

ALSPAC AVON LONGITUDINAL STUDY OF PARENTS AND CHILDREN

Access Policy

v. 13.0

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CONTENTS

Summary	1
1. Data access procedure: overview	2
1.1 The ALSPAC resource	2
1.2 Requesting access to data	2
1.3 Charges for access to existing data and new data collection	3
1.3.1 Charges	4
1.3.2 Charges for project amendments	5
1.3.3 Costs for grant proposals	5
1.3.4 Costs for pre-access information	5
1.3.6 Costs for new data collection	6
1.4 Management of the resource	6
1.4.1 ALSPAC Executive	6
1.4.2 Senior Management Team (SMT)	6
1.4.3 ALSPAC Board	6
1.4.4 Independent Scientific Advisory Board (ISAB)	7
1.4.5 ALSPAC Ethics and Law Committee (ALEC)	7
1.4.6 Clinical Advisory Group	7
1.5 Intellectual property	7
2. Types of data and rules governing access	8
2.1 Questionnaire, clinic and biosamples data	8
2.1.1 G2 data	8
2.2 Linkage data	9
2.2.1 Bespoke linkage	10
2.2.2 Secure Research Servers	10
2.3 High throughput array/omics data	10
2.4 Potentially identifying data	11
3. Data provision	12
3.1 The 'data buddy' process	12
3.2 Data Access Agreement	12
3.3 Unique project identifiers	13
3.4 Secure data transfer	13
4. Access to biological samples	14
5. New data collection	16
5.1 Prior to data collection	16
5.1.1 Management of the data collection exercise	16
5.1.2 Early planning of the data collection exercise	16
5.1.3 Case selection for sub-studies	17

5.1.4	Controls in sub-studies.....	17
5.1.5	Electronic data collection systems	17
5.1.6	Administration	17
5.1.7	Participant documents.....	17
5.1.8	Ethical approval.....	17
5.1.9	The Original Cohort Advisory Panel (OCAP) and other participant advisory forums	18
5.1.10	Piloting.....	18
5.1.11	Collection of new biological samples	18
5.2	During data collection.....	18
5.2.1	Response rates	18
5.2.2	Personal data and confidentiality	18
5.2.3	Dealing with participants	19
5.2.4	Disclosure and Barring Service (DBS) checks.....	19
5.2.5	Sending study invitations	19
5.2.6	Feeding back contact information	19
5.2.7	Feedback of research findings	19
5.2.8	Feedback of incidental findings.....	19
5.2.9	Return of data	19
5.2.10	Backing up data	20
5.2.11	Feedback of project statistics/reporting to PIs	20
5.3	After data collection.....	20
5.3.1	Participants' personal details	20
5.3.2	Data collected	20
5.3.3	Additional variables	20
5.3.4	Data cleaning and built files	20
5.3.5	Exclusive data access.....	20
6.	Summary of researcher responsibilities.....	22
6.1	Project proposals	22
6.2	Funding	22
6.3	Data access	22
6.4	Information Security	22
6.5	Confidentiality/security breaches	23
6.6	Destruction of data and return of derived variables	23
6.7	Publication.....	23
6.7.1	Peer reviewed papers and other research output.....	23
6.7.2	Theses.....	24
6.7.3	Policy briefings	24
6.7.4	Reports and other publications	25

6.7.5 Conference proceedings and other presentations	25
6.7.6 Other output	25
6.8 The media	25
Appendix Two: Linkage data	27
1. Schools Data (provided by the Department for Education)	27
2. Further and Higher Education Data (provided by the Department for Business, Innovations and Skills)	27
3. NHS (National Health Service) and ONS (Office for National Statistics) data	27
4. NHS Primary Care Data	27
5. NHS Secondary Care Data	28
6. Geospatial Records	28
7. Data access costs for linkage data	28
Appendix Three: Split-stage protocol	30
Split-stage protocol for derived data	30
Split-stage protocol for study administration	32
Appendix Four: Information Security Controls	34
Appendix Five: Types of Data	35
Appendix Six: Policy updates	37

Summary

ALSPAC is a longitudinal birth cohort study which enrolled pregnant women who were resident in one of three Bristol-based health districts in the former County of Avon with an expected delivery date between 1st April 1991 and 31st December 1992. Around 14,000 pregnant women were initially recruited. Detailed information has been collected on these women, their partners and subsequent children using self-completion questionnaires, data extraction from medical notes, linkage to routine information systems and from hands-on research clinics. Additional cohorts of participants have since been enrolled in their own right including fathers, siblings, children of the children and grandparents of the children. Ethical approval for the study was obtained from the ALSPAC Ethics and Law Committee (IRB00003312) and Local Research Ethics Committees.

The purpose of this document is to describe in detail the general processes and procedures involved in accessing the ALSPAC resource (defined as data already collected and the participants themselves for the purposes of new data collection). **We encourage and facilitate data sharing with all ‘*bona fide*’ researchers** (see the [MRC definition](#); please contact us if you are in any doubt as to whether you fit this definition), which includes both public and private users and aim to enable researchers to conduct their studies in a transparent and streamlined manner.

For an outline of researcher responsibilities, see Section 6.

1. Data access procedure: overview

1.1 The ALSPAC resource

ALSPAC is run as a resource to be used by the research community. We encourage and facilitate data sharing by researchers from all disciplines across the world to maximise use of the resource. The process for accessing data is the same for all, regardless of research area, institution, location or funding source, provided the proposed research is in the public interest and is **not** being carried out for personal or commercial gain.

The vast majority of data are available for immediate use on request and we do not consider the issue of potential overlap between research projects. The study website provides an up to date [list of publications that have used the resource](#) and also provides the title and a brief summary of [all approved applications to use the resource since April 2011](#). The website also describes the resource and [summarises the types of data available](#) and is a useful place to start to give you a good idea as to whether ALSPAC would be potentially valuable in addressing your research question. The ALSPAC [data dictionary](#) provides an overview of all the data held. It contains a series of PDFs, which are fully searchable and provide detailed information on the ALSPAC data that are currently available; it provides information on how data were collected, together with frequencies and coding details. This will be a valuable tool when preparing a proposal to access data and/or samples. The ALSPAC [variable catalogue](#) is a simple list of all variable names and labels that are available, grouped according to data source and timepoint. Alternatively, there is a [variable search tool](#) which enables users to readily search across all variables that have been released to date. The tool can be used to determine what data we have and to obtain variable names. Users may choose to use this tool rather than the variable catalogue described above to assist with their data request.

