# ALSPAC DATA ACCESS AGREEMENT

## Agreement Summary: Principal Investigator

<table>
<thead>
<tr>
<th>ALSPAC Reference (B Number):</th>
<th>B</th>
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<tbody>
<tr>
<td>Project Title:</td>
<td></td>
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<tr>
<td>Principal Investigator:</td>
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<tr>
<td>Recipient Institute:</td>
<td></td>
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<tr>
<td>Recipient Investigator(s) at PI Institution:</td>
<td>* List all individuals at your institution (name, job title) who will access the data</td>
</tr>
<tr>
<td>Collaborator(s) who do not receive data:</td>
<td>* List all individuals collaborating in this project who will not receive or have access to the individual-level ALSPAC data.</td>
</tr>
<tr>
<td>Lay Summary of Authorised Research (from the proposal form):</td>
<td>* Copy lay summary from ALSPAC proposal form into this field.</td>
</tr>
<tr>
<td>Access Period: The Access Period is from the date that this agreement is effective (when the last person to sign has signed) until the date specified on the proposal or amendment in Schedule 3.</td>
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<tr>
<td>Summary Licensed Datasets†:</td>
<td>* ALSPAC to summarise the sources used to compile the Licensed Datasets. E.g. mother completed questionnaires, child clinical assessment data and linked child education records. Note: if access to and use of the licensed datasets will not generate any output of meaningful value to ALSPAC directly (i.e. in addition to publicly available or published results) then provisions within clause 4 of the General Terms and Conditions on results shall not apply.</td>
</tr>
<tr>
<td>Linked Datasets:</td>
<td>* ALSPAC to summarise if linked records used. E.g. linked child education records.</td>
</tr>
<tr>
<td>Data provision mechanism:</td>
<td>* Provide details of how the Licensed Datasets will be made available to the Recipient Researchers. E.g. direct file transfer, via Secure eResearch Platform.</td>
</tr>
<tr>
<td>Data Access Cost Recovery Fee:</td>
<td>£</td>
</tr>
<tr>
<td>Recipient Institute’s Legal Contact(s):</td>
<td>*Please include the name and contact details of your institution’s legal contact(s)</td>
</tr>
<tr>
<td>Recipient Institute’s Data Protection / Information</td>
<td>*Please include the name and contact details of your institution’s Data Protection and Information Security (or equivalent) contact(s)</td>
</tr>
<tr>
<td>Security (or equivalent) Contact(s)</td>
<td><em>For institutes outside of the UK and EEA who must adhere to the Standard Contractual Clauses in schedule 5, please indicate your chosen option for processing personal data: clause II (h) (i) or (ii)</em></td>
</tr>
<tr>
<td>Institutes outside of the UK and EEA only - Obligations of the data importer:</td>
<td></td>
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<tr>
<td>ALSPAC Data Buddy (name and email):</td>
<td></td>
</tr>
<tr>
<td>Special Conditions:</td>
<td>* ALSPAC to set out here any additional conditions that are necessary to address the transfer of data to certain countries or platforms or where these are necessary to comply with the requirements of the owner of any Linked Datasets</td>
</tr>
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</table>

† ALSPAC reserve the right to amend the definition of the licensed dataset over the lifetime of the agreement.
**Introduction**

(A) The University of Bristol (the “**University**”), through the Avon Longitudinal Study of Parents and Children (the “**Study**”), has collected and is custodian of certain datasets and collections of interpretable data (“**Information**”). This is derived from information provided by or obtained from participants in the Study (“**Study Participants**”). It is also includes datasets collected by third parties (the “**Linked Datasets**”) which may be used in conjunction with the Information collected and/or derived from the Study Participants.

(B) The Recipient Investigator 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 Licensed Datasets comprised in the Information held by the Study. The Licensed Datasets are to be used by the Recipient Investigator 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 Recipient Investigator) 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 and the General Terms and Conditions set out over the page. **Please note that these terms and conditions are non-negotiable.**

<table>
<thead>
<tr>
<th>Signed for and on behalf of the University of Bristol by a duly authorised person</th>
<th>Signed for and on behalf of the Recipient Institute by a duly authorised person</th>
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<td>Print name</td>
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<td>Date</td>
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Signed by the Principal Investigator

<table>
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<tr>
<th>Print name</th>
<th>Date</th>
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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 front sheet to this document including but not limited to any Special Conditions (the “Front Sheet”).

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

**Effective Date**
The date on which the agreement shall come into force as set out in the Front Sheet (under Access Period)

**Licensed Datasets**
The controlled dataset(s) 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 Recipient Investigator or which may be varied by the University from time to time on notice in writing to the Recipient Institute.

**Linked Datasets**
Those datasets summarised in the Front Sheet and defined in Schedule 3 that are collected by third parties and made available to the University under license as may be updated from time to time by agreement between the University and the Recipient Investigator.

