UK Longitudinal Linkage Collaboration

UK Longitudinal Linkage Collaboration (UK LLC)
DATA ACCESS AGREEMENT

Agreement Summary

UK LLC Reference Number:	llc_
Project Title:	
Main Applicant at Recipient Institute:	
Recipient Institute and Department:	
Authorised Researcher(s) at Recipient Institute:	
Other Authorised Researchers and their Institutes (main applicant at each Institute in bold):	
Collaborator(s) who do not access data:	
Lay Summary of Authorised Research:	
Access Period:	**From: signature of contract date To:**
Summary of Licensed Datasets†:	
Applicable Database Specific Terms	*Embed document here, and attach separate document in Docusign.* T&Cs also included as separate document within Docusign envelope.
Data Access Cost Recovery Fee:	£N/A
If Protected Data is to be accessed, please state the legal basis (and special condition if special category personal data is involved) on which the Recipient Institute intends to rely	

Commercial use	☐ The Recipient Institute and Authorised Researcher(s) are permitted to use the Research Database for Commercial Purposes, subject to Clause 9.
International Transfers	☐ The Recipient Institute and Authorised Researcher(s) are based in the UK ☐ The Recipient Institute and Authorised Researcher(s) are based **outside** the UK and: ☐ UK adequacy regulations are in place for the destination country ☐ There are no UK adequacy regulations in place, but this Agreement incorporates the IDTA and a transfer risk assessment has been completed
UoB Principal Investigator:	Andy Boyd
Contract Effective Date:	**Date of signature**
Special Conditions:	

† UK LLC reserves the right to amend the definition of the licensed dataset over the lifetime of the agreement.

INTRODUCTION

(A) The University of Bristol (the "**University**"), has collected and is custodian of certain datasets and collections of Information in the UK LLC Research Database. This is derived from information provided by or obtained Study Participants. It also includes Linked Datasets, collected by third parties**,** which may be used in conjunction with the information collected and/or derived from the Study Participants.

(B) The Authorised Researcher is an employee of or holds an honorary research contract (or equivalent) with the Recipient Institute or is a student registered at the Recipient Institute and is under the supervision of an employee and wishes to use the Information from the Licensed Datasets held in the Research Database. The Licensed Datasets are to be used by the Authorised Researcher for the purposes of the Authorised Research as agreed by the Executive.

(C) The University is willing to provide the Recipient Institute (and through the Recipient Institute, the Authorised Researcher) with access to the Licensed Datasets for the Access Period on the terms and conditions of this Agreement.

The Agreement comprises the details set out above, the Front Sheet, the General Terms and Conditions and associated Schedules set out over the page.

Please note that these terms and conditions are non-negotiable.

Signed for and on behalf of the University of Bristol by a duly authorised person		**Signed for and on behalf of the Recipient Institute by a duly authorised person**	
Print name		**Print name**	
Date		**Date**	
		Signed by the Main Applicant at the Recipient Institute	
		Print name	
		Date	

Contents

Item		Page
1	DEFINITIONS	5
2	GRANT OF LICENCE	7
3	RESERVATION OF RIGHTS	7
4	LICENCE RESTRICTIONS	7
5	INTELLECTUAL PROPERTY RIGHTS AND RESULTS	8
6	AUTHORISED RESEARCHER	9
7	AUTHORISED RESEARCH	9
8	RESEARCH DATABASE	10
9	COMMERCIAL USE	10
10	INTERNATIONAL USERS	10
11	SECURITY AND CUSTODIANSHIP	10
12	DATA PROTECTION	10
13	FREEDOM OF INFORMATION ACT REQUESTS	11
14	COMPLAINTS BY DATA SUBJECTS	11
15	NOTIFICATION	11
16	PUBLICATION	11
17	AUDIT	12
18	CONFIDENTIALITY	12
19	DISCLAIMER	13
20	LIMITATION OF LIABILITY AND INDEMNITY	13
21	TERMINATION	14
22	CONSEQUENCES OF TERMINATION	14
23	PUBLICATIONS AND ACKNOWLEDGMENT	15
24	GENERAL PROVISIONS	15
SCHEDULE 1 – TYPES OF DATA		17
SCHEDULE 2 – INFORMATION SECURITY CONTROLS		19
SCHEDULE 3 – LICENSED DATASETS		21
SCHEDULE 4 – AUTHORISED RESEARCH		22
SCHEDULE 5 – IDTA		23

GENERAL TERMS AND CONDITIONS

These General Terms and Conditions form part of the Data Access Agreement between the University and the Recipient Institute (the "**Agreement**"). They shall be read in conjunction with and shall incorporate the information set out in the Agreement Summary on the front sheet to this document including but not limited to any Special Conditions (the "**Front Sheet**").

