 Notwithstanding any other provisions regarding Intellectual Property or licence grants under the Terms & Conditions (including the licence granted pursuant to clause 5.1), any and all access or use of the NHS Data by the Sub Licensee is subject to this Sub Licence.

- 2.3 If the Sub Licensee does not agree to the Sub-Licence at any given time in respect of any NHS Data, it must inform the Access Board through the Access Process and it must not access or use such NHS Data.
- 2.4 Without prejudice to paragraph 5, the Sub-Licensee acknowledges that any and all Intellectual Property in the NHS Data are and shall remain at all times the property of Our Future Health, NHS England or its licensors, as the case may be, and the Sub-Licensee shall have no rights in or to the NHS Data other than the right to use the NHS Data in accordance with this Sub-Licence. The parties acknowledge and agree that the parties do not intend for Findings or Results Data to constitute NHS Data or Manipulated Data, and the Sub-Licensee will use reasonable endeavours to ensure that Findings or Results Data do not contain NHS Data or Manipulated Data.

3. Licence and Intellectual Property

- 3.1 Our Future Health hereby grants to the Sub-Licensee a nonexclusive, nontransferable, suspendable (in whole or in part), revocable, royalty free, fully paid up, licence to access, use, view, store, process, copy, and Manipulate the NHS Data in respective of which approval has been granted via the Access Process, in the Relevant Territory for the duration of the relevant Term solely for the Purpose and only in accordance with the terms of the Terms & Conditions (including this Sub-Licence) including to create Manipulated Data, Derived Data, Results Data and Findings, via the Our Future Health TRE only.
- 3.2 The Sub-Licensee shall not be permitted to sublicense the NHS Data to any Third Party Contractor.
- 3.3 Notwithstanding paragraph 3.2, the rights granted by Our Future Health under paragraph 3.1 extend to any relevant Registered Researcher acting on behalf of the Sub-Licensee:
 - 3.3.1 in each case only in so far as they are an employee, agent or contractor acting on behalf of the Sub-Licensee; and
 - 3.3.2 where such Registered Researcher is located in the Relevant Territory.
- 3.4 The Sub Licensee acknowledges that, in respect of its processing of NHS Data:
 - 3.4.1 NHS England may require Our Future Health to notify NHS England of the existence of and information relating to this Sub-Licence, and to provide copies of this Sub-Licence to NHS England at any time. At the date that this Agreement was amended to include these NHSE Terms, Our Future Health agrees that the Relevant DSA specifies that this information includes start and end dates, name of organisation, territory of use, purpose, data specification and legal basis;
 - 3.4.2 if NHS England becomes aware that any such Sub-Licence does not include the mandatory terms stipulated in this Sub-Licence and/or the relevant DSA, this may result in the termination by NHS England of the relevant DSA and/or the Sub-Licence , (which would automatically revoke any authorisation granted by Our Future Health to process NHS Data);

- 3.4.3 breach of any of the terms of any such Sub-Licence by the Sub-Licensee may result in the termination by NHS England of the relevant data sharing framework with Our Future Health (and thereby terminate this Sub-Licence and/or these Terms & Conditions) (which would automatically revoke any authorisation granted by Our Future Health to process NHS Data); and
- 3.4.4 the information provided to NHS England in relation to any Sub-Licenses pursuant to Paragraph 3.4.1 may be shared, subject to Paragraph 9.8, publicly by NHS England at its own discretion including by disclosure on a data release register.
- 3.5 The Sub Licensee acknowledges that:
 - 3.5.1 any and all Intellectual Property Rights in the NHS Data are and shall remain at all times the property of Our Future Health, NHS England or its licensors, as the case may be;
 - 3.5.2 it shall have no rights in or to the NHS Data other than the right to use the NHS Data in accordance with the express terms of these Terms & Conditions and as authorised under the relevant DSA with Our Future Health.