**Authorised Research**
The research summarised in the Front Sheet and defined in Schedule 4.

**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.

**Collaborator Institute(s)**
The organisation(s) referred to in the Front Sheet.

**ALSPAC Access Policy**
The ALSPAC access policy that describes the proposal process in detail including any costs associated with conducting research at ALSPAC, which may be updated from time to time and is available at: [http://www.bristol.ac.uk/media-library/sites/alspac/documents/researchers/data-access/ALSPAC_Access_Policy.pdf](http://www.bristol.ac.uk/media-library/sites/alspac/documents/researchers/data-access/ALSPAC_Access_Policy.pdf)

**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.

**Data Protection Legislation**
For the purposes of this Agreement, “Data Protection Legislation” means the UK Data Protection Legislation and the UK General Data Protection Regulations ([Retained EU Legislation]) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)) and any other directly applicable European Union regulation related to data protection, where “UK Data Protection Legislation” means any data protection legislation in force from time to time in the UK including the Data Protection Act 1998 or 2018 or any successor legislation.
**Data Access Fee**
The fees payable by the Recipient Institute for access to the data, the details of which appear in the Front Sheet.

**Host Platform**
The platform identified in the Front Sheet where the Licensed Datasets are hosted or any replacement platform adopted by the University the details of which will be notified to the Research Institute.

**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.

**Executive**
The ALSPAC Executive.

**Special Conditions**
Any special conditions set out in the Front Sheet.

**Study**
The Avon Longitudinal Study of Parents and Children.

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

1. **Grant of licence**: Subject to the terms of this agreement, in consideration of the payment of the Data Access Fee, the University grants the Recipient Institute (and through the Recipient Institute, the Recipient Investigator) 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 Licensed Datasets, as defined in the Authorised Research Application, solely for the purposes of the Authorised Research.

2. **Reservation of rights**: All intellectual property rights throughout the world, whether existing now or in the future and whether registered or unregistered, subsisting in the Licensed 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 third parties that contributed the Linked Data, and neither the Recipient Institute nor the Recipient Investigator shall have any rights in or to the Licensed Datasets other than in accordance with this agreement.

3. **Licence restrictions**: The Recipient Institute shall:

   (a) 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;
   (b) only make copies of the Licensed Datasets to the extent necessary to undertake the Authorised Research and for back-up and disaster recovery purposes;
   (c) not permit any third party other than the Recipient Investigator and bona fide members of the Recipient Investigator’s research team who are included in the project proposal with ALSPAC, to have access to the Licensed Datasets;
(d) not attempt to link the Licensed Datasets (wholly or partly) with any other data held by or available to the Recipient Investigator, different Recipients or by the Recipient Institute for other projects, unless specified and agreed in the initial data request;
(e) 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;
(f) comply with the ALSPAC Access Policy;
(g) request permission from the University (via ALSPAC) in advance if any Licensed Datasets are to be transferred across any country’s border, or if the Data is to be accessed from outside the UK. The Recipient Institute shall comply with any additional obligations to be imposed by the University to ensure compliance with Applicable Laws in such circumstances. This will include the European Commission approved standard contractual clauses set out at Schedule 5 which cover international transfers of personal data;
(h) hold the data securely in accordance with clause 8, and not attempt to try and identify any Study Participants from the Licensed Datasets, and where inadvertent disclosure has taken place to notify the Executive as soon as is practicable and notify the Executive 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 agreed research project);
(i) not attempt to remove any Data from the Host Platform or to permit anyone else to have access to the Data unless this is expressly permitted under the terms of this agreement; and
(j) provide confirmation to the Executive of destruction of the Licensed Dataset if such destruction is requested by the Executive. Confirmation must be provided in written form and can be submitted to alspac-exec@bristol.ac.uk within twenty-eight (28) days of request.

4. Intellectual Property Rights and Results:

The definitions of Raw Data, Resource Data, Derived Data, Meta Data, Synthetic Data, Researcher Analyses and Researcher Results shall have the meaning given to such terms in Schedule 1.

(a) Ownership of the Raw Data, Resource Data, Derived Data, Meta Data, Synthetic Data (including copyright and related rights, database rights and sui generis database rights) shall, subject to clause 4(b), vest in the University and shall form part of the ALSPAC resource (“ALSPAC Data”). The Recipient Institute hereby assigns to the University absolutely (or to such other person as the University shall nominate) with full title guarantee all its right, title and interest in and to all rights (including Intellectual Property Rights) in the Derived Data, Raw Data and Documentation the Recipient collects.
(b) Ownership of the connected data within the Linked Datasets and any Resource Data and Derived Data to the extent it is generated from the Linked Datasets (including copyright and related rights, database rights and sui generis database rights) shall, unless the University advises otherwise, vest in the third party that permitted the connected data to be included in the Licensed Datasets.
(c) 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, transferable, royalty-free license to use all Recipient Institute Results for research, teaching and other non-commercial purposes.
(d) The Recipient Institute shall provide the University with a complete electronic copy of any Raw Data, Derived Data and Meta Data generated from access to and use of the Licensed Datasets by the Recipient Investigator, the Recipient Institute Results and the syntax used to generate them within a period of six (6) months of completion of the Authorised Research.
(e) All data within any of the Licensed Datasets must be returned to the University or destroyed (as directed by the University) on completion of the Authorised Research or on termination of this agreement, whichever is sooner.
(f) If access to and use of the Licensed Datasets will not result in any Recipient Institute Results the provisions of clauses 4(c) and (d) shall not apply.
5. **Recipient Investigator**: The Recipient Institute warrants that the Recipient Investigator(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 Recipient Investigator 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 Recipient Investigator 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 Recipient Investigator. The Recipient Institute shall ensure that the Recipient Investigator(s) employment contract or honorary contract (as the case may be) includes terms binding them to maintaining data confidentiality.