Subject to any Special Conditions agreed between the Parties as set out in the Front Sheet, the parties agree as follows:

1 DEFINITIONS

The following terms shall have the meaning shown against them where they are used in the Agreement:

Applicable Law	All laws, regulations, orders, guidance (including codes of practice and guidance issued by the Information Commissioner), directions or determinations that are applicable to the obligations of the Recipient under this Agreement including but not limited to the Data Protection Legislation, as amended or re-enacted from time to time.
Authorised Research	The research summarised in the Front Sheet and defined in Schedule 4.
Authorised Researcher(s)	The individual(s) named as authorized researcher(s) at the Recipient Institute on the Front Sheet.
Collaborator(s)	The co-applicants and the data users identified in the Front Sheet as updated from time to time by agreement with the University.
Commercial Purposes	Means the commercial use, including profit making activities, of the Information contained within the Research Database, as it is defined, and to the extent that it is permitted, in the Database Specific Terms which relate to each piece of Information accessed.
Data Controller	Shall have the meaning set out in Data Protection Legislation.
Database Specific Terms	Means the terms and conditions which apply to each individual Licensed Dataset, as set out on the Front Sheet.
Data Protection Legislation	Means any data protection legislation in force from time to time in the UK, including the Data Protection Act 2018, the UK GDPR, Regulation (EU) 2016/679 known as the General Data Protection Regulation (to the extent that it applies) and any successor legislation, together with all guidance and codes of practice issued or adopted by a regulator (or group of regulators) with jurisdiction over the data sharing arrangements contemplated in this Agreement, as amended from time to time.
Data Security and Protection Toolkit	The annual self-assessment toolkit provided by the NHS to ensure data security.
Effective Date	The date on which the Agreement shall come into force as set out in the Front Sheet.
Executive	The UK LLC Management Group.
Good Industry Practice	Means the degree of skill, care, prudence, foresight and operating practice which would reasonable and ordinarily be expected from time to time of a skilled and experienced person engaged in the same or similar type of

	undertaking or carrying out the same or similar activities as the Recipient Institute or Authorised Researcher.
IDTA	Means the version of the International Data Transfer Agreement issued by the Information Commissioner's Office under s119A(1) of the Data Protection Act 2018 which is in force at the time of the Contract Effective Date and which, where relevant, is appended at Schedule 5.
Information	One or more individual pieces of information or contained within the Research Database.
Intellectual Property Rights	The patents, rights to inventions, copyright and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up, goodwill and the right to sue for passing off, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.
Licensed Dataset(s)	The Information summarised in the Front Sheet and defined in Schedule 3 for which access is to be granted as may be updated from time to time by agreement between the University and the Authorised Researcher or which may be varied by the University from time to time on notice in writing to the Recipient Institute.
Linked Dataset(s)	The datasets which contain Linked Data (as defined in Schedule 1).
Longitudinal Study Dataset(s)	The datasets which contain Longitudinal Study Data (as defined in Schedule 1).
Longitudinal Population Studies	The various longitudinal population studies whose data has fed in to the Longitudinal Study Datasets.
Party / Parties	Either or both of the University and the Recipient Institute.
UK LLC	The UK Longitudinal Linkage Collaboration.
UK LLC Data Access & Acceptable Use Policy	The UK LLC Data Access & Acceptable Use Policy that describes the proposal process in detail including any costs associated with conducting research at UK LLC, which may be updated from time to time and is available at: Apply | UK Longitudinal Linkage Collaboration (ukllc.ac.uk)
Recipient Institute(s)	The organisation(s) referred to in the Front Sheet.
Research Database	The database which contains the Source Data.
Restricted Transfer	Means the disclosure, grant of access or other transfer of Personal Data to any person located in any country or territory outside the UK.
Source Data	The data contained within the UK LLC, as described in Schedule 1.
Source Data Owner	The owner of the Source Data, as detailed in the Database Specific Terms and the definitions in Schedule 1.
Special Conditions	Any special conditions set out in the Front Sheet.
Study Participants	The participants in the contributing Longitudinal Population Studies.

Trusted Research Environment	The secure research system used by the Research Database to host and curate the Information and to establish the working area in which the Longitudinal Study Datasets and Linked Datasets are used by the Collaborator(s) for the Authorised Research.
UK GDPR	Means the UK GDPR as defined in the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019.
UK LLC Data Use Register	Means the register of access to the Research Database held and maintained by UK LLC and found at https://ukllc.ac.uk/data-use-register.

2 GRANT OF LICENCE

2.1 Subject to the terms of this Agreement, the University grants the Recipient Institute (and through the Recipient Institute, the Authorised Researcher) a non-exclusive, non-transferable, revocable licence from the Effective Date and during the Access Period to access (and in some instances hold, store, and make copies of), view, combine or aggregate (wholly or in part) and adapt the Information, as defined in the Authorised Research application, solely for the purposes of the Authorised Research.

3 RESERVATION OF RIGHTS

3.1 All intellectual property rights throughout the world, whether existing now or in the future and whether registered or unregistered, subsisting in the Longitudinal Study Datasets and Linked Datasets (including copyright and related rights, database rights and *sui generis* database rights) shall remain the property of the University or, in the case of Linked Data, to the Source Data Owner, and neither the Recipient Institute nor the Authorised Researcher shall have any rights in or to the Longitudinal Study Datasets and Linked Datasets other than in accordance with this Agreement.

4 LICENCE RESTRICTIONS

4.1 The Recipient Institute shall:

4.1.1 only use the Licensed Datasets for the purposes of carrying out the Authorised Research as described in Schedule 4 and in accordance with this Agreement (including any Special Conditions set out in the Front Sheet) and all Applicable Law;

4.1.2 only make copies of the Licensed Datasets within the Trusted Research Environment to the extent necessary to undertake the Authorised Research and for back-up and disaster recovery purposes;

4.1.3 not permit any third party other than the Authorised Researcher and bona fide members of the Authorised Researcher's research team who are included in the project proposal, to have access to the Research Database or the Trusted Research Environment;

4.1.4 to ensure that each user connects to the Trusted Research Environment using their specific user account and that the Authorised Researcher and collaborators will keep their account details secret;