4. Manipulated Data

- 4.1 In consideration for the grant of access to the processing of NHS Data and in accordance with paragraph 5.4 (below), the Sub Licensee hereby assigns to NHS England absolutely with full title guarantee any and all Intellectual Property Rights (including copyright and database rights) in any Manipulated Data from creation.
- 4.2 For the avoidance of doubt, in respect of the Intellectual Property Rights in the Manipulated Data assigned to NHS England by the Sub Licensee under paragraph 4:
 - 4.2.1 The Sub Licensee must ensure that any display of NHS data including Manipulated Data, wherever possible, cites the copyright of NHS England and/or any licensor of NHS England as appropriate as follows:

“Copyright © (year), NHS England. Re used with the permission of the NHS England [and/or [name of licensor]]. All rights reserved.”
 - 4.2.2 Where practicable, any outputs generated from use of NHS Data will cite the source of the NHS Data as:

“This work uses data that has been provided by patients and collected by the NHS as part of their care and support. The data are collated, maintained and quality assured by the National Disease Registration Service, which is part of NHS England. Access to the data was facilitated by the NHS England Data Access Request Service.”
- 4.3 Whilst NHS England obtains ownership of Manipulated Data NHS England does not take ownership of any data of the Sub Licensee or any third party that has been or will be obtained independently of NHS England data sharing agreements.

- 4.4 NHS England does not by virtue of paragraph 4 have a right to use or take ownership of any data belonging to the Sub Licensee or any third party which is Manipulated to create the Manipulated Data, and Manipulated Data shall be deemed to be included in the authorised access under paragraph 4 from the date when such rights arise.

5. Derived Data

- 5.1 All Derived Data and any and all Intellectual Property Rights in Derived Data shall be owned exclusively by the Sub-Licensee. In consideration for the grant of the licence set out at paragraph 3.1, the Sub-Licensee agrees to be bound by any terms set out in the Special Conditions regarding the making accessible (in hardcopy or electronic format), copying, processing, Manipulating, creating, storing and any other use of the Derived Data.
- 5.2 On demand by Our Future Health, the Sub Licensee shall make a declaration (the form and content of which will be notified to the Sub Licensee by NHS England at the relevant time) of any data created under the relevant DSA which it believes is Derived Data to NHS England. The Sub Licensee will make available to Our Future Health, upon request, copies of any data declared to be Derived Data under this paragraph 5.2.
- 5.3 Where the Sub Licensee has made a declaration upon the request of Our Future Health under paragraph 5.2, Our Future Health (or NHS England) shall verify whether the data declared is Derived Data and inform the Sub Licensee of the outcome of its verification. The Sub Licensee hereby agrees that Our Future Health's (or NHS England's) verification is final and binding on whether data is classed as Derived Data or otherwise.
- 5.4 NHS England (or Our Future Health acting on its behalf) may call upon the Sub Licensee at any time to execute such documents and perform such acts as may be required for the purpose of giving full effect to paragraphs 3 and 4, in particular paragraph 4.1. The Sub Licensee 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 Sub-Licence, in particular paragraph 4.1.

6. Sub-Licensee general responsibilities in relation to NHS Data

- 6.1 The Sub Licensee shall:
- 6.1.1 use the NHS Data only in accordance with the Purpose;
 - 6.1.2 process the NHS Data only in accordance with the terms of this Sub-Licence (including the Schedules to these terms), the relevant DSA, and any Special Conditions;
 - 6.1.3 maintain good information governance standards and practices, meeting or exceeding the Data Security and Protection Toolkit (DSPT) required of its organisation type;
 - 6.1.4 subject to Paragraph 3.3, not share the NHS Data with any third party (other than any third party Processor permitted under these Sub-Licence terms) without the

- prior written consent of NHS England;
- 6.1.5 ensure that Personnel processing the NHS Data are suitably trained and made aware of their responsibilities in handling the NHS Data;
- 6.1.6 ensure that all Personnel, prior to accessing or using NHS Data, are made fully aware of, and comply with the terms and conditions set out in this Sub-Licence and the relevant DSA;
- 6.1.7 promptly and in any event within 28 days of the applicable date, the applicable date being the earlier of:
 - 6.1.7.1 the expiry or termination of this Sub-Licence; or
 - 6.1.7.2 the expiry or termination of the relevant DSA permanently destroy or erase the NHS Data and all NHS Data licensed under the relevant DSA, together with all hard and soft copies of the same and provide NHS England with a Certification of Destruction. NHS England reserves the right to verify the deletion of the NHS Data (which may be through Our Future Health acting on its behalf or otherwise), including, without limitation by carrying out an audit in accordance with paragraph 7, and the Sub Licensee will cooperate with NHS England (and/or Our Future Health) in relation to the same;
- 6.1.8 immediately notify any Data Breach to Our Future Health as soon as the Sub Licensee discovers such Data Breach; and:
 - 6.1.8.1 where the Sub Licensee is obliged to complete the DSPT, the Sub Licensee and Our Future Health shall assess whether a “Serious Incident Requiring Investigation” (as defined in the DSPT) report needs to be made (and Our Future Health shall assist and consult with the Sub Licensee for such assessment); or
 - 6.1.8.2 where the Sub Licensee is not obliged to comply with the DSPT, the Sub Licensee 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
- 6.1.9 immediately notify Our Future Health if it no longer has a legal basis on which to process NHS Data.
- 6.2 Unless specified in the Purpose, (or as otherwise authorised by an NHS England director in writing), the Sub Licensee must not combine the NHS Data with any other data held by the Sub Licensee and must not attempt to identify any individual from the NHS Data, or use or Manipulate the NHS Data in any way that re identifies any individual from the NHS Data.
- 6.3 The Sub Licensee shall when using and processing the NHS Data comply with and have regard at all times to:
 - 6.3.1 all Applicable Law;