6. **Authorised Research**: 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 ALSPAC data should be published in an ‘open access’ publication wherever possible and always if funded by Wellcome. 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.

7. **Linked Data**: The Recipient Institute acknowledges and accepts that where in accordance with this agreement it is granted access to Licensed Datasets that include Linked Datasets, the University may impose such other restrictions and conditions on or in connection with such access as the University may require. This is to enable the University to comply in full with any restrictions or conditions imposed on the University by the owner(s) of the data within the Linked Datasets. If the Recipient Institute fails to accept or comply with such restrictions and conditions the University may immediately withdraw the rights of access to such Linked Datasets. Furthermore, it may require the immediate return or destruction of any data derived from the Linked Datasets, including but not limited to Resource Data and Derived Data.

8. **Security and Custodianship**: The Recipient Institute shall ensure that the Licensed Datasets are kept in a secure manner and only transferred in an encrypted form and shall use all reasonable security practices and systems as set out in Schedule 2 applicable to the use of the Licensed Datasets to prevent, and take prompt and proper remedial action against, unauthorised access, copying, modification, storage, reproduction, display or distribution of the Licensed Datasets. The Recipient Institute agrees to comply with the University’s reasonable directions regarding the security of the Licensed Datasets in addition to the Recipient Institute’s own data security policies. If the Recipient Institute makes any amendment to their own data security policies it shall promptly notify the University of this.

9. **Data protection**: If and to the extent that the Licensed Datasets comprise personal data and/or sensitive personal data (Protected Data) within the meaning of the Data Protection Legislation or any other Applicable Law, the Recipient Institute warrants that it will:

   (a) 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;
   (b) 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;
   (c) not transfer the Protected Data to any destination outside the European Economic Area without the University’s prior written consent and subject to such further conditions as the University may specify;
   (d) 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.
(e) become the data controller (as defined in the Data Protection Act or any other Applicable Law) in relation to any Protected Data received under this agreement.

(f) 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.

10. **Complaints by data subjects:** 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 such person with full co-operation and assistance in relation to any such complaint, notice or communication.

11. **Notification:** 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 the Licensed Datasets or any security breach that could compromise the security or integrity of the Licensed Datasets, the Recipient Institute shall promptly notify the Executive (by email to alspac-exec@bristol.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 any of the Licensed Datasets.

12. **Audit:** The Recipient Institute shall keep detailed, accurate and up-to-date records (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 of this agreement. Where the owner of any Linked Datasets has any additional audit or reporting requirements the Recipient Institute shall comply with such additional requirements at its costs and expense.

13. **Confidentiality:** The Recipient Institute shall keep the Licensed 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 and students, investigator(s) shall:

(a) keep confidential all Licensed Datasets and other information of a confidential nature (whether written or oral) concerning this agreement and the business affairs of the ALSPAC 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”);

(b) not without the prior written consent of the University disclose the Licensed Datasets, or the Confidential Information either in whole or in part to any other person save to the Recipient Investigator 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 ALSPAC Data User Responsibilities Declaration Form;

(c) that prior to preparing results of the Authorised Research for publication and dissemination beyond the Recipient Investigator and Collaborator, that the Recipient Investigator and Collaborator will consider risks to the confidentiality of the Study Participants and to 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 effectively anonymous; and

(d) 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.

(e) The provisions of this Clause 13 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:

   (i) known to the receiving Party prior to the date of this agreement and not obtained directly or indirectly from the other Party; or
(ii) 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
(iii) 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
(iv) required to be disclosed by legal process, law or regulatory authority.

(f) The Recipient Institute hereby undertakes to the University to make all relevant employees, agents and students aware of the confidentiality of the Confidential Information and provisions of this Clause 13 and Schedule 2 and without limiting the foregoing to ensure compliance by such employees, agents and students with the provisions of this Clause 13.

14. Disclaimer: The University expressly does not guarantee, represent or warrant that:

(a) the Licensed Dataset are accurate, complete, reliable or secure;
(b) the Licensed Dataset are of satisfactory quality or fit for any particular purpose or capable of being used in connection with the Authorised Research; or
(c) use of the Licensed Dataset 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.

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

15. Limitation of liability:

(a) 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.
(b) Subject to Clause 15(a), 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).

16. Termination: 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:

(a) the Recipient Institute to the University at any time in writing;
(b) the University in the event that the Recipient Investigator 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;
(c) 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);
(d) 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;
(e) the University if the Recipient Institute does anything that may cause damage to the University’s reputation;
(f) the University if the Recipient Institute:
   i. is deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986;
   ii. 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);
iii. 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

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

17. **Consequences of termination:** On termination of this agreement for any reason, the Recipient Institute shall as soon as reasonably practicable return or destroy (as directed in writing by the University) the Licenced Datasets and all other data or information provided by the University in connection with this agreement. 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.