4.1.5 not attempt to link the Licensed Datasets (wholly or partly) with any other data held by or available to the Authorised Researcher, different Recipients or by the Recipient Institute for other projects, unless specified and agreed in the initial data request;

4.1.6 not attempt to identify any Study Participant from the Licensed Datasets, or use or manipulate the Source Data in any way that re-identifies any Study Participant;

4.1.7 not disseminate, distribute, extract, exploit or otherwise use the Licensed Datasets (wholly or in part) for any commercial purposes or for any purpose that is subject to consulting or

licensing obligations to third parties, unless authorised to do so on the Front Sheet and in accordance with clause 9;

4.1.8 comply with the UK LLC Data Access & Acceptable Use Policy;

4.1.9 hold the data securely in accordance with clause 11, and where inadvertent disclosure has taken place to notify the Executive as soon as is practicable and in reasonable detail as to how this occurred and not attempt to contact the Study Participants (unless contact has been approved as part of the Authorised Research); and

4.1.10 not attempt to remove or copy any Information from the Trusted Research Environment or to permit anyone else to have access to the Research Database unless this is expressly permitted under the terms of this Agreement.

5 INTELLECTUAL PROPERTY RIGHTS AND RESULTS

5.1 The definitions of Source Data, Longitudinal Study Data, Linked Data, Derived Data, Meta Data, Synthetic Data, Manipulated Data, and Researcher Analyses shall have the meaning given to such terms in Schedule 1.

5.2 **Source Data forming the Licensed Dataset**

5.2.1 Source Data is comprised of Longitudinal Study Data, Linked Data, Synthetic Data and Derived Data along with any relevant Meta Data relating to the Source Data. The Licensed Dataset may contain any combination of the above. The University manages the rights to, or owns itself, all rights in the Source Data.

5.2.2 The Recipient Institute is hereby granted a non-exclusive, revocable, non-transferable, license to use the Source Data within the Licensed Dataset for research, teaching and other non-commercial purposes as approved by the University under this Agreement until the end of the Authorised Research project so long as the University maintains a relevant data sharing agreement with any third party data owner, and retains the rights to sub-licence the Source Data.

5.2.3 Where the Licensed Dataset contains Source Data from NHS England, the licence shall only be valid for use within the UK.

5.3 **Use of Licensed Datasets and creation of Derived Data and Manipulated Data**

5.3.1 Where the Recipient Institute uses a Licensed Dataset to produce Derived Data or Manipulated Data the following shall apply:

(a) **Derived Data**

(i) Ownership of Derived Data will remain with the University, who manage the rights over the Source Data used to create the Derived Data.

(ii) The Derived Data, with their explanatory documentation, must be returned to UK LLC to feed back into the resource and become part of the Source Data.

(iii) The University grants to the Recipient Institute non-exclusive, revocable, non-transferable licence to use the Derived Data for research, teaching and other non-commercial purposes as approved by the University under this Agreement, until the end of the Authorised Research project or expiry of relevant Data Sharing Agreement if using Linked Data.

(b) **Syntax and methodology associated with the Derived Data.** Ownership of any syntax and methodology associated with the Derived Data shall remain with the

creator, and, where necessary, the Recipient Institute shall grant an irrevocable, perpetual, transferable, sub-licensable royalty-free license to use the syntax and methodology used in creating the Derived Data for research, teaching and other non-commercial purposes.

(c) **Manipulated Data.** Ownership of Manipulated Data and any associated syntax and methodologies shall revert back to the Source Data Owner, but the Recipient Institute shall be granted a non-exclusive, revocable, non-transferable license to use the Manipulated Data and any associated syntax and methodology research for the Authorised Research, until the end of the Authorised Research project.

5.4 **Research Results**

5.4.1 Researcher Analyses shall be owned by the Recipient Institute, but where required, the Recipient Institute will share aspects of these (including Code Lists used, Cohort Definitions and Analysis Syntax) publicly and with other users of the UK LLC.

5.4.2 Analyses and results (if any) derived from access to and use of the Licensed Datasets ("**Recipient Institute Results**") shall be owned by the Recipient Institute. The Recipient Institute grants to University an irrevocable, perpetual, worldwide, sub-licensable to the third parties that permitted the connected data to be included in the Longitudinal Study Datasets and Linked Datasets, transferable, royalty-free license to use all Recipient Institute Results for research, teaching and other non-commercial purpose.

5.5 The Recipient Institute shall provide the University with a complete electronic copy of any Derived Data and Meta Data generated from access to and use of the Licensed Datasets by the Authorised Researcher, the Recipient Institute Results and the syntax used to generate them as soon as possible after and within 6 months of completion of the Authorised Research.

5.6 If access to and use of the Licensed Datasets will not result in any Recipient Institute Results the provisions of clauses 5.4 and 5.5 shall not apply.

6 AUTHORISED RESEARCHER

6.1 The Recipient Institute warrants that the Authorised Researcher(s) is an employee of or holds an honorary research contract with the Recipient Institute or is a student registered at the Recipient Institute and is under the supervision of an employee. If the Authorised Researcher ceases to be an employee of or to hold an honorary research contract with the Recipient Institute during the Access Period, the Recipient Institute shall promptly notify the University in writing. The Recipient Institute shall be responsible for ensuring that the Authorised Researcher is aware of the Recipient Institute's obligations under this agreement and shall at all times remain liable for the acts or omissions of the Authorised Researcher. The Recipient Institute shall ensure that the Authorised Researcher(s) employment contract or honorary contract (as the case may be) includes terms binding them to maintaining data confidentiality. The Recipient Institute shall keep a record of all persons who access the Research Database.