- 6.3.2 Good Industry Practice;
 - 6.3.3 Guidance; and
 - 6.3.4 the data security requirements set out in the DSA and Annex 1.
- 6.4 The Sub Licensee shall indemnify Our Future Health and NHS England in full for any liabilities, losses, demands, claims, damages, amounts agreed in settlement, reasonable costs and expenses incurred in connection with:
- 6.4.1 any loss of the NHS Data by the Sub Licensee;
 - 6.4.2 unauthorised or unlawful use of the NHS Data beyond the Purpose(s) by the Sub Licensee;
 - 6.4.3 any breach of these Terms & Conditions or this Sub Licence by the Sub Licensee; and
 - 6.4.4 any monetary penalty notice imposed on Our Future Health or NHS England by the Information Commissioner under Data Protection Law as a result of the Sub Licensee's breach of this Sub-Licence.
- 6.5 The Sub Licensee shall not have the right to assign, novate, transfer, charge, dispose of or deal in any other manner with this Sub-Licence, or any of its rights or beneficial interests under such terms, or purport to do the same, nor sub contract any or all of its obligations under this Sub-Licence without the prior written consent of both NHS England and Our Future Health.

7. Data Protection

- 7.1 To the extent that any of the NHS Data constitutes Personal Data (or constitutes Anonymised Data, but then the NHS Data becomes Personal Data in the hands of the Sub Licensee), the Sub Licensee shall hold and process such NHS Data at all times:
- 7.1.1 as Controller of the Personal Data (unless specifically agreed with Our Future Health that the Sub Licensee's role is as a Processor);
 - 7.1.2 in accordance with Data Protection Law; and
 - 7.1.3 using appropriate technical and organisational security measures against unauthorised or unlawful processing of NHS Data and against accidental loss or destruction of, or damage to, the NHS Data.
- 7.2 To the extent the Sub Licensee processes Personal Data in connection with this Sub-Licence or any DSA, the Sub Licensee agrees that, for the purposes of Data Protection Law, it processes such Personal Data either:
- 7.2.1 as an independent Controller in its own right (subject to paragraph 7.1.1 above); or

- 7.2.2 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.
- 7.3 Nothing in this Sub-Licence or in any DSA is intended to construe either party to these Terms & Conditions as:
 - 7.3.1 the Processor of the other party (save where specifically agreed otherwise); or
 - 7.3.2 a Joint Controller or independent controller with the other party with respect to the Personal Data processed in connection with this Sub-Licence or any DSA.
- 7.4 Where the NHS Data includes Personal Data, the Sub Licensee shall:
 - 7.4.1 store and process such Personal Data securely, and permanently destroy or erase it when it is no longer needed for the Purpose;
 - 7.4.2 not Publish such Personal Data without the prior written consent of NHS England. Such consent may (at NHS England'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;
 - 7.4.3 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 England;
 - 7.4.4 take reasonable steps to ensure the reliability of each of its Personnel who have access to such Personal Data;
 - 7.4.5 inform Our Future Health immediately if it receives any communication from the ICO which relates to such Personal Data, unless explicitly prohibited from doing so by the ICO;
 - 7.4.6 ensure access to such Personal Data by Personnel is managed, auditable and restricted to those needing to process such Personal Data;
 - 7.4.7 only be entitled to appoint a Processor to process such Personal Data on behalf of the Sub Licensee where permitted under the terms of the relevant DSA (and only in relation to NHS Data provided under that DSA) or with the prior written consent of NHS England and shall remain fully responsible to NHS England under the terms of this Sub-Licence and the relevant DSA for the actions of its Processors; and
 - 7.4.8 not transfer to or process such Personal Data outside the European Economic Area except with the express prior written consent of NHS England and only in circumstances when such transfer is permitted under, and complies with the requirements of, Data Protection Law and Applicable Law.