Searchable indexes of ALSPAC variables are also available via [CLOSER Discovery](#). This is a search engine that enables researchers to explore the content of eight leading UK longitudinal studies. This detailed search tool provides metadata on phenotypic and environmental variables across the CLOSER longitudinal studies.

Access to ALSPAC research data must be requested using the formal procedures described in this document and is subject to eligibility, the ALSPAC funder's terms and conditions and University of Bristol policies and procedures.

1.2 Requesting access to data

Researchers are required to complete an [online proposal form](#). This proposal should have clearly stated aims and hypotheses and describe the relevant exposure, outcome and confounders that will be considered, justifying the data you require. For multiple projects you must submit multiple forms; **one per project**.

For requests requiring secondary data only, you will get a decision within 10 working days of submission to inform you of the outcome. Please note that in some cases we may need to complete a Data Privacy Impact Assessment (DPIA) which will affect the time taken to approve a proposal (see section 6.4). For more complex proposals involving non-standard data, the approval process is likely to take longer, but you will be contacted within 10 working days to advise you of the progress.

Once a proposal has been approved, you will receive advice on the next stages of the process. Please see later sections for timescales relating to applications for biological samples or new data collection. In some cases, approval may be refused due to the lack of relevant data or biological samples. The Executive also reserve the right to impose additional restrictions as appropriate.

The Executive reserve the right to check that all objectives in the original proposal are completed by cross reference to publications and make any additional analyses that were in the initial proposal but that have not been published via letters to journals and/or on our website, in order to avoid publication bias.

If a researcher is seeking funds for their research from a funding body, the Executive must receive the completed ALSPAC research proposal form at least **one month prior** to the submission deadline. It may not be possible to approve those received less than one month before the submission deadline in time for the

deadline. It is the responsibility of the researcher to ensure compliance with their funder's terms and conditions with respect to their use of ALSPAC data and samples.

Supervisors are ultimately responsible for their students in the same way that PIs are responsible for their researchers. We request that any **proposals for projects that are to be completed by students are therefore submitted by the supervisor** rather than the student themselves. Each student project (by this we mean research that will in part or in whole contribute to a student's submitted work) must be submitted separately, regardless of how similar multiple projects might be and whether or not they fall under the remit of a researcher's existing approved project. Student projects should be identified as such when submitting the proposal by ticking the appropriate box on the online proposal form.

Any proposals that include the collection of new data (see Section 5), should usually include a member of the Executive (or a Bristol-based scientist nominated by the Executive) as a co-applicant so they can act as guarantor for the proposed new data. We therefore suggest you approach the Executive with such a proposal at least **two months prior** to the submission deadline.

An amendment to your original proposal (to be submitted via the same [online system](#) as your original proposal) must be completed if any of the following change during the course of your approved project:

- Significant extension of research scope (note we may request this is submitted as a new project if the Executive deem appropriate);
- Change in start or end date;
- Additional researchers accessing the data;
- Change in institution;
- Any additional data required;
- Change of funding source.

1.3 Charges for access to existing data and new data collection

ALSPAC receives funding from Wellcome, the Medical Research Council and the University of Bristol to support *core* activities. These do not extend to providing support for individual projects and researchers will be expected to meet any, and all costs for data access and provision. All researchers accessing ALSPAC data will be charged on a cost recovery basis unless a grant proposal is being submitted (see section 1.3.3). This cost will vary depending on the types of data requested and the amount of time required to facilitate your request. Once a proposal has been approved and the applicant informed of the cost these **are non-negotiable**.

Costs will be determined on a project-by-project basis and will reflect only the true costs to ALSPAC of providing the resources requested. Once a proposal has been agreed in principle an accurate costing will be provided. Current charges for data requests are provided overleaf (Table 1) and example costings can be seen in Appendix One. There are three types of data requests detailed in Table 1: 1) Basic costs for data that is readily available; 2) Bespoke data that requires additional work to release and 3) Amendments to the original request. We reserve the right to charge additional costs not detailed in Table 1, if a project requires more resource than typically expected. These costs will be discussed with researchers in advance as required.

Data will **not** be provided until all necessary paperwork is completed and an invoice has been settled or a purchase order number is received by our finance department.

Costs are reviewed on a regular basis (although access to education data may be subject to change at short notice as ALSPAC's access to these data are subject to unforeseen changes beyond our control). Costs that are quoted are therefore accurate at the time they are provided and it is the researcher's responsibility to check that costs haven't changed if there is a significant lapse in time between obtaining the quote and starting the project.

VAT will be charged in addition to the table costs, where applicable.

1.3.1 Charges

Table 1: Charges to be applied for data requests (prices correct as of April 2020)

Type of data requested		Charge (+ VAT where applicable)
1.	Basic fee – (this includes the cost of the PI’s Data Access Agreement (DAA)) – any data available in the data warehouse [clearly described in ALSPAC data dictionary].	£1750
	Additional DAA*	£355
	Omics data (any bulk data release including any of the following) GWAS dataset no imputations GWAS imputed with HapMap GWAS imputed with 1000 genomes GWAS imputed with HRC Methylation data (from ARIES project) Gene expression CNV UK10K	£750
	MRI scans	£300
2.	Bespoke data (these charges are in addition to basic fee)	
	G2 (Children of the Children) data**	£1250
	Other ‘physical’ data ; scans; sound file; videos etc. [per time sweep, per participant cohort and per type of data/media] †	£1250
	Adding other data not available in ALSPAC data dictionary as part of the core datasets e.g. linkage, variables obtained from other researchers, typed SNPs etc **	£250 per data type
	Data requiring split stage protocol (see Appendix 3)	£750
	Linked Health and Education Records	Appendix 2 for details
	Other linkage data (e.g. linked geographical data, other third party data– see Section 2.2)	
3.	Amendment fee - to add additional data available in the data warehouse [clearly described in ALSPAC data dictionary] to the dataset at a later date – additional charges will apply as above for other data types	£500

* A DAA is required for all sites receiving data and the cost is *per* additional site.