7 AUTHORISED RESEARCH

7.1 The Recipient Institute warrants that appropriate ethical approval has been obtained for the Authorised Research (having regard to the nature of the Authorised Research and applicable law) and that, where the Authorised Research has not been approved by a recognised funder, the Authorised Research will be undertaken with the intention of generating new knowledge and understanding using rigorous scientific methods and with the intention of publishing the research findings in the scientific community for wider scientific and eventual public benefit. Results produced from the Authorised Research by the Recipient Institute using UK LLC data should be published in an 'open access' publication wherever possible and always if funded by Medical Research Council. If the Recipient Institute wishes to test any additional hypotheses which are outside the scope of the Authorised Research, it shall obtain the Executive's prior written consent.

8 RESEARCH DATABASE

8.1 The Research Database contains a number of individual databases, the Longitudinal Study Datasets and Linked Datasets, each of which are governed by their own Database Specific Terms. The Recipient Institute acknowledges and accepts that where in accordance with this Agreement it is granted access to the Research Database it must comply with:

8.1.1 The terms of this Agreement;

8.1.2 The Database Specific Terms which relate to each piece of Information accessed; and

8.1.3 Any Special Conditions, as set out in the Front Sheet.

If the Recipient Institute fails to accept or comply with such restrictions and conditions the University may immediately withdraw the rights of access to the Research Database, including but not limited to Longitudinal Study Datasets, Linked Datasets, Source Data, and the Trusted Research Environment.

9 COMMERCIAL USE

9.1 The Research Database may only be used for Commercial Purposes where permitted on the Front Sheet and by the Database Specific Terms relevant to the Information accessed.

10 INTERNATIONAL USERS

10.1 To the extent that any processing of Protected Data under this Agreement involves a Restricted Transfer:

10.1.1 The necessary consents, as dictated by the Database Specific Terms, must first be in place; and

10.1.2 The Parties agree that the IDTA shall be deemed incorporated by reference into and form part of this Agreement.

11 SECURITY AND CUSTODIANSHIP

11.1.1 The Recipient Institute shallensure that the Licensed Datasets and access to the Trusted Research Environment are managed in a secure manner and shall use all reasonable security practices and systems as set out in Schedule 2 applicable to the use of the Licensed Datasets and Trusted Research Environment to prevent, and take prompt and proper remedial action against, unauthorised access, copying, modification, storage, reproduction, display or distribution of the Source Data.

12 DATA PROTECTION

12.1 If and to the extent that the Licensed Datasets, individually or together with other pieces of Information, are Protected Data, the Recipient Institute shall be the Data Controller of that Protected Data, and warrants that it will:

12.1.1 process the Protected Data only to the extent and in such as manner as is necessary for the purposes of carrying out the Authorised Research and in accordance with all Applicable Law and Good Industry Practice;

12.1.2 comply with the University's instructions for the processing of the Protected Data including any instructions for the anonymisation of the Protected Data or any request by the University to amend, transfer or delete the Protected Data;

12.1.3 not extract the Protected Data to any destination outside the Trusted Research Environment without the University's prior written consent and subject to such further conditions as the University may specify;

12.1.4 not Publish Protected Data without the prior written consent of the Source Data Owner;

12.1.5 take appropriate technical and organisational measures against the unauthorised loss or destruction of, or damage to, the Protected Data to ensure a level of security appropriate to the harm that might result from the same and the nature of the Protected Data to be protected;

12.1.6 maintain a data registration under the Data Security and Protection Toolkit (or equivalent as agreed with the University) as required by the Recipient Institute type;

12.1.7 ensure that an appropriate legal basis for the processing of Protected Data has been identified, and immediately notify the University if the legal basis identified is no longer applicable; and

12.1.8 comply with all other applicable laws, statutes, regulations and codes relating to anti-bribery and anti-corruption including but not limited to the Bribery Act 2010 and not engage in any activity, practice or conduct which would constitute an offence under the Bribery Act 2010 if such activity practice or conduct had been carried out in the UK.

13 FREEDOM OF INFORMATION ACT REQUESTS

13.1 Where a Recipient Institute receives a request for information under the Freedom of Information Act 2000 which concerns any Information derived from the Research Database, it shall take into account the Source Data Owner's views before responding to any request.

14 COMPLAINTS BY DATA SUBJECTS

14.1 If the Recipient Institute receives any complaint, notice or communication which relates directly or indirectly to the processing of the Protected Data or to either Party's compliance with Applicable Law, it shall immediately notify the University's Information Rights Officer (by email to data-protection@bristol.ac.uk) and it shall provide full co-operation and assistance in relation to any such complaint, notice or communication.

15 NOTIFICATION

15.1 If any Protected Data is lost or disclosed or destroyed or becomes damaged, corrupted, or unusable or the Recipient Institute becomes aware of any misuse of Information or of the Licensed Datasets or any security breach that could compromise the security or integrity of the Licensed Datasets, the Recipient Institute shall promptly notify both the Executive (by email to info@ukllc.ac.uk and the University's Information Rights Officer (by email to data-protection@bristol.ac.uk) and, at the Recipient Institute's expense, fully cooperate with the Executive's requests to remedy the issue as soon as reasonably practicable. The Recipient Institute shall also promptly notify the University if it finds any errors in the Research Database.