8. Confidentiality

8.1 The Sub Licensee must:

- 8.1.1 keep the NHS Data confidential, and shall not disclose it to any third party save where expressly permitted to do so in accordance with this Sub-Licence and the relevant DSA; and
- 8.1.2 use the NHS Data only in so far as is necessary to perform its obligations and exercise its rights under the Terms & Conditions (including this Sub-Licence) and the relevant DSA.

8.2 The Sub Licensee shall be responsible for any unauthorised disclosure or use of the NHS Data made by any of its Personnel and shall take all reasonable precautions to prevent such unauthorised disclosure or use.

8.3 If the Sub Licensee is obliged to respond to requests under FOIA and a request is received regarding the NHS Data, the Sub Licensee must consult with NHS England and Our Future Health prior to any release of the Data and shall take into account NHS England and Our Future Health's views before responding to any request. Notwithstanding this paragraph 8.3, the Sub Licensee accepts that the Sub Licensee is responsible in its absolute discretion for determining whether information regarding the NHS Data is exempt from disclosure under FOIA.

9. Audit and specific rights

9.1 NHS England (and Our Future Health or any auditors of or other advisers to NHS England and/or Our Future Health) shall be entitled at any time during the Term and for a period of 12 months after the termination or expiry of this Sub-Licence, to audit the Sub Licensee's compliance with the requirements of this Sub-Licence.

9.2 NHS England (and any auditors of or other advisers to NHS England) and/or Our Future Health shall be entitled to audit the Sub-Licensee's use of the NHS Data which may include the auditing of the hosting and IT infrastructure, security, processes and procedures where appropriate. The rights of NHS England (and any auditors of or other advisers to NHS England)) and/or Our Future Health under this paragraph 9 to audit the Sub-Licensee's use of the NHS Data includes the right for NHS England (and any auditors of or other advisers to NHS England) and Our Future Health to audit the use of the NHS Data by any Third Party Contractor. The Sub-Licensee must include such provisions as are necessary to give NHS England (and any auditors of or other advisers to NHS England)) and/or Our Future Health that right in any subcontract or other agreement or arrangement under which the Sub-Licensee permits such Third Party Contractor to have access to the NHS Data and must use its best endeavours to procure that NHS England (and any auditors of or other advisers to NHS England) shall have access to the sites used by any such person to access the NHS Data as if that person were the Sub-Licensee where appropriate.

9.3 Subject to paragraph 9.4, NHS England will give the Sub-Licensee or Third Party Contractor not less than ten Working Days' notice of any proposed audit and will not carry out more than two audits within any 12 month period – unless either a) a previous audit reported

issues for which follow up review is required or reasonable evidence emerges that NHS Data is NOT being used in accordance with this agreement.