** This fee is to cover the additional work currently required to link G2 data and undertake disclosure controls (see section 2.1.1)

† This fee is to cover the cost of re-identifying the physical data to send out, handling derived variables and incorporating them into the dataset

‡ All other linkage data to be costed on a case by case basis.

** This covers the additional work this entails

Costs for example projects are included in Appendix One: Example data access costs. Please note that access to biological samples will incur additional costs (see section 4 for further information).

If you submit a proposal for a new project but already have all the necessary variables you require from a previous project, we are still required to regenerate a new data set in order to ensure that i) the original data access agreement is adhered to, ii) any recent withdrawal of consents are accounted for and iii) relevant data updates are applied. However, in this instance and given the previous construction of a similar data set, we will charge an amendment fee (see Table 1) rather than the full cost recovery fee. Additional charges such as DAA costs and further amendments may apply.

1.3.2 Charges for project amendments

Additional data requests (i.e. data that were not included in the original proposal but subsequently required for any reason) will be subject to the costs shown in Table 1. Administrative amendments will not be charged unless a new DAA is required as the result of adding a co-applicant in a different Institution (each DAA is charged at £355).

See Section 1.2 for details on how to submit an amendment.

1.3.3 Costs for grant proposals

If you are submitting a grant (including PhD studentships and personal fellowships) for secondary data analysis, you must include a set '**Data Management Fee**' of **£7500** (+ VAT where applicable), this includes researchers based at the University of Bristol. This fee covers access to existing data (any data available in the data warehouse and clearly described in the ALSPAC data dictionary) and the administration of your proposal only; if you are proposing to collect new data or request biological samples, these will be costed separately (see sections 4 and 5). Similarly, if you require any non-standard data, appropriate costs will be added onto the data management fee.

The data management fee equates to the basic data access costs as detailed in section 1 of Table 1, one DAA, plus up to three data request amendments (additional DAAs will be subject to charge). If your project requires additional data described in section 2 of Table 1, we will need to add these costs to the data management fee and will provide these costs when your project is approved. Please provide sufficient time to enable us to accurately cost your project. We request you submit your project **four weeks prior** to submission to the funder (if you are collecting new data we require six weeks – please see section 5).

If a grant is successful, we request a copy of the award letter and will invoice you for the full amount *before* data can be provided. Please be aware that in order to take into account fluctuating exchange rates you may want to consider including a small amount of contingency if you are not seeking funds in GBP.

If your grant does not require secondary data analysis, e.g. it is a qualitative study, a pilot study for new data collection techniques or similar, then a fixed fee of **£700** (+ VAT where applicable) must be included. This covers the administration of your proposal *only*. Additional costs will be provided separately depending on your requirements.

Any negotiations with funders regarding changes in requested funds *must* involve the Executive at all stages. The Executive are happy to provide a letter of support once your research has been approved and the budget has been agreed. Please note that if a grant that includes a Data Management Fee is successfully funded, that project will include up to three amendments at no additional cost. If you submit more than three amendments during the life of the project you will be charged for these as detailed above (see Section 1.3.2).

If a grant is not successful but you resubmit elsewhere at a later date, please ensure that you obtain up to date costs. You should submit an amendment to your original project indicating a change in funder requesting any change in costs.

1.3.4 Costs for pre-access information

On occasion, researchers require more detailed information than can be gleaned from the ALSPAC data dictionary, e.g. cross-referenced data for inclusion in grant proposals. These will be dealt with on a case-by-

case basis and will almost certainly incur additional resource and time, which may need to be paid for. Any requests must therefore be made to the Executive to ensure sufficient time to agree requirements and/or release data under our usual agreements.

1.3.6 Costs for new data collection

Projects involving new data collection (see section 5) will need to be fully costed. The PI must liaise with the Executive to request a costing following approval of their project proposal, and before any grant is submitted. Questionnaires are currently charged at £6397.70 per A5 page per questionnaire. VAT may be added as appropriate. ALSPAC will calculate the number of A5 pages required. Costs for clinical measures and sub studies involving hands-on data collection will vary according to the requirements of the project. We require a *minimum* of **four weeks' notice** before the grant deadline in order to provide accurate costs and obtain agreement from the University of Bristol finance department. We regard accurate costings and appropriate planning as critical for providing the best support for new data and we reserve the right to decline new data collection activity requests if we do not have sufficient notice.

1.4 Management of the resource

The team is led by Professor Nic Timpson (Principal Investigator) and Professor George Davey Smith (Scientific Director).

The Principal Investigator (PI) has overall responsibility for all areas of activity in ALSPAC. The PI is supported by the ALSPAC Executive in the execution of ALSPAC activities. Members of the Executive are Professor Nic Timpson (Principal Investigator), Ms Lynn Molloy (Chief Operating Officer), Dr Susan Ring (Executive Director, Bioresource) and Dr Kate Northstone (Executive Director, Data). The Executive is supported by members of the Senior Management Team (SMT) for all operational activity.

The various committees governing ALSPAC are described below.

1.4.1 ALSPAC Executive

The PI of ALSPAC has overall responsibility for all areas of activity. Members of the Executive support the PI with the management of the study, which includes the approval of data access proposals and new data and sample collection projects, and meet on a weekly basis. The Executive refer to the Scientific Director (SD) for issues regarding scientific direction, the Board for unresolved issues/problems and to the Independent Scientific Advisory Board (ISAB) for data and sample access requests that it has been unable to adjudicate on. [The terms of reference of the ALSPAC Executive](#) are available on the website.