16 PUBLICATION

16.1 The Recipient Institute acknowledges and agrees that:

16.1.1 The University will publish information into the public domain about applications made under this process, such information to include:

(a) the decisions relating to those applications;

(b) the Recipient Institution name;

(c) A summary of the proposed/Authorised Research; and

(d) Details of the Licenced Datasets accessed.

16.1.2 The University may publish information about onward sharing of any Source Data on the UK LLC Data Use Register. This will include the name of the Recipient Institution, a summary of the proposed/Authorised Research and details of the Longitudinal Study Datasets and/or Linked Datasets accessed.

17 AUDIT

17.1 The Recipient Institute shall keep detailed, accurate and up-to-date records sufficient to enable the University (or its licensors) to verify the Recipient Institute's compliance with the terms of this Agreement. The Recipient Institute shall permit the University and its third-party representatives, on reasonable notice during the Recipient Institute's normal business hours, to have access to and take copies of such records for the purpose of auditing the Recipient Institute's compliance with the terms of this Agreement. Such audit rights shall continue for three years after termination or expiry of this Agreement. Where the Source Data Owner has any additional audit or reporting requirements the Recipient Institute shall comply with such additional requirements at its costs and expense.

18 CONFIDENTIALITY

18.1 The Recipient Institute shall keep the Source Data, including Longitudinal Study Datasets and Linked Datasets, confidential and, in particular, undertakes not to use or disclose any Protected Data in such a manner as to compromise or otherwise infringe the rights of any data subject in relation to such Protected Data. The Recipient Institute hereby undertakes to the University that it shall procure that its employees, agents, students and investigators shall:

18.1.1 keep confidential all Source Data, including Longitudinal Study Datasets, Linked Datasets, and other information of a confidential nature (whether written or oral) concerning this Agreement and the business affairs of the UK LLC and the University that it shall have obtained or received as a result of the discussions leading up to or entering into or performance of this (the "**Confidential Information**");

18.1.2 not without the prior written consent of the University disclose the Source Data, including Longitudinal Study Datasets and Linked Datasets, or the Confidential Information either in whole or in part to any other person save to the Authorised Researcher and Collaborators or its employees, agents and students involved in the implementation or evaluation of the Authorised Research who have a need to know the same for the performance of their duties and who have signed the UK LLC Data User Responsibilities Declaration Form;

18.1.3 prior to preparing results of the Authorised Research for publication and dissemination beyond the Authorised Researcher and Collaborator, the Authorised Researcher and Collaborator will consider risks to the confidentiality of the Study Participants and ensure that the results are transformed and presented in such a way that the risk of the Study Participants identity being disclosed is reduced to the point where the information is anonymous; and

18.1.4 to use the Confidential Information solely in connection with the implementation of the Authorised Research and not otherwise for its own benefit or the benefit of any third party.

18.1.5 The provisions of this Clause 18 shall not apply to the whole or any part of the Confidential Information to the extent that it can be shown by the receiving Party to be:

(a) known to the receiving Party prior to the date of this Agreement and not obtained directly or indirectly from the other Party; or

(b) obtained from a third party who lawfully possesses such Confidential Information which has not been obtained in breach of a duty of confidence owed to any Party by any person; or

(c) in the public domain in the form in which it is possessed by the other Party other than as a result of a breach of a duty of confidence owed to such other Party by any person; or

(d) required to be disclosed by legal process, law or regulatory authority.

18.1.6 The Recipient Institute hereby undertakes to the University to:

(a) make all Authorised Researchers and relevant employees, agents and students aware of the confidentiality of the Confidential Information and provisions of this Clause 18 and Schedule 2 and without limiting the foregoing to ensure compliance by such employees, agents and students with the provisions of this Clause 18; and

(b) ensure that all Authorised Researchers and relevant employees, agents and students processing Information from the Research Database are suitably trained and made aware of their responsibilities in handling Information, particularly where Information is Protected Data.

19 DISCLAIMER

19.1 The University expressly does not guarantee, represent or warrant that:

19.1.1 the Source Data is accurate, complete, reliable or secure;

19.1.2 the Source Data is of satisfactory quality or fit for any particular purpose or capable of being used in connection with the Authorised Research; or

19.1.3 use of the Licensed Datasets will be free from infringement of third-party intellectual property rights, and other third-party property rights. The Recipient Institute shall therefore be responsible for any claims arising out of or in connection with the Recipient Institute's use of the Licensed Dataset except to the extent that such claims have arisen out of or in connection with any negligence or wilful default of the University.

19.2 Except as expressly stated in this Agreement, all warranties, conditions and terms, whether express or implied by statute, common law or otherwise are hereby excluded to the extent permitted by law.

20 LIMITATION OF LIABILITY AND INDEMNITY

20.1 The University does not exclude or limit its liability to the Recipient Institute for death or personal injury arising from its negligence or for any other matter in respect of which it would be unlawful for the University to exclude or limit its liability.

20.2 Subject to Clauses 20.1 and 20.4, the University's total aggregate liability in contract, tort (including negligence and breach of statutory duty howsoever arising), misrepresentation (whether innocent or negligent), restitution or otherwise, arising in connection with this Agreement shall in all circumstances be limited to £1,000 (one thousand pounds).

20.3 Subject to Clauses 20.1 and 20.4, the Recipient Institution's total aggregate liability in contract, tort (including negligence and breach of statutory duty howsoever arising), misrepresentation (whether innocent or negligent), restitution or otherwise, arising in connection with this Agreement shall in all circumstances be limited to £1,000 (one thousand pounds).