- 9.4 If NHS England, acting reasonably, has any concerns that:
- 9.4.1 the terms of this Sub-Licence and/or any DSA are not being adhered to by the Sub Licensee and/or any Third Party Contractor; or
 - 9.4.2 the terms of any Associated DSA are not being adhered to by the relevant recipient under that Associated DSA, NHS England (and any auditors of or other advisers to NHS England) and/or Our Future Health on NHS England's behalf shall be entitled to carry out one or more audits on the Sub Licensee and/or the Third Party Contractor, including making unannounced visits and carrying out spot checks of the Sub Licensee's sites and Third Party Contractor's Sites. There shall be no restriction on the number of audits NHS England (and any auditors of or other advisers to NHS England or Our Future Health as required by NHS England) may carry out under this paragraph 9.4.2, and the restriction on the number of audits that NHS England (and any auditors of or other advisers to NHS England) may carry out within a 12 month period shall not apply to any audits carried out under this paragraph 9.4.2.
- 9.5 The Sub-Licensee shall, for the purpose of any audit carried out under this paragraph 9, provide or procure the access to the Sub-Licensee'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 England (and any auditors of or other advisers to NHS England) are permitted to take copies of relevant documents and data pursuant to such audit where appropriate.
- 9.6 The Sub Licensee shall provide and shall procure that its Third Party Contractor provides such information as NHS England (and any auditors of or other advisers to NHS England) reasonably requests in order to verify the Sub Licensee's compliance with the terms of this Sub-Licence and/or any DSA.
- 9.7 The cost of any audit carried out under this paragraph 9 shall be borne by NHS England where it is carried out by NHS England or Our Future Health where it is carried out by Our Future Health unless, in NHS England's and/or Our Future Health's reasonable opinion, the audit reveals that the Sub Licensee or Third Party Contractor either has not complied, or is not complying, with any of the Sub Licensee's obligations under the Sub-Licence, or any DSA, in which case the Sub Licensee shall promptly reimburse NHS England for all reasonable costs of the audit and the full cost of any investigation which NHS England may commence prior to an audit taking place.
- 9.8 Subject to paragraphs 9.9, 9.10, 9.11 and 9.12, Our Future Health agrees not to disclose to any third party except NHS England, any confidential information relating to the Sub Licensee received or obtained (i) under paragraph 5.1 with respect to the Sub Licensee's Derived Data, and (ii) in the course of carrying out any audit under this paragraph 9.
- 9.9 The restrictions on disclosure and use of the Sub Licensee's confidential information contained in paragraph 9.8 shall not apply to information to the extent that it is or was:

- 9.9.1 already in the possession of or becomes available to NHS England in either case free of any obligation of confidentiality;
 - 9.9.2 required to be disclosed by NHS England 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
 - 9.9.3 at the time of receipt by NHS England, is in the public domain or after such receipt comes into the public domain other than as a result of breach by NHS England of this paragraph 9.
- 9.10 NHS England shall be entitled to share confidential information received or obtained by NHS England and/or Our Future Health in the course of carrying out any audit under this paragraph 9 with government organisations in accordance with its performance of its functions including the Department of Health and Social Care, Government Legal Department, National Audit Office and any auditors or advisors to NHS England,
- 9.11 NHS England shall be entitled to Publish the auditor's findings and any audit report.
- 9.12 NHS England is obliged to respond to requests under FOIA. NHS England must consult with the Sub Licensee prior to any release of confidential information received under this paragraph 9 and shall take into account the Sub Licensee's views before responding to any request. Notwithstanding this paragraph 9.12, Sub Licensee acknowledges and accepts that NHS England is responsible in its absolute discretion for determining whether the information is exempt from disclosure under FOIA.

10. Suspension, Termination and Remediation process

- 10.1 Where any NHSE Contract or any part of a NHSE Contract in respect of any NHS Data is suspended or terminated, Our Future Health shall notify the Sub-Licensee without undue delay of such suspension and termination and the rights granted under this Sub-Licence in relation to the affected NHS Data will suspend or terminate (respectively) automatically on (and to the extent affected by) such suspension or termination.
- 10.2 Without limitation to paragraph 9 and NHS England's other rights and remedies under this Sub-Licence, where: (i) the Sub Licensee is in breach of the Sub-Licence or any DSA; or (ii) there is a breach of any Associated DSA; or (iii) (in NHS England's reasonable opinion) there has been or is likely to be a breach of any Associated DSA, NHS England (and Our Future Health acting on NHS England's behalf or otherwise) may:
- 10.2.1 suspend provision of all or part of the NHS Data to the Sub Licensee until the breach or suspected breach is resolved to NHS England's reasonable satisfaction;
 - 10.2.2 suspend the licence(s) granted to the Sub Licensee under paragraph 3.1 in relation to all or part of the NHS Data until the breach or suspected breach is resolved to NHS England's reasonable satisfaction; and/or
 - 10.2.3 destroy or erase all or part of the NHS Data received by the Sub Licensee in accordance with Applicable Law, and Guidance, and produce a Certificate of