1.4.2 Senior Management Team (SMT)

Executive members are supported by members of the Senior Management Team (SMT) who manage all operational activity within the study. Membership of SMT comprises senior managers from the key operational teams (operations, administration, data access, data pipeline, data systems, data linkage and security, clinic, G2 and bioresource). [The terms of reference of SMT](#) are available on the website.

1.4.3 ALSPAC Board

The Board provides oversight of the Executive and supports the SD and PI with scientific strategy. The Board chaired by the Head of Population Health Science at the University of Bristol (Professor Matt Hickman) which is comprised of senior faculty, clinical and institution staff. The Board requires the presence of at least one practising clinician. The Board meets on a quarterly basis starting from September 2017. [The terms of reference of the ALSPAC Board](#) are available on the website.

1.4.4 Independent Scientific Advisory Board (ISAB)

The Independent Scientific Advisory Board provides advice, support and guidance to the SD and PI on ALSPAC's scientific direction, strategy and operations, and the furtherance of its scientific mission. ISAB reviews complex, controversial or disputed proposals for access to data and samples that have been referred on by the Executive. ISAB meets every six months and is chaired by Professor Tim Frayling. [The terms of reference of ISAB](#) are available on the website.

1.4.5 ALSPAC Ethics and Law Committee (ALEC)

Studies involving the collection of biological samples, ionising radiation, NHS staff or premises are reviewed by the [NHS Research Ethics Committee \(NHS REC\)](#). All other studies, such as those involving questionnaires or qualitative research, and policy changes to the way participants are handled go through the independent [ALSPAC Ethics and Law Committee \(ALEC\)](#). The committee meets every two months and is chaired by Dr Mike Shere. The membership comprises clinicians, researchers, lawyers and participants. [The terms of reference of ALEC](#) are available on the website.

1.4.6 Clinical Advisory Group

The ALSPAC Clinical Advisory Group provides advice and support on clinical matters to the ALSPAC Executive. The Group can provide clinical advice to researchers planning new data and sample collection grants via the ALSPAC Executive email account alspac-executive@bristol.ac.uk

1.5 Intellectual property

The University of Bristol owns the ALSPAC resource: any data generated and the biosamples collected. As such, any requests to access the data must be made through the Executive. Any data generated through an approved project must be returned to the resource to encourage ongoing use by the research community.

2. Types of data and rules governing access

A wide range of data are available through the resource. ALSPAC collects data directly through questionnaires and hands-on assessment clinics. Data is derived from biological samples and other types of media we collect such as videos, scans and audio files. We also link to data made available by various third parties.

It is worth noting that sampler sets are available on the [UK Data Archive](#). These are available for use by bona fide researchers.

The data dictionary includes detailed documentation on the data collected via questionnaires and clinics and some other subsets of data and is [freely available for download from the website](#). The variable catalogue shows every single variable name and label, grouped according to data source. In addition, a [variable searching tool](#) is available which may be preferred by some users. Searchable indexes of some ALSPAC variables are also available via [CLOSER Discovery](#). This detailed search tool provides metadata on phenotypic and environmental variables across the eight CLOSER longitudinal studies. If you have any questions regarding general ALSPAC data, please email ALSPAC-data@bristol.ac.uk (for linkage data, please see Section 2.2).

Proposals for access may be refused. Reasons for refusal include the following:

- Lack of availability of data/samples;
- Applicant not being a bona fide researcher (see Summary);
- The proposed work, in the view of the Executive, risks bringing the study into disrepute;
- The proposed work risks disclosure of identifiable information relating to any individual participant;
- In the view of the Executive, there is a conflict of interest in relation to the proposed project;
- The proposed outputs of the project are outside the scope of the ALSPAC ethical approval, funders' terms and conditions or the University of Bristol's policies and procedures;
- Access to data obtained via linkage to health and administrative records is subject to complying with the terms imposed on ALSPAC by the original data owners (see Section 2.2).
- Biological samples are a finite resource and therefore need to meet the criteria outline in Section 4.

Any challenge against a refused proposal will be considered by ISAB (described in Section 1.4.4).

2.1 Questionnaire, clinic and biosamples data

We ensure data collected by questionnaire and our hands-on clinics are made available as soon as possible after data collection is complete (normally around 6 months), with the exception of that collected from G2 (see section 2.1.1). Non-genetic results obtained from biosamples are made available as soon as all assays have been completed and the data have been cleaned. All potential identifiers are removed, and disclosure risks are considered such that data may be grouped where appropriate.

2.1.1 G2 data

Data from G2 (please see [here](#) for a summary of the data being collected) will be provided subject to extra costs. Currently, there are additional requirements around linking datasets and issues of disclosure that have to be considered. These depend on the data requested and will therefore be considered on a project by project basis.

If you are planning a proposal to access data from G2 you are strongly advised to discuss your plans with the G2 team prior to submission. The team will be happy to provide further information about data collection, availability and future plans. Please contact: alspac-coco90s@bristol.ac.uk and the team will get back to you as soon as possible.

G2 data from any individual data collection will be first released once 500 participants have been achieved. From that point on, updates will be made annually in September. This is non-negotiable: if you request data from G2, you will receive the current released version.