20.4 Where the breach of this Agreement is also a breach of Data Protection Law, the limit on liability of the Party in breach shall be £500,000.

20.5 Subject to the limits set out in Clauses 20.2, 20.3 and 20.4 above, the University shall indemnify the Recipient Institute for any breach of Applicable Laws by the University which renders the Recipient Institute liable for any costs, fines, claims or expenses, howsoever arising. The Recipient Institute shall also indemnity the University for any breach of Applicable Laws by the Recipient Institute which renders the University liable for any costs, fines, claims or expenses, howsoever arising.

21 TERMINATION

21.1 This Agreement and the licence granted to the Recipient Institute under this Agreement shall terminate automatically upon expiry of the Access Period subject to earlier termination by:

21.1.1 the Recipient Institute to the University at any time in writing;

21.1.2 the University in the event that the Authorised Researcher ceases to be an employee of or under an honorary research contract (or the equivalent) with the Recipient Institute and the Recipient Institute is unable to procure a replacement acceptable to the Executive;

21.1.3 the University in the event that any Study Participant withdraws consents to the use of their Protected Data (though the University may ask the Recipient Institute to delete any relevant records without terminating this Agreement at its discretion);

21.1.4 the University in the event that the Recipient Institute commits a material breach of any term of this Agreement which, if capable of remedy, has not been remedied within a period of thirty days after being notified by the University in writing to do so;

21.1.5 the University if the Recipient Institute does anything that may cause damage to the University's reputation;

21.1.6 the University if the Recipient Institute:

(a) is deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986;

(b) is the subject of a petition filed, notice given, resolution passed or order made for or in connection with its winding up (other than for the purpose of a solvent amalgamation or reconstruction of that Party);

(c) is the subject of an application or order made for the appointment of an administrator or if a notice of intention to appoint an administrator is given or an administrator is appointed in respect of that Party; or

(d) suspends or ceases, or threatens to suspend or cease, carrying on all or a substantial part of its operations.

21.1.7 the University if the licence agreement between the University and any third party ceases.

21.1.8 The University if the agreement between the University and the provider of the Trusted Research Environment infrastructure ceases.

22 CONSEQUENCES OF TERMINATION

22.1 On termination of this Agreement for any reason, the Recipient Institute shall promptly and securely destroy or erase (together with all hard and soft copies of the same and as directed in writing by the University) the Source Data and all other data or information provided by the University in connection with this Agreement and in any event within 28 days of the date of termination or expiry of this Agreement. Where Database Specific Terms prescribe a deadline for destruction shorter than 28 days, that shorter deadline shall apply. Termination or expiry of this Agreement shall not affect any rights, remedies, obligations or liabilities of the parties that have accrued up to the date of termination or

expiry, including the right to claim damages in respect of any breach of the Agreement which existed at or before the date of termination or expiry.

23 PUBLICATIONS AND ACKNOWLEDGMENT

23.1 The Recipient Institute will provide any potential publications to the Executive at least one (1) month prior to submission of the publication accordance with the UK LLC Data Access & Acceptable Use Policy. The Recipient Institute will acknowledge the UK LLC in all publications and presentations arising from the Authorised Research in the form specified by the UK LLC Data Access & Acceptable Use Policy and in any data distribution notes, metadata or publication checklist provided by the University and shall include reference to those individuals identified by the Executive as having played a key scientific role in the generation of the Longitudinal Study Datasets.

23.2 For clarity publication may not include the Longitudinal Study Datasets or Linked Datasets:

23.2.1 without prior approval of the Executive, and

23.2.2 without acknowledgement of UK LLC.

24 GENERAL PROVISIONS

24.1 **Interpretation**: The following rules shall apply to the interpretation of this Agreement:

24.1.1 the Special Conditions (as set out in the Front Sheet) form part of this Agreement, however in the event of any ambiguity or inconsistency between the terms and conditions of this Agreement and the Special Conditions, the terms and conditions of this Agreement shall prevail;

24.1.2 unless the context otherwise requires, words in the singular include the plural and vice versa;

24.1.3 a reference to a statute or statutory provision is a reference to it as amended, extended or re-enacted from time to time and shall include all subordinate legislation made from time to time under that statute or statutory provision;

24.1.4 any words following the terms include or including or similar shall be illustrative and not limit the sense of the words preceding those terms;

24.1.5 a reference to writing or written includes e-mail but not fax.

24.2 **Notices**: Any notice given to a Party under or in connection with this Agreement shall be in writing and shall be delivered by hand or by pre-paid first-class post or other next working day delivery service to the addresses specified at the beginning of this Agreement or to such other addresses as the Parties shall notify to the other in writing. Any notice shall be deemed to have been received, if delivered by hand, on signature of a delivery receipt or, if sent by pre-paid first-class post or other next working day delivery service, at 9.00 am on the second working day after posting or at the time recorded by the delivery service. This clause does not apply to the service of any proceedings or other documents in any legal action.

24.3 **Entire agreement**: This Agreement, including the Front Sheet, Schedules and any Annexes (which are incorporated into and made a part of this Agreement) constitutes the entire agreement between the relevant Parties and supersedes all previous discussions, correspondence, negotiations, arrangements, understandings and agreements between them relating to its subject matter. Each Party acknowledges that in entering into this Agreement it does not rely on, and shall have no remedies in respect of, any representation or warranty (whether made innocently or negligently) that is not set out in this Agreement.