Destruction; and/or

- 10.2.4 produce, or cooperate with any Sub Licensee who is a party to an Associated DSA to produce, a remediation plan detailing how the Sub Licensee (and, if applicable, any Sub Licensee who is a party to an Associated DSA) will resolve the breach or suspected breach to NHS England's reasonable satisfaction, together with a project plan.
- 10.2.5 terminate (a) provision of all or part of the affected NHS Data and/or (b) the Sub Licence in relation to all or part of the affected NHS Data
- 10.3 On termination or expiry for whatever reason of the Sub Licence:
 - 10.3.1 under no circumstances shall the Sub Licensee continue to use the NHS Data without a licence in place which relates to that NHS Data;
 - 10.3.2 promptly and in any event within 28 days of the date of termination or expiry of the Sub Licence, the Sub Licensee will securely and permanently destroy or erase the NHS Data licensed under this Sub Licence, together with all hard and soft copies of the same and provide Our Future Health and NHS England with a Certificate of Destruction. NHS England reserves the right to verify the deletion of the NHS Data, including by carrying out an audit in accordance with paragraph 9, and the Sub Licensee will cooperate with NHS England (and Our Future Health acting on NHS England's behalf or otherwise) in relation to the same.
- 10.4 Without prejudice to NHS England's rights and remedies under this Sub-Licence where in NHS England's reasonable opinion the Sub Licensee has not complied, or is not complying, with any of the Sub Licensee's obligations under this Sub-Licence, the Sub Licensee shall be liable to promptly reimburse NHS England 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 England activity due to any resulting ICO investigation and any additional media and communication activity and costs.
- 10.5 Without prejudice to the other provisions of this paragraph 10, the parties acknowledge and agree that any termination under this Schedule 2 may result in the need for a mutually agreed upon winddown plan in consideration of any ongoing Stage 1 Studies or Stage 2 Studies relying on data or Cohort Participants from the Resource, subject to Our Future Health having the right to do so under the NHSE Contract.
- 10.6 The parties agree that any termination or suspension referred to in this paragraph 10 shall:
 - 10.6.1 only impact this Schedule 2 and the NHSE Data that is the subject of the termination or suspension;
 - 10.6.2 not impact the Research Institution's or Our Future Health's other rights under this Agreement (including the licences under clause 5.1); and
 - 10.6.3 without prejudice to any termination rights under clause 10 or otherwise under this

Agreement, not give rise to termination of the Agreement.

Annex 1

NHS Data Security Requirements

Section A

1. Without prejudice to the Sub Licensee's other obligations in respect of information security, the Sub Licensee 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 NHS Data or accidental loss, destruction or damage of such NHS Data; and
 - 1.1.2 the nature of the NHS Data;
 - 1.2 take reasonable steps to ensure the reliability of the Sub Licensee's Personnel who have access to the NHS Data which shall include:
 - 1.2.1 ensuring all such Personnel understand the confidential nature of the NHS Data and the issues which arise if proper care is not taken in the processing of the NHS 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 NHS Data. Where requested to do so the Sub Licensee 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 NHS Data, including through the use of procedures to identify changes in personal circumstances which may affect an individual's ability to process the NHS Data in accordance with the terms of this Sub License;
 - 1.3 provide Our Future Health with such information, assistance and co operation as Our Future Health may require from time to time to establish Our Future Health's and/or the Sub Licensee's compliance with the Data Protection Law; and
 - 1.4 inform Our Future Health as soon as reasonably practicable of any particular risk to the security of the NHS Data of which it becomes aware, and of the categories of NHS Data and individuals which may be affected.
2. The Sub Licensee shall promptly, and in any event not later than reasonably required in order to enable Our Future Health to fulfil its duties under the Data Protection Law, provide such information as Our Future Health requires relating to the identity of any third parties to whom the NHS Data has been disclosed by the Sub Licensee to the extent Our Future Health requires this information to comply with its duties under the Data Protection Law.

3. The Sub Licensee shall implement and maintain security and risk assessment standards, facilities, controls and procedures appropriate to the nature of the NHS 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 Sub-Licensee shall ensure that all its Personnel who have access to the NHS 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 NHS Data supplied under this Sub-Licence.
4. The Sub Licensee 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 NHS 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 NHS Data and that training is provided in relation to the need to keep such passwords secure;
 - 4.3 it has in place procedures to identify wrongful use of NHS Data, including the monitoring of wrongful access;
 - 4.4 that suitable and effective authentication processes are established and used to protect NHS Data;
 - 4.5 that NHS 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 Sub Licensee 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 NHS Data transferred electronically is encrypted using only the Advanced Encryption Standard (AES) 256 bits specification;
 - 4.7 that NHS Data stored on laptops or other portable media is encrypted and that the Sub Licensee maintains an accurate, up to date asset register, including all such portable media used to process the NHS Data;
 - 4.8 that Personnel are not able to access the NHS Data from home or via their own electronic device other than through a secure electronic network and that NHS 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 NHS Data. Such physical security measures shall be as identified in the Sub Licensee's data protection policy;
 - 4.10 without prejudice to the Sub Licensee's obligations to NHS England in relation to the disposal of NHS Data, all NHS Data which is disposed of must be disposed of in accordance with Applicable Law and Guidance (including the NHS England Destruction and Disposal of Sensitive Data Good Practice Guidelines), (and provided it does not conflict with the