2.2 Linkage data

ALSPAC collect data using linkage to routine education, health, administrative and environmental records. Linkage can either be conducted at an individual level (e.g. primary care records) or an institutional level (e.g. a school). These data are collected from external organisations. To do this, ALSPAC enter into data usage agreements with the relevant data owners. These data usage agreements specify the conditions under which ALSPAC can share these data with third parties (e.g. researchers). The data access conditions differ for each data set we link to, and they also change over time. The rules governing access for these different types of data are described in more detail in Appendix Two. Necessarily, we consider the following when we adjudicate requests to access linkage data:

- The scope of the research investigation: Linked data are provided solely for the investigation of a single research hypothesis. Requested data should be relevant to the research investigation.
- Consent status: Access to linked data is frequently subject to participant consent status. Participants are free, at any time, to withdraw from the study, or withdraw their consent from linking to third-party data. Once released it is acceptable that researchers can retain the data for the duration of the research investigation, regardless of consent change. However, if additional data are requested these will be filtered on *current* consent status which may result in a different sample size.
- Changing access conditions: Data access conditions can (and do) change over time, sometimes with little warning. ALSPAC, and third-party data users, are required to comply with any new data sharing conditions. This may impact research investigations in unforeseeable ways.
- Trusted Research Environment (TRE): Projects requesting linked health and education records will have data provided via ALSPACs Secure eResearch Platform (SeRP). The SeRP platform provides full functionality for epidemiological investigations with increased governance oversight. This comes at a direct cost to ALSPAC (as we lease this infrastructure from Swansea University) but is necessary to maintain access to data. All analysis will take place in the SeRP server and it is not possible for research users to export anything from the server. Instead, all outputs come via the ALSPAC linkage team who assess them for disclosure risk.
- Data quality: ALSPAC provide linked data on the understanding that these are routine records being used for a secondary (i.e. research) purpose. We make no guarantees regarding the accuracy of the data and have no means of verifying the data. Where possible we will document the data using information provided by the data owner and provide quality information about the linkage process where available.
- International researchers: Some data usage agreements specify that data cannot be sent outside of the UK or the European Economic Area (EEA) – these requirements are beyond our control.

The ALSPAC Data Linkage Team will provide an estimate for any data access costs during project negotiations. Details of the costing structure can be found in Appendix Two.

It should be noted that we are required (as requested by the Information Commissioner's Office) to post a lay summary of all projects using linked health data on the ALSPAC website. It must remain there for 4 weeks before the project team can be provided with data, in order to give participants the opportunity to inform us if they want to opt out of any specific project.

We encourage potential users to contact the linkage team in advance of submitting their project proposal.

Please contact the Data Linkage Team (alspac-linkage@bristol.ac.uk) if you are interested in using any of the data detailed in this section. More detailed information on each type of linkage data we hold is described in Appendix Two.

2.2.1 Bespoke linkage

The ALSPAC Data Linkage Team has a strong track record of conducting bespoke linkages to both NHS and administrative records. Please contact the team to discuss your project.

Linkage to external administrative datasets is a dynamic process we use to enhance the ALSPAC data resource. This document will be updated regularly to reflect progress of this enhancement, however, for the most up to date picture of the extent and availability of linked administrative data, researchers are advised to [contact the linkage team](#).

2.2.2 Secure Research Servers

The ALSPAC Data Linkage Team have established two secure research servers. We have an analysis secure server, and a separate server that is primarily used for data curation.

The primary secure server for research analysis is the ALSPAC UK Secure eResearch Platform (UKSeRP). This is provided as a service to ALSPAC by the University of Swansea. This is a remotely accessible and effectively anonymous research environment. All analysis of linked health and education records for non-University of Bristol users will take place on the UKSeRP, this will also apply to most University of Bristol users.

ALSPAC hold cancer and mortality records for which there is no current agreement to transfer this to the UKSeRP or to permit access beyond University of Bristol staff for permitted projects. For a limited number of University of Bristol users, it may be possible to permit access to a secure University of Bristol server. The ALSPAC data linkage team are seeking permissions to move these data to UKSeRP and open access more widely.

For both servers, the protection of our participants confidentiality and the security of these sensitive data is paramount. It is not permitted for users to directly extract any data from either system (either physically or by copying information from the screen). All extracts of *population data* must go through the ALSPAC data linkage team who will conduct disclosure control checks. The extraction of *individual level* data is unlikely to be permitted (if you have a need for this, please discuss it with the ALSPAC Data Linkage Managers). It is the responsibility of the user in the first instance to ensure the data are non-disclosive (it is mandatory that all users undergo training in this before access is provided). There is a cost-recovery charge levied on the disclosure checks process (this will be described to you by the ALSPAC Data Linkage Managers as part of the application process).

2.3 High throughput array/omics data

Details of genotype data available from the ALSPAC participants are available on our [website](#) and in the data dictionary. This includes genome wide microarray data (GWAS data) and expression data.

Whole genome sequence data for 2000 individuals has been generated as part of the [UK10K project](#). Sequence data linked to a limited number of phenotypic variables is available from the [UK10K team](#). Sequencing data linked to other ALSPAC phenotypes is available on application using the normal processes described in this document.

In addition, methylation data (Illumina Infinium human methylation 450 bead array) has been generated as part of the ARIES project (Accessible Resource for Integrated Epigenomic Studies) on 1000 mother-child pairs. Aggregate DNA methylation data can be accessed via the [mQTL Database](#).

If you require any bespoke genetics data not described above, please [contact us](#) prior to submitting a proposal to discuss your needs.

2.4 Potentially identifying data

Some of the data that ALSPAC have collected could be used to readily identify study participants. These include but are not limited to: personal details such as names, addresses (including postcodes) dates of birth; “free text” information that could contain identifiers; or other clinical data in a format that could readily identify a participant.

The study team will not link *any* of these data directly to the published data resource; this would breach the agreements we have in place with participants to maintain their confidentiality and may enable a study participant engaged in research to identify themselves. Instead a split-stage process is required if a researcher wishes to make use of any potentially identifying data (e.g. to administer data collection at a specialist clinical facility, or to derive air pollution measures from residential addresses using specialist skills or equipment).

The aim of the ‘split-stage protocol’ is to create the conditions where research collaborators are able to access identifiable information, while maintaining a distinction and organisational separation between this data use and subsequent use of de-identified attribute data.

Depending on the request, the Executive may request that a researcher makes an application to ALEC to review and approve the specific request in the context of the overall project and specific hypotheses being tested. ALEC may ask the researcher to attend a meeting to explain their proposal. If a proposal requires detailed potentially identifying data (such as videotapes) to address a scientific question, then a bespoke Material Transfer Agreement (MTA) must be completed before the data will be released.

For more details about how the split-stage protocol works, please see Appendix Three. Table 1 provides details of the costs for data that require the split-stage protocol.