24.4 **Assignment and other dealings**: This Agreement is personal to the Recipient Institute and it shall not assign, transfer or otherwise deal in any other manner with any of its rights and obligations under this Agreement without the prior written consent of the University. The University may at any time assign, transfer or otherwise deal in any other manner with any of its rights and obligations under this Agreement without the prior written consent of the Recipient Institute.

24.5 **Variation**: No variation of this Agreement shall be effective unless made in writing and signed by authorised signatories of the relevant Parties. The Recipient Institute expressly confirms and agrees that the Authorised Researcher(s) is/are authorised to agree a variation to the Licensed Datasets from time to time via the UK LLC approved mechanism - such mechanism to be notified when available.

24.6 **Waiver**: No failure or delay by a Party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict the further exercise of that or any other right or remedy. No single or partial exercise of any right or remedy shall preclude or restrict the further exercise of that or any other right or remedy.

24.7 **No partnership or agency**: Nothing in this Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between any of the Parties, constitute any Party the agent of another Party, or authorise any Party to make or enter into any commitments for or on behalf of any other Party.

24.8 **Third party rights**: A person who is not a Party to this Agreement shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any of its terms. This does not affect any right or remedy of a third party which exists or is available apart from that Act.

24.9 **Governing law and jurisdiction**: This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales and each Party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle the same.

SCHEDULE 1 – TYPES OF DATA

The Research Database consists of data from a number of sources, as outlined below. At the date of this Agreement, the intention is that Authorised Researchers will be able to use the source data to create anonymous outputs, for the purpose of the Authorised Research.

1 Source Data

The Source Data comprises Longitudinal Study Data, Linked Data, Synthetic Data and Derived Data along with any relevant Meta Data.

Longitudinal Study Data: means data collected by the contributing longitudinal population studies that have been collected directly from, or about, Study Participants whose de-identified data have been deposited in the UK LLC Trusted Research Environment by the contributing study. These data are frequently collected under licence to the original rights owner. UK LLC use these data under licence. Neither the Recipient Institute nor the Researcher gain ownership of these data and will need to comply with any specific requirements or conditions imposed by the original owner of the data.

Linked Data: means data collected by external third parties that are linked to Study Participants in the UK LLC Trusted Research Environment through record linkage using their personal identifiers or other attributes (such as residential address). These data are frequently collected under licence to the original rights owner. UK LLC use these data under licence. Neither the Recipient Institute nor the Researcher gain ownership of these data and will need to comply with any specific requirements or conditions imposed by the original owner of the data. Arrangements to link data from Linked Datasets to Study Participants are typically conducted by the UK LLC on behalf of the contributing Longitudinal Population Study(ies) and will be subject to any licence conditions imposed by the Source Data Owner of the Linked Datasets.

Synthetic Data: means data that are representations of the Source Data that are artificially generated rather than relating to real individuals. Synthetic data are typically created using statistical techniques so that while the data are not 'real' they may retain a similar underlying structure and distribution as the real Resource Data. The University retains ownership of the Synthetic Data and for the avoidance of confusion or mistakes, the distribution and handling of synthetic data must still use rigorous and secure processes.

Derived Data: means individual-level data generated from analyses or functional combinations of the UK LLC Source Data. An example of a Derived Data variable includes Body Mass Index (BMI), being a function of height and weight. UK LLC manages the ownership rights of the Source Data of these Derived Data when fed back into the UK LLC by researchers.

Meta Data: means information which describes the Longitudinal Study Data, Linked Data and/or Derived Data, and the way in which the data were generated. Meta Data include variable names and labels, data collection protocols, information about the tools and techniques used to collect the data, the staff involved, the time and place of data collection, details of quality control and error – i.e. the 'provenance' of the data which allow future researchers to understand and accurately use these data in a secondary context. The contributing studies and external third parties will provide Meta-Data to support Authorised Users and prospective users and the public. Neither the Recipient Institute nor the Authorised Researcher gain ownership of these meta-data and will need to comply with any specific requirements or conditions imposed by the original owner of the meta-data. The UK LLC will generate additional meta-data when processing Longitudinal Study Data and Linked Data and will make these accessible in a clear and understandable format.

2 Outputs from the research process

The following category is typically individual-level data which is identified by an UK LLC generated case ID number.

Derived Data: is as defined above, but where it is created by the Authorised Researcher or Recipient Institute, and the resulting Derived Data cannot be identified as originally from any Linked Data, ownership will remain with the Recipient Institute subject to the provisions of clause 4 above.

An example of a Derived Data variable includes Body Mass Index (BMI), being a function of height and weight. UK LLC retains ownership of these Derived Data and these data, with their explanatory documentation, must be returned to UK LLC to feed back into the resource and become part of the Resource Data. Researchers are only permitted to keep the Derived Data until the end of their Authorised Research project. The syntax or methodology documentation used to create the Derived Data will be provided by the UK LLC, and is the property of the UK LLC.

If the Derived Data comes from Linked Data that was sourced from NHS England, then NHS England retain the right to finally determine whether Derived Data is Derived Data or Manipulated Data.

Manipulated Data: means any information created by the Recipient Institute using Source Data, where the results can be identified as originally from the Source Data Owner.

The following categories must be transformed to the point where they are anonymous and typically at an aggregate level (e.g. tables of results) before extraction from the Trusted Research Environment. All published outputs must be assessed for disclosure risk and transformed to control for identified risks by UK LLC staff or their agents prior to being permitted to leave the Trusted Research Environment.