18. **Publications and acknowledgment:** 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 ALSPAC Access Policy. The Recipient Institute will acknowledge the Study in all publications and presentations arising from the Authorised Research in the form specified by the ALSPAC Access 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 Licensed Datasets. For clarity publication may not include the Licensed Dataset.

19. **Costs:** The Licensed Datasets are supplied at cost (being the Data Access Fee(s)), the details of which are set out in the Front Sheet of this agreement. The University shall not be obliged to provide the Licensed Datasets until the Recipient Institute’s has paid in full for the use of the Licenced Datasets. If VAT is properly chargeable on the Data Access Fee(s) then this shall be payable by the Recipient Institute.

20. **General provisions**

(a) **Interpretation:** The following rules shall apply to the interpretation of this agreement:

i. the Special Terms (as set out in the Schedule) 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 Terms, the terms and conditions of this agreement shall prevail;

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

iii. 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;

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

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

(b) **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.

(c) **Entire agreement:** This agreement and its Front Sheet, Schedules, Annex’s (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.

(d) **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.

(e) **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 Recipient Investigator(s) is/are authorised to agree a variation to the Licensed Datasets from time to time via the ALSPAC Online Proposal System (https://proposals.epi.bristol.ac.uk/).

(f) **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.

(g) **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.

(h) **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.

(i) **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.

(j) **Standard Contractual Clauses (SCC):** For all Recipient Institutions outside of the United Kingdom (UK) and the European Economic Area (EEA) the SCCs in Schedule 5 will apply. These have been written in line with requirements of UK and European law and the content is non-negotiable.
Schedule 1

Types of Data

ALSPAC Data Types and Ownership Rights

New data, datasets or information that have been created, collated or linked to in the course of the Authorised Research using the Licensed Data (wholly or in part) or ALSPAC sample as its source and where, during the creation of new data, datasets or information, the Licensed Data (including data attribution or textual content) has been copied, replicated, reproduced and/or generalised, data.

1. New Data Collection and Processing

The collection and processing of these data types are typically conducted by ALSPAC. In limited circumstances (e.g. the collection of image data by medical imaging experts using specialist equipment) exceptions to this rule may be made; in these circumstances additional conditions may be imposed by the University following discussion with the relevant Research Institution.

Raw Data: means the original data (in any format, e.g. questionnaires, photos, interview transcripts, scanned images, biological samples, biological assays) as collected from participants (using any mechanism). Note that both biological samples and biological assays are considered raw data. Assay Data includes, by way of example: biochemical analyses (lipids such as HDL or LDL cholesterol) and genetic sequence data. Where new data are collected from ALSPAC participants then the University will be the owner of these data, and Researchers are required to supply ALSPAC with these data in their raw form (i.e. the form in which they were generated) and provide sufficient documentation to interpret them. These Raw Data will be archived by ALSPAC and cleaned or derived information (Resource Data) based on these may be made available to other researchers [on the Host Platform].

Linked Data: means data collected by external third parties that are linked to ALSPAC participants 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. ALSPAC use these data under licence. Neither the Research Institution 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 ALSPAC participants are typically conducted by the ALSPAC data linkage team and will be subject to any licence conditions imposed by the owner of the data within the Linked Datasets.

Meta Data: means information which describes the 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. Researchers must collect full and rich meta-data when generating new data and return these promptly to ALSPAC in a clear and understandable format.

2. ‘Licensed Dataset’

Sub-sets of information from the following categories comprise the information typically given to a Researcher:

Resource Data: means real individual-level data collected by various means (e.g. directly by ALSPAC, via Linked Datasets, from Raw Data, from previously created Derived Data), which have been processed and made available to researchers by ALSPAC (where required for the approved research) for the duration of the Research. The University retains ownership (or manages ownership rights of third-party owners) of the Resource Data (in all forms, copies, transformations).

Meta Data: means information that explains and contextualises the other types of data (including Raw Data, Resource Data, and Derived Data). An example would be calibration data for a data collection device, the details about inviting a participant to take part in a data collection exercise, or the assay results from quality control samples.
Meta data are generated by ALSPAC as part of data collection and processing, but also by Researchers as part of creating Derived Data. Ownership of these Meta Data belong to ALSPAC (as it forms an integral part of the Resource Data), but Researcher authorship is acknowledged.

**Synthetic Data:** means data that are representations of the Resource 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.

3. **Outputs from the research process**

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

**Derived Data:** means individual-level data generated from analyses or functional combinations of the Resource Data. An example of a Derived Data variable includes Body Mass Index (BMI), being a function of height and weight or principal component scores derived from diet data. ALSPAC retains ownership of these Derived Data and these data, with their explanatory documentation, must be returned to ALSPAC 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 is the property of the Researcher (or the original rights owner, as appropriate), but ALSPAC shall be granted a non-exclusive royalty free and perpetual license to access, use and distribute this [Meta Data].