3. Data provision

3.1 The 'data buddy' process

When the Executive has approved your project, a data buddy will be assigned to you. Your data buddy will assist you throughout the duration of your project; advising you on how to make your formal data request, costing your proposal, administering the necessary paperwork including the [Data Access Agreement \(DAA\)](#) and the [Data User Responsibilities Agreement \(DURA\)](#), and ultimately providing you with your dataset. They will not provide statistical, methodological or other support without prior agreement and the relevant costs being covered. Standard datasets are prepared within two weeks of all paperwork being completed and invoices being settled (or purchase numbers being provided); however, some types of data may take longer (see Section 2).

3.2 Data Access Agreement

Protecting the confidentiality of the study families is a primary concern of the Executive and the ALSPAC study team. This is a particular issue as ALSPAC is a regionally based study that recruited children born within a defined period. The PI, and any member of their team who will directly access the data, will be requested to adhere to a number of clauses regarding confidentiality (please see our [DURA](#)). It is the PI's responsibility to ensure that all their staff (or members of the research group) are known to ALSPAC, have completed a confidentiality form, and are made aware of, and are adhering to, their data usage responsibilities (including all relevant ALSPAC policies and procedures).

In addition, the Data Access Agreement (DAA) is a legal document laying out the terms and conditions under which ALSPAC shares data and is **non-negotiable**. It must be signed by the Principal Investigator (PI), the recipient institution's legal signatory and ALSPAC's legal signatory. If the study includes researchers at different institutions who will be receiving the data, a DAA will need to be completed for each institution. A sample copy of the DAA is available [on our website](#). We recommend you share a copy with your legal signatory prior to applying for access to our data to ensure they are willing to sign up to the terms. This is particularly applicable to institutions in the United States – we would encourage any prospective data user in the US to check the terms of the DAA prior to applying for access. No data will be released until these documents have been signed and returned.

If for some reason an Institution cannot sign the DAA there are other options that could be considered to facilitate your research:

1. Data is released via UKSeRP under an amended DAA which has reduced information security requirements. In this scenario datasets are not physically shared, instead data will remain in UKSeRP and analyses will take place via remote access to the secure environment, with restrictions and controls on data upload and download from the environment.
Additional charges apply in this case: Each project will be costed on a project-by-project basis and the cost depends on several factors including:
 - Length of project (time)
 - Number of users requiring access to the data
 - Which statistical software is required in UKSeRP
2. A researcher comes to work on ALSPAC premises to analyse the data.
Additional charges apply in this case: Price on application.
3. A researcher pays for a member of ALSPAC staff, or a member of staff at an eligible institution which would sign the DAA, to analyse the data on their behalf.
Additional charges apply in this case: Price on application.

3.3 Unique project identifiers

For each project a unique set of identifiers is created. If a PI has more than one project, separate identifiers will be attached to each dataset relative to each project, thus datasets *cannot* be combined.

3.4 Secure data transfer

All data transferred electronically must be encrypted using AES-256 encryption (this can be achieved using compression tools such as WinZip or 7-Zip). Data users will be assigned a password for a project when the first dataset is provided.

4. Access to biological samples

ALSPAC has collected many biosamples since the start of the study. There are over 250 different sample types on the database which are defined by:

- Participant group (e.g. original cohort, mother, father, CoCo90s (Children of the Children of the 90s))
- Main sample type (e.g. plasma or urine)
- Additives (e.g. EDTA or heparin plasma)
- Time point (e.g. antenatal, 7yr, 17yr etc.)
- Aliquot size.

Details of available samples is provided [on our website](#) and on the [UKCRC Tissue Directory](#).

Ethical approval was obtained for all sample collections (details for specific samples available on request). This usually included consent for future research including genetic studies. Occasionally analysis will not be covered by existing ethical approval and further review will be needed before samples can be released. Where possible samples are stored in multiple aliquots to limit the need for freeze thaw cycles and thereby enable as much analysis as possible. However, the number of aliquots varies between sample types and for some samples (e.g. buffy coats, hair, teeth) only one aliquot was produced.

If you are a planning proposal to access biological samples you are strongly advised to discuss your plans with the laboratory team prior to submission who will be happy to provide further information about samples or laboratory procedures, contact Bristol Bioresource Laboratories (bbl-info@bristol.ac.uk) -*please allow 10 working days for a response.*

To use existing biological samples or to carry out specific genotyping on ALSPAC DNA you need to complete the [online research proposal form](#) describing your proposed research. You must ensure you complete the specific sections on the biological samples and genotyping including details of the type of sample required, amount needed and, in the case of DNA, the minimum concentration required.

The majority of material in the ALSPAC biorepository are finite samples, i.e. there are limited stocks available. The exception is lymphoblastoid cell lines and DNA derived from these cell lines as they can be grown to provide more material. The Executive are responsible for ensuring that samples are used for projects that maximise the amount of data obtained from available samples and that these data are subsequently made available to other researchers.

Proposals that request finite samples must satisfy the following criteria to be approved:

- Scientific strength of the proposal must justify use of ALSPAC cohort samples, i.e. the data obtained from the samples will be analysed in conjunction with other data held by ALSPAC. Requests for projects that could be carried out using samples available elsewhere will not be approved.
- The analysis proposed does not already exist for the same time point. Requests to repeat or carry out very similar analysis will not be approved unless there are compelling reasons.
- Evidence must be provided to show methodology is appropriate given the processing history of the samples, e.g. evidence from published literature or pilot data generated on samples processed in a similar manner. ALSPAC samples will not be released for method development.
- The assay test platform should have proven quality assurance measures in place.
- The methodology should include measures to ensure the quality of any remaining sample is not jeopardised and can be used in further assays which can be used on freeze thawed samples.
- The volume requested is reasonable and does not seriously deplete the resource.
- The work proposed is within the scope of the consents obtained for the specific samples.