Researcher Analyses: means methodologies, applications and mathematical devices used by Researchers, such as power calculations, algorithms and statistical correlations. Researcher Analysis do not include any Source Data, Derived Data, or Researcher Results. Researcher Analyses are the property of the Researcher, although UK LLC require Researchers to share aspects of these (including Code Lists used, Cohort Definitions and Analysis Syntax) publicly and with other users of the resource.

Researcher Results: means respectively the qualitative conclusions of the Researcher and the anonymised outcomes of the quantitative Researcher Analyses which underpin those conclusions. These are the information which are typically published and disseminated in standard academic methods. These are the property of the Researcher; although the University retains and may exercise the right to evaluate publications prior to submission and to request changes if the Researcher Results are considered possibly to risk Study Participant confidentiality or to risk bringing the Research Database and/or the University into disrepute.

SCHEDULE 2 – INFORMATION SECURITY CONTROLS

This Schedule sets out the information security and governance requirements applicable to access to and processing of the Information under this Agreement. These requirements are intended to ensure that appropriate technical and organisational measures are implemented and maintained to protect the confidentiality, integrity and availability of the Information. Where obligations are stated as applying to the Recipient Institute (Section A), they shall be satisfied by the organisation as a whole. Where obligations are stated as applying to Authorised Researchers (Section B), they shall apply individually to each person granted access to the UK LLC Trusted Research Environment. The Recipient Institute remains responsible for ensuring that all Authorised Researchers comply with the requirements applicable to them under this Schedule, and compliance with this Schedule is without prejudice to the Recipient Institute's other obligations under this Agreement or applicable law. For the avoidance of doubt, references in this Schedule to access, retention, destruction or security of the Information are to be interpreted as applying within the UK LLC Trusted Research Environment and do not authorise the local storage or processing of the Information outside it.

Section A – Organisational Requirements

These clauses apply to the Recipient Institute (e.g. university, NHS body, company).

A1. Governance and Accountability

The Recipient Institute shall establish, maintain and comply with appropriate data protection and information security governance arrangements, including the nomination of an individual with responsibility and accountability for compliance with applicable data protection law and information security requirements.

A2. Policies and Procedures

The Recipient Institute shall maintain up to date data protection and information security policies and procedures appropriate to the nature of the Information and the risks associated with its processing, and shall ensure that such policies are communicated to, and complied with by, all Authorised Researchers.

A3. Security Assurance

Where the Recipient Institute is required to complete the Data Security and Protection Toolkit , it shall maintain a current Data Security and Protection Toolkit submission with an outcome of "Standards Met" or equivalent. Where the Recipient Institute is not within scope of the Data Security and Protection Toolkit, it shall maintain certification to ISO/IEC 27001 or demonstrate equivalent information security assurance acceptable to the University. For the avoidance of doubt, compliance with any assurance framework does not remove or diminish the Recipient Institute's obligation to comply with the requirements set out in this Schedule.

A4. Access Management

The Recipient Institute shall implement and maintain role based access controls and documented joiner, mover and leaver processes to ensure that access to the Information is granted only to Authorised Researchers and is promptly revoked when no longer required.

A5. Technical Security Controls

The Recipient Institute shall implement appropriate technical and organisational measures to protect the confidentiality, integrity and availability of the Information, including secure system configuration, encryption, backup arrangements and security monitoring proportionate to the risks involved.

A6. Training and Vetting

The Recipient Institute shall ensure that all Authorised Researchers are appropriately vetted and have completed suitable data protection and information security training prior to being granted access to the Information and on a regular ongoing basis thereafter.

A7. Incident Management and Notification

The Recipient Institute shall maintain incident management procedures and shall notify the University without undue delay of any actual or suspected security incident, breach, or material risk affecting the Information, in accordance with the requirements of this Agreement.

A8. Retention and Destruction

The Recipient Institute shall ensure that the Information is retained only for as long as necessary for the purposes set out in this Agreement and is securely destroyed or irreversibly deleted when no longer required, in accordance with applicable law, guidance and organisational policies.

Section B – Authorised Researcher Requirements

These clauses apply personally and directly to each Authorised Researcher.

B1. Secure Access and Environment

Authorised Researchers shall access the Information only from secure, approved locations and via secure electronic networks. Access must not take place from public or unsecured networks, or in environments where the Information may be visible to anyone who is not an Authorised Researcher.

B2. Authentication and Credentials

Authorised Researchers shall use only their own authorised credentials to access the Information, shall comply with password and authentication requirements (including multi factor authentication where required), and shall not share login details with any other person.

B3. Device Security

Authorised Researchers shall access the Information only using devices that meet applicable organisational, UK LLC and NHS England security requirements, including encryption, up to date software, and the use of appropriate technical and organisational measures.

B4. Acceptable Use

Authorised Researchers shall access and use the Information only for the purposes approved under this Agreement and shall not misuse, copy, disclose, attempt to extract, or otherwise process the Data in any unauthorised manner, nor take any action that could compromise the security, integrity or availability of the Information or systems.

B5. Confidentiality and Incident Reporting

Authorised Researchers shall maintain the confidentiality of the Information at all times and shall immediately report any actual or suspected security incident, loss, misuse or unauthorised disclosure of the Information to the Recipient organisation in accordance with its incident management procedures.

SCHEDULE 3 – LICENSED DATASETS

[Insert embedded spreadsheet of licenced datasets]

SCHEDULE 4 – AUTHORISED RESEARCH

[Insert embedded research application]

SCHEDULE 5 – IDTA

[to be inserted where relevant]