*The following categories must be transformed to the point where they are effectively anonymous and typically at an aggregate level (e.g. tables of results). Some data – for example anonymised verbatim quotes from an in-depth interview) may be considered Research Results. In these cases, the data must be published selectively (i.e. it is not permissible to upload the Resource Data (e.g. a participants full transcript) to a journal to accompany a publication). All published outputs must be assessed for disclosure risk and transformed to control for identified risks.*

**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 Resource Data, Derived Data, or Researcher Results. Researcher Analyses are the property of the Researcher, although ALSPAC encourage Researchers to share these 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 participant confidentiality or to risk bringing the Study into disrepute.
Schedule 2

Information Security Controls

1. The Information contained within the Licensed Datasets is classified by the University as being ‘Strictly Confidential’ and the Recipient Institute shall ensure that:
   (a) Access to these data shall only be available to specifically authorised staff being those persons named in the application to ALSPAC for access to the data and who have signed the ALSPAC Data User Responsibilities Declaration Form and the minimum number of IT Services staff required to maintain the systems hosting the Licensed Datasets;
   (b) Physical documents containing the Information within the Licensed Dataset, or extracts or derived information, shall be kept in secure environments (locked cupboards in locked buildings) and only accessible to the named Investigator(s) when not in use;
   (c) Electronic files containing the Information, or extracts or derived information, shall be stored on hardware located in secure environments (locked locations in locked buildings). Access to the Electronic Files must be restricted to only the named investigator(s). The hardware used to store the Electronic files must be encrypted to the AES-256bit standard and accessible using strong passwords (at least 12 characters using a mix of letters, cases, numbers and symbols);
   (d) Electronic information is transported in an encrypted format using encryption to the AES-256bit standard and strong passwords (at least 12 characters using a mix of letters, cases, numbers and symbols). Where the electronic information is being transported physically then the device must also be encrypted to AES-256bit standard. Encryption keys must be held securely and not transported using the same mechanism as the encrypted Information contained within the Licensed Dataset;
   (e) Physical information being transported must not be left unattended during transit;
   (f) The Information contained within the Licensed Dataset must be disposed of securely, where physical copies are shredded so the information is non-recoverable, and the hardware storing the electronic copies of the Licensed Information must be physically destroyed at the end of their useful life in such a way the information is non-recoverable;
   (g) The Recipient Institute is responsible for ensuring their electronic file infrastructure is fit for purpose and it is secured through the implementation of access control mechanisms; regular patching of software and hardware; use of current anti-virus software; the conducting of penetration testing and swift resolution of any vulnerabilities found;
   (h) The Recipient Investigator(s) monitor the copying of the Information contained within the Licensed Dataset and its derivatives to ensure that an inventory of all copies is compiled, and the location of all copies is known and recorded;
   (i) That where the Recipient Institute uses third party provided services as part of its electronic or physical service provision to the Recipient Investigator(s) then the according service provision contracts include sufficient terms to uphold these Information Security requirements.
Schedule 3
Licensed Datasets
Schedule 5

Standard Contractual Clauses

Relating to Clause 20 (j):

Standard Contractual Clauses (SCC): For all Recipient Institutions outside of the United Kingdom (UK) the SCCs in Schedule 5 will apply. These have been written in line with requirements of UK and European law and the content is non-negotiable.

These Standard Contractual Clauses are deemed to be amended from time to time, to the extent that they relate to a restricted transfer which is subject to the Data Protection Legislation, to reflect any change (including any replacement) made in accordance with those Data Protection Legislation (i) by the Commission to or of the equivalent contractual clauses approved by the Commission under EU Directive 95/46/EC or the GDPR; or (ii) by an equivalent competent authority to or of any equivalent contractual clauses approved by it or by another competent authority under Data Protection Legislation.

Standard Contractual Clauses for the transfer of personal data from the Community to third countries (controller to controller transfers)

Data transfer agreement

between

University of Bristol (hereinafter “data exporter”) and

Recipient Institute named on the summary page on this agreement (hereinafter “data importer”)

each a “party”; together “the parties”.

Definitions

For the purposes of the clauses:

(a) “personal data”, “special categories of data/sensitive data”, “process/processing”, “controller”, “processor”, “data subject” and “supervisory authority/authority” shall have the same meaning as in Directive 95/46/EC of 24 October 1995 (whereby “the authority” shall mean the competent data protection authority in the territory in which the data exporter is established);

(b) “the data exporter” shall mean the controller who transfers the personal data;

(c) “the data importer” shall mean the controller who agrees to receive from the data exporter personal data for further processing in accordance with the terms of these clauses and who is not subject to a third country’s system ensuring adequate protection;

(d) “clauses” shall mean these contractual clauses, which are a free-standing document that does not incorporate commercial business terms established by the parties under separate commercial arrangements.

The details of the transfer (as well as the personal data covered) are specified in Annex B, which forms an integral part of the clauses.

I. Obligations of the data exporter

The data exporter warrants and undertakes that:
(a) The personal data have been collected, processed and transferred in accordance with the laws applicable to the data exporter.

(b) It has used reasonable efforts to determine that the data importer is able to satisfy its legal obligations under these clauses.

(c) It will provide the data importer, when so requested, with copies of relevant data protection laws or references to them (where relevant, and not including legal advice) of the country in which the data exporter is established.