Final aliquots of the majority of sample type will be retained for future global discovery projects. The exceptions to this are those sample types where only one aliquot was originally produced (hair, teeth, and whole placentae). In addition, white blood cell pellets (either buffy coats or peripheral blood lymphocyte preparations) are reserved for production of DNA, RNA or cell lines since they were specifically collected for these purposes. White blood cells will not be released as DNA. RNA and cell lines will be produced in-house

and managed by the ALSPAC team. Reasonable requests for DNA will be approved and an appropriate aliquot provided.

Proposals which might significantly deplete stocks of finite biological samples or have insufficient evidence of the validity of an assay will be subjected to independent peer review (by a sub group of ISAB) to ensure they meet the conditions above and that the amount of material required is acceptable. The ALSPAC Executive will notify you of this requirement where necessary. Please note this means the approval of requests to access ALSPAC samples will take considerably longer than those for data alone and we try to complete the process within 6 weeks.

If two or more researchers are requesting the same samples either to carry out the same analysis or a different assay the proposals will be referred to ISAB who will make the decision regarding which proposal (if any) offers the best use of the material.

If a request is approved samples will be supplied with the following conditions:

- Costs incurred in providing samples will be covered by the applicant. These will include costs for retrieval, additional processing necessary for the specific project, shipping costs (both out and return) and linking data. Costs will be provided on a case by case basis depending on the work involved and may be subject to VAT.
- All results generated from samples must be returned to ALSPAC for inclusion in the data resource and will be made available to other researchers.
- Where it is possible to use samples that have been thawed and refrozen, samples which have been returned from other projects will be supplied in preference to unused stock if available.
- ALSPAC reserve the right to specify where analysis will be carried out in order to ensure results obtained are comparable to existing data.
 - Illumina bead chip analysis on ALSPAC samples will be run in house (e.g. HumanMethylationEPIC BeadChip).
 - LGC genomics hold sets of ALSPAC DNA for single SNP genotyping and their service is normally quicker and more economic both in terms of DNA use and genotyping costs than supplying DNA to individual researchers. Any order to genotype ALSPAC DNA at LGC Genomics must be placed via the ALSPAC laboratory.
 - We have preferred laboratories for outsourcing biochemical and metabolomic analysis please contact the laboratory to discuss such requests.
- BBL will advise if current ethical approval will cover a project. For some work, it will be necessary to submit a new application and BBL will assist with this process.

Samples, including DNA, are provided under the terms of a Material Transfer Agreement ([MTA](#)) or in the case of University of Bristol staff a Service Level Agreement ([SLA](#)). Each agreement will include a project specific appendix detailing the samples ALSPAC will supply and the analysis to be completed. Samples will not be released until an agreement has been completed and signed. Please note that for samples that are classified as relevant material under the Human Tissue Act (HTA) the [HTA MTA](#) should be used instead. Once your proposal is approved we will provide word files with the specific appendix for you to complete, sign and return to us.

Please note if your project requires grant funding samples will be reserved until the outcome of the first funding application is known or 12 months whichever is shortest. After this time ALSPAC cannot guarantee sample availability as they may be released to other projects. Researchers will be expected to discuss plans for further funding applications with the Executive.

Note if a participant withdraws consent whilst samples are being analysed researchers may be asked to destroy relevant samples and provide evidence that this has been completed. Costs of supplying samples cannot be refunded in these cases.

5. New data collection

The ALSPAC study team collects new data from the study families using self-completed postal and online questionnaires and at ALSPAC study clinics. Data collection may be on the whole cohort or on a specific sub sample. The current plan for data collection can be viewed on our website.

Researchers are encouraged to apply for funding for data collection at least 18 months in advance of the proposed start date for data collection. The costs of new data collection must be agreed with the Executive (described in Section 1.3.6).

The following are essential requirements for new data collection to be undertaken (additional requirements may also apply on a case by case basis):

- A requirement of ALSPAC's core funders is that a member of the Executive (or a Bristol-based scientist nominated by the Executive) is named as a co-applicant so they can act as guarantor for the proposed new data.
- All new data collection is discussed with our participant advisory group (see Section 5.1.10) to test acceptability. We would strongly encourage researchers to provide sufficient time between submitting their proposal to the Executive and their grant deadline so that the participant advisory group may consider the measurements, particularly if they are sensitive. If this is not done, researchers must understand that approval to collect the new data is conditional on our participant advisory group agreeing with the collection or providing no evidence to suggest that a significant proportion of participants would be upset or refuse such collection.

Ethical approval will be required from either ALEC or an NHS REC depending upon the nature of the study (Section 5.2). We appreciate that in most cases this will be sought after grant submission, but no data collection will be undertaken without appropriate ethics approval.

5.1 Prior to data collection

Approval for any questionnaire or hands-on data collection (as part of a questionnaire, main clinic or through a sub-study) must be obtained from the Executive *before* funding is sought. Once the proposal has been approved in principle by the Executive, SMT will review the proposal in more detail and assess feasibility, resourcing, timescales, recruitment, any case selection requirements, participant overload and other practical and ethical considerations. SMT will then advise the PI if there are any issues which need to be addressed at an early stage in order for the study to proceed. The timing of new data collection is subject to both participant and staff burden. We reserve the right to negotiate the timing of any new data collection once it has been funded.

5.1.1 Management of the data collection exercise

The study PI is primarily responsible for the study and ALSPAC will play a supporting and advisory role in delivering the project. ALSPAC is required to adhere to certain policies, particularly around contact with participants and the feedback of results, which protect the confidentiality of participants. All studies will be obliged to conform to these.

5.1.2 Early planning of the data collection exercise

A planning ('set-up') meeting will be arranged between the PI and the ALSPAC study team in Bristol as soon as we have confirmation that a new data collection exercise has been funded. The responsibility for project deliverables, objectives, timescales, finances and policies for the study will be agreed at this meeting. Changes following this setup meeting will need to be agreed by both parties, and major changes to the study design may need to be submitted to the Executive as an amendment to the original proposal before they can be actioned.

Particularly during the early stages of the study design, regular meetings will be required to facilitate planning and problem solving.

Prior to commencing data collection, ALSPAC staff will work through a 'pre-start checklist' with the PI to ensure that the project is ready to begin, and implementation plans are fit for purpose. Any outstanding actions will need to be identified at this stage and agreed with the PI for data collection to begin.

