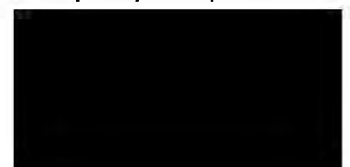


ALSPAC DATA ACCESS AGREEMENT

Agreement Summary:

ALSPAC Reference (B Number):	B4752
Project Title:	Genetic and environmental factors in child adjustment and mental health
Principal Investigator:	<div></div> Postdoctoral researcher
Recipient Institute:	Masaryk University, RECETOX Kamenice 753/5, pavilion A29 625 00 Brno Czech Republic
Recipient Investigator(s) at PI Institution:	<div></div> Postdoctoral researcher
Collaborator(s) who do not receive data:	N/A
Lay Summary of Authorised Research (from the proposal form):	<p>Understanding the factors associated with adolescent psychosocial adjustment and mental health is crucially important as mental health challenges that arise during these years often have enduring consequences throughout adulthood. Research indicates that mental health disorders in adolescence can hinder social, educational, and occupational outcomes, resulting in significant long-term impairments (Kessler et al., 2005). Mental health problems and health-compromising behaviors can often be traced back to adolescence, with 50% of mental health difficulties being established by the age of 15 (Kessler et al., 2005; Sawyer et al., 2012). The economic burden of mental health problems in young populations is profound, with estimates indicating both direct healthcare expenses and substantial indirect costs associated with increased social service needs, and the economic impact on families (Gustavsson et al., 2011; Knapp et al., 2011).</p> <p>Factors leading to maladjustment and mental health problems in children and adolescents are often multifaceted, typically arising from a combination of individual vulnerabilities and environmental stressors. The individual factors include increased genetic risk for externalizing behaviors and depression, difficult temperament (e.g., high neuroticism), or developmental delays. One of the most salient environmental stressors is childhood adversity (i.e., adverse childhood experiences), typically operationalized as various forms of abuse, neglect, and household disfunction experienced before age 18 (Felitti et al., 1998; Hughes et al., 2017). Adverse childhood experiences are strongly associated with a socioeconomic disadvantage (Lacey, et al., 2022) and are structured by socioeconomic factors at both the family (Walsh et al., 2019) and macro level (Lewer et al., 2019). Thus, poverty and socioeconomic inequality can</p>



be considered as drivers of adverse childhood experiences (ACE; Institute of Health Equity, 2020; Walsh et al., 2019).

Environmental effects not only complement genetic influences but also interact with them, embodying the gene-environment (GxE) concept—the idea that environments modify genetic effects. For example, the effects of genetic risk on problem behaviors was amplified in environments characterized by poverty or maladaptive parenting (Chubar et al., 2020; Jensen et al., 2017). The existing studies on GxE usually follow the diathesis-stress model, which suggests that individuals with pre-existing vulnerability (such as genetic risk) are more susceptible to negative outcomes when exposed to adverse environments (Colodro-Conde et al., 2018; Zuckerman, 1999).

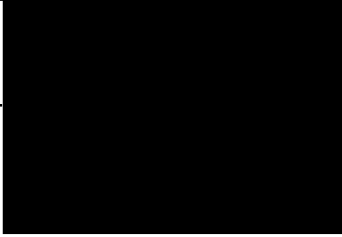
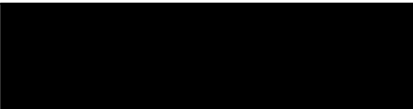
Lastly, large-scale societal conditions, including economic downturns, socioeconomic transformations, and geopolitical conflicts have a profound influence on well-being and mental health (Deindl, 2013). As countries considerably differ in their socioeconomic conditions, the scale in which they are affected by crises and by their response to them (Cascini et al., 2022), country characteristics are an important factor contributing to variation in young people’s mental health.

The aim of this project is twofold: a) to test the environmental risk (defined as childhood adversity and socioeconomic disadvantage) and genetic risks for maladjustment and mental health difficulties in ALSPAC cohort, and b) to examine the association between socioeconomic inequality, childhood adversity and adolescent mental health across two sister cohorts (ALSPAC and ELSPAC-CZ) that represent different socioeconomic environments. Data collection of both cohorts took place during the 1990s; however, while this was a time of relative stability in the United Kingdom, Czechoslovakia (later Czech Republic) was undergoing a turbulent post-communist transformation. This project will be the first to harmonize and directly compare data from both cohorts.

References:

- Colodro-Conde, L., Couvy-Duchesne, B., Zhu, G., Coventry, W. L., Byrne, E. M., Gordon, S., ... & Martin, N. G. (2018). A direct test of the diathesis–stress model for depression. *Molecular psychiatry*, 23(7), 1590–1596.
- Deindl, C. (2013). The influence of living conditions in early life on life satisfaction in old age. *Advances in Life Course Research*, 18, 107–114.
- Felitti, V. J., Anda, R. F., Nordenberg, D., Williamson, D. F., Spitz, A. M., Edwards, V., Koss, M. P., & Marks, J. S. (1998). Relationship of childhood abuse and household dysfunction to many of the leading causes of death in adults: The adverse childhood experiences (ACE) Study. *American Journal of Preventive Medicine*, 14(4), 245–258.
[https://doi.org/10.1016/S0749-3797\(98\)00017-8](https://doi.org/10.1016/S0749-3797(98)00017-8)
- Gustavsson, A., et al. (2011). Cost of disorders of the brain in Europe 2010. *European Neuropsychopharmacology*, 21(10), 718–779.