foregoing, in accordance with the Sub Licensee's policy for the disposal of NHS 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 England); and

- 4.11 that the Sub Licensee 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 Sub Licensee shall nominate in writing an individual to take responsibility and be accountable for compliance with Data Protection Law, and shall provide to Our Future Health and/or NHS England 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 Sub Licensee must demonstrate, and will allow Our Future Health to audit, that it:

A: meets or exceeds the DSPT standards required by Our Future Health for their organisation type Organisation Code:

If A does not apply, B and/or C, as Our Future Health may require and specify in this Sub-Licence or otherwise in writing to the Sub Licensee:

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 Our Future Health'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, Section B of this Annex 1, which Our Future Health reserves the right to audit in accordance with Paragraph 9 of Schedule 2.
4. Where the Recipient has provided information under this Sub-Licence about what other security assurance it has in place, and without prejudice to Sub Licensee's other obligations under this Sub License, the Sub Licensee 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 Sub License, and which are consistent with the purposes recorded in the Sub Licensee'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 Our Future Health;
- 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 Our Future Health any security incidents relating to the Data, and any instances of breach of any of the terms of this Sub License; and
- 4.8 comply with any specific legislation in relation to the Data (such as the Statistics and Registration Services Act 2007).

Annex 2

Applicable Law and Guidance

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, as applicable in UK domestic law by virtue of the European Union (Withdrawal) Act 2018, as amended (“**UK GDPR**”)
- The Data Protection Act 2018
- Health and Social Care (National Data Guardian) Act 2018

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 England 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 England Code of Practice on confidential information (HSCIC, 2014).
- Confidentiality: NHS Code of Practice 2003.
- The NHS Care Record Guarantee 2011 (Version 5).
- 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 UK GDPR.

Research Law

- The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended from time to time).
- 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 Sub Licensee.
- International Conference on Harmonisation (ICH) guidelines on Good Clinical Practice as amended from time to time

Annex 3

Associated DSA

DSA Reference	DARS-NIC-411795-X5N2V-v0.9
DSA Start Date	29/11/2023
DSA End Date	28/11/2026
DSA Purpose	Purposes intended and expected to achieve benefit to UK health and social care system, and consistent with the DSA Purpose statement available via https://app.powerbi.com/view?r=eyJrIjojOWEwZGY3ZmQtNTJiYS00M2RmLWEyNzgtZDUyNjgzNWYzZTMwliwidCI6IjM3YzM1NGlyLTg1YjAtNDdmNS1iMjlyLTA3YjQ4ZDc3NGVlMyJ9 (by selecting the Our Future Health DSA through such link).
Relevant Territory	<p>Those specific territories as specified in the Access Process and as agreed between Our Future Health and NHS England within the relevant DSA. For the avoidance of doubt, the list of countries included within the definition of Relevant Territory can be found on the Our Future Health research website here: https://research.ourfuturehealth.org.uk/territories-of-access/. This list may be updated by Our Future Health from time to time (to add or remove territories) pursuant to the relevant DSA.</p> <p>If the researcher is located in the Relevant Territory included within the list on the Our Future Health research website, then the transfer of Personal Data from the UK to these countries and the Processing of the Personal Data in those countries is permitted.</p> <p>No transfer to or Processing in jurisdictions that are not on the Relevant Territory list are permitted. Any request to expand the Relevant Territory list of countries must be reviewed and approved by NHS England and an amendment to the relevant DSA made to include the additional country (-ies) within the relevant DSA. Should NHS England determine, upon assessment, that a country on the expanded list is deemed high risk, the jurisdiction will not be permitted. NHS England will inform Our Future Health and Our Future Health will stop providing the Sub Licensee with access to NHS Data from this country.</p>