(d) It will respond to enquiries from data subjects and the authority concerning processing of the personal data by the data importer, unless the parties have agreed that the data importer will so respond, in which case the data exporter will still respond to the extent reasonably possible and with the information reasonably available to it if the data importer is unwilling or unable to respond. Responses will be made within a reasonable time.

(e) It will make available, upon request, a copy of the clauses to data subjects who are third party beneficiaries under clause III, unless the clauses contain confidential information, in which case it may remove such information. Where information is removed, the data exporter shall inform data subjects in writing of the reason for removal and of their right to draw the removal to the attention of the authority. However, the data exporter shall abide by a decision of the authority regarding access to the full text of the clauses by data subjects, as long as data subjects have agreed to respect the confidentiality of the confidential information removed. The data exporter shall also provide a copy of the clauses to the authority where required.

II. Obligations of the data importer

The data importer warrants and undertakes that:

(a) It will have in place appropriate technical and organisational measures to protect the personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected.

(b) It will have in place procedures so that any third party it authorises to have access to the personal data, including processors, will respect and maintain the confidentiality and security of the personal data. Any person acting under the authority of the data importer, including a data processor, shall be obligated to process the personal data only on instructions from the data importer. This provision does not apply to persons authorised or required by law or regulation to have access to the personal data.

(c) It has no reason to believe, at the time of entering into these clauses, in the existence of any local laws that would have a substantial adverse effect on the guarantees provided for under these clauses, and it will inform the data exporter (which will pass such notification on to the authority where required) if it becomes aware of any such laws.

(d) It will process the personal data for purposes described in Annex B, and has the legal authority to give the warranties and fulfil the undertakings set out in these clauses.

(e) It will identify to the data exporter a contact point within its organisation authorised to respond to enquiries concerning processing of the personal data, and will cooperate in good faith with the data exporter, the data subject and the authority concerning all such enquiries within a reasonable time. In case of legal dissolution of the data exporter, or if the parties have so agreed, the data importer will assume responsibility for compliance with the provisions of clause I(e).
(f) At the request of the data exporter, it will provide the data exporter with evidence of financial resources sufficient to fulfil its responsibilities under clause III (which may include insurance coverage).

(g) Upon reasonable request of the data exporter, it will submit its data processing facilities, data files and documentation needed for processing to reviewing, auditing and/or certifying by the data exporter (or any independent or impartial inspection agents or auditors, selected by the data exporter and not reasonably objected to by the data importer) to ascertain compliance with the warranties and undertakings in these clauses, with reasonable notice and during regular business hours. The request will be subject to any necessary consent or approval from a regulatory or supervisory authority within the country of the data importer, which consent or approval the data importer will attempt to obtain in a timely fashion.

(h) It will process the personal data, at its option, in accordance with:

(i) the data protection laws of the country in which the data exporter is established, or

(ii) the data processing principles set forth in Annex A.

Data importer to indicate which option it selects and include on Summary Pages in this agreement: (h) - (i) or (ii)

(i) It will not disclose or transfer the personal data to a third party data controller located outside the European Economic Area (EEA) unless it notifies the data exporter about the transfer and

(i) the third party data controller processes the personal data in accordance with a Commission decision finding that a third country provides adequate protection, or

(ii) the third party data controller becomes a signatory to these clauses or another data transfer agreement approved by a competent authority in the EU, or

(iii) data subjects have been given the opportunity to object, after having been informed of the purposes of the transfer, the categories of recipients and the fact that the countries to which data is exported may have different data protection standards, or

(iv) with regard to onward transfers of sensitive data, data subjects have given their unambiguous consent to the onward transfer

III. Liability and third party rights

(a) Each party shall be liable to the other parties for damages it causes by any breach of these clauses. Liability as between the parties is limited to actual damage suffered. Punitive damages (i.e. damages intended to punish a party for its outrageous conduct) are specifically excluded. Each party shall be liable to data subjects for damages it causes by any breach of third party rights under these clauses. This does not affect the liability of the data exporter under its data protection law.

(b) The parties agree that a data subject shall have the right to enforce as a third party beneficiary this clause and clauses I(b), I(d), I(e), II(a), II(c), II(d), II(e), III(h), III(l), III(a), V, VI(d) and VII against the data importer or the data exporter, for their respective breach of their contractual obligations, with regard to his personal data, and accept jurisdiction for this purpose in the data exporter’s country of establishment. In cases involving allegations of breach by the data importer, the data subject must first request the data exporter to take appropriate action to enforce his rights against the data importer; if the data exporter does not take such action within a reasonable period (which under normal circumstances would be one month), the data subject may then enforce his rights against the data importer directly. A data subject is entitled to proceed directly against a data exporter that has
failed to use reasonable efforts to determine that the data importer is able to satisfy its legal obligations under these clauses (the data exporter shall have the burden to prove that it took reasonable efforts).

IV. Law applicable to the clauses

These clauses shall be governed by the law of the country in which the data exporter is established, with the exception of the laws and regulations relating to processing of the personal data by the data importer under clause II(h), which shall apply only if so selected by the data importer under that clause.