	<p>Hughes, K., Bellis, M. A., Hardcastle, K. A., Sethi, D., Butchart, A., Mikton, C., Jones, L., & Dunne, M. P. (2017). The effect of multiple adverse childhood experiences on health: A systematic review and meta-analysis. <i>The Lancet Public Health</i>, 2(8), e356–e366. https://doi.org/10.1016/S2468-2667(17)30118-4</p> <p>Institute of Health Equity. (2020). Health equity in England: The Marmot review 10 years on. https://www.health.org.uk/publications/reports/the-marmot-review-10-years-on</p> <p>Jensen, S. K., Berens, A. E., & Nelson, C. A. (2017). Effects of poverty on interacting biological systems underlying child development. <i>The Lancet Child & Adolescent Health</i>, 1(3), 225-239.</p> <p>Kessler, R.C., Berglund, P., Demler, O., Jin, R., Merikangas, K.R., & Walters, E.E. (2005). Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication Archives of General Psychiatry, 62, 593-602.</p> <p>Knapp, M., McDaid, D., & Parsonage, M. (Eds.). (2011). Mental health promotion and mental illness prevention: The economic case. London: Department of Health.</p> <p>Lacey, R. E., Howe, L. D., Kelly-Irving, M., Bartley, M., & Kelly, Y. (2022). The Clustering of Adverse Childhood Experiences in the Avon Longitudinal Study of Parents and Children: Are Gender and Poverty Important? <i>Journal of Interpersonal Violence</i>, 37(5), 2218–2241. https://doi.org/10.1177/0886260520935096</p> <p>Lewer D., King E., Bramley G., Fitzpatrick S., Treanor M. C., Maguire N., & Story A. (2019). The ACE Index: Mapping childhood adversity in England. <i>Journal of Public Health</i>. Advance online publication. 10.1093/pubmed/fdz158</p> <p>Sawyer, S.M., Afifi, R.A., Bearinger, L.H., Blakemore, S.-J., Dick, B., Ezech, A.C., et al. (2012). Adolescence: A foundation for future health. <i>Lancet</i>, 379, 1630-1640.</p> <p>Walsh D., McCartney G., Smith M., Armour G. (2019). Relationship between childhood socioeconomic position and adverse childhood experiences (ACEs): A systematic review. <i>Journal of Epidemiology & Community Health</i>, 73(12), 1087–1093. [DOI] [PMC free article] [PubMed] [Google Scholar]</p> <p>Zuckerman M. Diathesis-stress models. In: <i>Vulnerability to Psychopathology: A Biosocial Model</i>. American Psychological Association; 1999:3-23. doi:10.1037/10316-001</p>
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 4.
Summary Licensed Datasets†:	<p>Data types: Questionnaire and clinic data, Omics datasets</p> <p>Participant groups:</p> <p>_____</p> <p>Please see the attached proposal in schedule 4 for details.</p>






	<i>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.</i>	
Linked Datasets:	N/A	
Data provision mechanism:	Direct file transfer	
Data Access Cost Recovery Fee:	£3140	
Recipient Institute's Legal Contact(s):		
Recipient Institute's Data Protection / Information Security (or equivalent) Contact(s)		
International Data Transfer Agreement ("IDTA"):	N/A	
ALSPAC Data Buddy (name and email):		
Special Conditions:	N/A	

† 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 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.**

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	See above
Date	20th August 2025	Date	See above
		Signed by the Principal Investigator	
			
		Print name	
		Date	21/07/2025

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 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: https://www.bristol.ac.uk/media-library/sites/alspac/documents/researchers/data-access/ALSPAC_Access_Policy.pdf
Applicable Law	All laws, regulations, orders, guidance, codes of practice, directions or determinations that are applicable to the obligations of the Recipient Institute under this agreement including but not limited to the Data Protection Legislation and equivalent legislation applicable to the Recipient Institute
Data Protection Legislation	For the purposes of this Agreement, “ Data Protection Legislation ” means the UK Data Protection Legislation and the UK GDPR (meaning Regulation (EU) 2016/679 of the European Parliament and of the Council of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018) 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 the IDTA (if applicable) 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 Data Protection Legislation in such circumstances. This will include the Recipient Institute entering into an IDTA if the Recipient Institute is based in a country that **does not** have an adequacy decision in line with Data Protection Legislation.
- (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 [REDACTED] 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 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 (i) the University's prior written consent and subject to such further conditions as the University may specify or (ii) an International Data Transfer Agreement being first entered into by the parties;
 - (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 Legislation) 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 [REDACTED]) 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 [REDACTED]) and the University's Information Rights Officer (by email to [REDACTED]) 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 Licensed 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) International Data Transfer Agreement (IDTA): If the Recipient Institute is based in a country outside the UK that **does not** have an adequacy decision in line with Data Protection Legislation an IDTA will be required. This will be provided by the University in addition to this agreement. The IDTA has been written by the UK Information Commissioners Office in line with requirements of UK 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 [ALSPAC] 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.

4. Documentation

A document which describes in full any type of data described in section 1-3 above.

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 Licenced 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



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Schedule 4
Authorised Research



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