V. Resolution of disputes with data subjects or the authority

(a) In the event of a dispute or claim brought by a data subject or the authority concerning the processing of the personal data against either or both of the parties, the parties will inform each other about any such disputes or claims, and will cooperate with a view to settling them amicably in a timely fashion.

(b) The parties agree to respond to any generally available non-binding mediation procedure initiated by a data subject or by the authority. If they do participate in the proceedings, the parties may elect to do so remotely (such as by telephone or other electronic means). The parties also agree to consider participating in any other arbitration, mediation or other dispute resolution proceedings developed for data protection disputes.

(c) Each party shall abide by a decision of a competent court of the data exporter’s country of establishment or of the authority which is final and against which no further appeal is possible.

VI. Termination

(a) In the event that the data importer is in breach of its obligations under these clauses, then the data exporter may temporarily suspend the transfer of personal data to the data importer until the breach is repaired or the contract is terminated.

(b) In the event that:

(i) the transfer of personal data to the data importer has been temporarily suspended by the data exporter for longer than one month pursuant to paragraph (a);

(ii) compliance by the data importer with these clauses would put it in breach of its legal or regulatory obligations in the country of import;

(iii) the data importer is in substantial or persistent breach of any warranties or undertakings given by it under these clauses;

(iv) a final decision against which no further appeal is possible of a competent court of the data exporter’s country of establishment or of the authority rules that there has been a breach of the clauses by the data importer or the data exporter; or

(v) a petition is presented for the administration or winding up of the data importer, whether in its personal or business capacity, which petition is not dismissed within the applicable period for such dismissal under applicable law; a winding up order is made; a receiver is appointed over any of its assets; a trustee in bankruptcy is appointed, if the data importer is an individual; a company voluntary arrangement is commenced by it; or any equivalent event in any jurisdiction occurs
then the data exporter, without prejudice to any other rights which it may have against the data importer, shall be entitled to terminate these clauses, in which case the authority shall be informed where required. In cases covered by (i), (iii), or (iv) above the data importer may also terminate these clauses.

(c) Either party may terminate these clauses if (i) any Commission positive adequacy decision under Article 25(6) of Directive 95/46/EC (or any superseding text) is issued in relation to the country (or a sector thereof) to which the data is transferred and processed by the data importer, or (ii) Directive 95/46/EC (or any superseding text) becomes directly applicable in such country.

(d) The parties agree that the termination of these clauses at any time, in any circumstances and for whatever reason (except for termination under clause VI(c)) does not exempt them from the obligations and/or conditions under the clauses as regards the processing of the personal data transferred.

VII. Variation of these clauses

The parties may not modify these clauses except to update any information in Annex B, in which case they will inform the authority where required. This does not preclude the parties from adding additional commercial clauses where required.

VIII. Description of the Transfer

The details of the transfer and of the personal data are specified in Annex B. The parties agree that Annex B may contain confidential business information which they will not disclose to third parties, except as required by law or in response to a competent regulatory or government agency, or as required under clause I(e). The parties may execute additional annexes to cover additional transfers, which will be submitted to the authority where required. Annex B may, in the alternative, be drafted to cover multiple transfers.

VIX. Data protection indemnity

VIX-1 Subject to the cap in Clause VIX-5 each Party shall indemnify on demand and keep indemnified the other Parties from and against all and any Losses that are sustained, suffered or incurred by, awarded against or agreed to be paid by the other Parties to the extent arising from that Party’s breach of its obligations under this Agreement and/or failure to comply with the Data Protection Laws, including all Losses resulting from:

a) any monetary penalties or fines levied by the ICO on the other Parties (to the extent that any monetary penalties or fines have not been levied by the ICO on the other Parties in respect of the same breach of its obligations under this Agreement and/or failure to comply with the Data Protection Laws);

b) the costs of an investigative, corrective or compensatory action required by the ICO, or the defence of any proposed or actual enforcement action taken by the ICO;

c) any Losses suffered or incurred by, awarded against, or agreed to be paid by the other Parties pursuant to a claim, action or challenge made by a third party to or against the other Parties (including by a Data Subject); and

d) except to the extent covered by clauses VIX -1 (a) to (c) (inclusive), any Losses suffered or incurred, awarded against or agreed to be paid by the other Parties.

VIX-2 Indemnification under this clause VIX is contingent upon:

a) the Parties to be indemnified ("Indemnified Parties") promptly notifying the other Parties ("Indemnifying Parties") of any claim, action, challenge or notice that may give rise to a claim under this clause VIX ("Claim");

b) the Indemnifying Parties (solely or jointly, as appropriate) having sole control of the defence and settlement of any such Claim, and
c) the Indemnified Parties providing reasonable co-operation and assistance to the Indemnifying Parties in defence of such Claim.

VIX-3 Indemnification under this clause VIXI shall not cover the Indemnified Parties to the extent that any Claim results from its or their negligence or wilful misconduct.

VIX-4 Nothing in this clause VIXI shall restrict or limit the Indemnified Parties’ general obligation at law to mitigate any Losses it or they suffer or incur as a result of any event giving rise to a Claim.

VIX-5 The maximum liability of any Party, including any indemnities under this clause VIX shall be limited to five million pounds (£5,000,000). To the extent that the value of any Claim exceeds such amount, the Parties acknowledge and agree that they shall not pursue any further or additional claim for damages suffered or incurred as a result of any event giving rise to a Claim.
ANNEX A (TO SCHEDULE 5)

1. **Purpose limitation:** Personal data may be processed and subsequently used or further communicated only for purposes described in Annex B or subsequently authorised by the data subject.

2. **Data quality and proportionality:** Personal data must be as accurate as possible and, where necessary, kept up to date. The personal data must be adequate, relevant and not excessive in relation to the purposes for which they are transferred and further processed.

3. **Transparency:** Data subjects must be provided with information necessary to ensure fair processing (such as information about the purposes of processing and about the transfer), unless such information has already been given by the data exporter.

4. **Security and confidentiality:** Technical and organisational security measures must be taken by the data controller that are appropriate to the risks, such as against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, presented by the processing. Any person acting under the authority of the data controller, including a processor, must not process the data except on instructions from the data controller.

5. **Rights of access, rectification, deletion and objection:** As provided in Article 12 of Directive 95/46/EC, data subjects must, whether directly or via a third party, be provided with the personal information about them that an organisation holds, except for requests which are manifestly abusive, based on unreasonable intervals or their number or repetitive or systematic nature, or for which access need not be granted under the law of the country of the data exporter.

   Provided that the authority has given its prior approval, access need also not be granted when doing so would be likely to seriously harm the interests of the data importer or other organisations dealing with the data importer and such interests are not overridden by the interests for fundamental rights and freedoms of the data subject. The sources of the personal data need not be identified when this is not possible by reasonable efforts, or where the rights of persons other than the individual would be violated. Data subjects must be able to have the personal information about them rectified, amended, or deleted where it is inaccurate or processed against these principles. If there are compelling grounds to doubt the legitimacy of the request, the organisation may require further justifications before proceeding to rectification, amendment or deletion. Notification of any rectification, amendment or deletion to third parties to whom the data have been disclosed need not be made when this involves a disproportionate effort.

   A data subject must also be able to object to the processing of the personal data relating to him if there are compelling legitimate grounds relating to his particular situation. The burden of proof for any refusal rests on the data importer, and the data subject may always challenge a refusal before the authority.

6. **Sensitive data:** The data importer shall take such additional measures (eg relating to security) as are necessary to protect such sensitive data in accordance with its obligations under clause II.

7. **Data used for marketing purposes:** Where data are processed for the purposes of direct marketing, effective procedures should exist allowing the data subject at any time to “opt-out” from having his data used for such purposes.

8. **Automated decisions:** For purposes hereof “automated decision” shall mean a decision by the data exporter or the data importer which produces legal effects concerning a data subject or significantly affects a data subject and which is based solely on automated processing of personal data intended to evaluate certain personal aspects relating to him, such as his performance at work, creditworthiness, reliability, conduct, etc. The data importer shall not make any automated decisions concerning data subjects, except when:
   
   (a) (i) such decisions are made by the data importer in entering into or performing a contract with the data subject, and
   
   (ii) (the data subject is given an opportunity to discuss the results of a relevant automated decision with a representative of the parties making such decision or otherwise to make representations to that parties.

   Or

   (b) where otherwise provided by the law of the data exporter.
ANNEX B (TO SCHEDULE 5)

Data Subject

The personal data transferred concern the following categories of data subjects: Participants of the Avon Longitudinal Study of Parents and Children (ALSPAC) who have consented for their data to be used for research.

Purposes of transfer(s)

The transfer is made for the following purposes: To enable the Recipient Institution and therefore the Recipient Investigators to conduct research as outlined in the approved proposal (and amendments if applicable) in Schedule 4. The proposal may be amended from time to time via an amendment that is reviewed and approved by ALSPAC.

Categories of data

The personal data transferred may be disclosed only to the following recipients or categories of recipients: Bona fide researchers who are employed by or hold an honorary contract or equivalent with the Recipient Institution and have been included on the approved proposal in Schedule 4 or added later via an approved amendment and have completed ALSPAC’s Data User Responsibility Agreement (DURA) agreeing to these statements: [link]

Sensitive data (if appropriate)

The personal data transferred concern the following categories of sensitive data: The majority of data held by ALSPAC and available for researchers to access is health data collected for research purposes via questionnaires or in clinic. The specific variables shared are outlined in Schedule 3 and may be updated from time to time via an amendment that is reviewed and approved by ALSPAC. Depending on the request, some data may be considered particularly sensitive e.g. mental health data. Highly sensitive data, and third party linked data, will be shared following strict protocols described in the ALSPAC Access Policy: [link]

Additional useful information (storage limits and other relevant information)

Data is only released when the Data Access Agreement and Data User Responsibility Agreements have been fully signed (and fees have been paid if applicable). When the project ends, any newly derived data will be securely returned to ALSPAC and all datasets will be deleted by the Recipient Institute.

Contact points for data protection enquires
Data Importer: See summary pages.

Contact points for data protection enquires
Data exporter: See summary pages.