5.1.3 Case selection for sub-studies

The PI will define the criteria for case selection where appropriate, based on the ALSPAC data and samples available. An ALSPAC member of research staff will produce the case selection in collaboration with the PI. The case selection criteria originally requested by the PI in their application may need adjusting, depending on the number of participants who are ultimately available to take part. However, once data collection has started changes to the case selection criteria should be avoided wherever possible.

In order to prevent overburdening of study participants, ALSPAC may seek to manage the number of sub-studies taking place at any one time.

5.1.4 Controls in sub-studies

ALSPAC has an ethical requirement to ensure that where individuals are recalled for assessment on the basis of a particular characteristic all necessary steps are taken to ensure that disclosure of this characteristic in relation to an identified individual is avoided. A study may therefore be required to include controls (or additional participants in order to protect disclosure risk in cases) in order to mask the characteristics of participants to researchers, staff and other participants. The number of controls/additional participants required and any additional steps needed to maintain confidentiality will vary between studies, and will be determined in conjunction with ALEC.

5.1.5 Electronic data collection systems

A database for the collection and storage of data will be set up by ALSPAC staff in conjunction with a member of the PI's team who can then input variables into the framework system provided. This will ensure that the variables collected are labelled in a consistent and systematic manner, comparable with any previous studies, and ultimately allow the integration of the data collected into the main ALSPAC resource.

5.1.6 Administration

The data collection exercise will be set up on the ALSPAC participant contact management and booking system ('Arcadia') to allow for the printing and mailing of invites to participants, phone call reminders and the like. It will also provide a record of all contacts participants receive for the study.

5.1.7 Participant documents

ALSPAC will work with the PI to put any specific study documents (invitation letters, information sheets, consent forms etc.) into the ALSPAC 'house style'. This ensures that the design, wording and information given in each study are consistent. The ALSPAC Communications and Participation team and our Original Cohort Advisory Panel (OCAP, See Section 5.1.9) must sign off any paperwork prior to submission for ethical approval.

5.1.8 Ethical approval

ALSPAC will advise the PI on their ethical application and where to submit their proposal, although the application must be completed and submitted by the PI. Those studies which do not involve human tissue, use of NHS staff or premises or ionising radiation should be submitted to [ALEC](#), others to an NHS REC of the PI's choice. The REC with most experience of ALSPAC study proposals is South West – Central Bristol. A University of Bristol Research and Enterprise Development (RED) [research registration checklist is available](#) which should also be submitted for University of Bristol governance purposes for those proposals seeking REC approval.

5.1.9 The Original Cohort Advisory Panel (OCAP) and other participant advisory forums

Depending on the nature of the data collection exercise it may be appropriate to submit the study protocols, participant documents and so on to OCAP or other participant groups as required. ALSPAC will advise on whether this is necessary, and PIs may be asked to attend an OCAP meeting to explain their study. ALSPAC will work with PIs to incorporate feedback from participant advisory forums into their study design.

5.1.10 Piloting

ALSPAC strongly advise that a pilot takes place for each new data collection exercise, which must be funded by the PI. ALSPAC will work with the PI to organise and conduct this pilot. The pilot will ensure that the study design, methodology and data collection systems are fit for purpose.

5.1.11 Collection of new biological samples

Any request to collect new samples from ALSPAC study participants must be approved by the Executive. The Executive will provide details of the costs which need to be covered, these will include costs of contacting participants, collecting the samples, processing and storing samples with the Bristol Bioresource Laboratories (BBL), shipping to external laboratories and any in house analysis by BBL. Sufficient funds must be in place before sample collection can commence. Sample collection may be part of a main clinic sweep or a sub-study.

In order to maximise the value of the ALSPAC resource residual samples will be stored for future use. Priority will be given to the analysis outlined in the original proposal, but sample remains will be aliquoted, added to the ALSPAC biorepository and made available for further analysis.

Appropriate ethical approval must be obtained for all sample collections. Where the sample collected is classed as “relevant material” under the Human Tissue Act (HTA), a favourable opinion must be obtained from an NHS Research Ethics Committee (NHS REC).

Consent forms and participant information sheets must be approved by the Executive Director, Bioresource (who is also the HTA designated individual) before submission for ethical approval. These should include a statement asking for generic consent for future non-genetic research and, if applicable, a separate statement for future genetic research. Participants should have the option not to consent for these, in which case residual samples will not be stored in the biorepository for future use.

Before collection begins the collection and processing protocols must be agreed with the Executive Director, Bioresource and the ALSPAC Clinic Manager. This will include details of how samples will be labelled to ensure samples entering the biorepository are uniquely identifiable.

Some sample analysis can be carried out in house by BBL or samples can be shipped to other laboratories for analysis. An MTA will be set up with receiving laboratories before samples are released (examples of an agreement for HTA relevant materials and other samples are [available on the ALSPAC website](#)). All data derived from samples from ALSPAC participants will be incorporated into the main ALSPAC resource.

5.2 During data collection

5.2.1 Response rates

Response rates are unpredictable and cannot be guaranteed, especially amongst the study young people. Attention should be paid to ensuring that the case selection is large enough relative to the target numbers. ALSPAC will advise the PI on measures which may be taken to increase the response rate, which will need to be included in the funding coming to ALSPAC if not included in the original costings. The [ALSPAC cohort profile papers](#) give historical response rates for various projects. More recent response rates are available through the relevant documents in the [data dictionary](#).

5.2.2 Personal data and confidentiality

Under no circumstances will ALSPAC provide the PI or their study team with personal details (names and addresses) of participants unless the participants have consented to take part in their particular data collection exercise, in which case such details will be given for administrative reasons only (for example if it has been agreed that the PI's staff will make telephone bookings with participants who have responded to a study invite). All data collected must be recorded against an anonymous study ID. Mailings to participants will be sent via the ALSPAC administration team, unless agreed otherwise.

Any participant personal data must be stored and transferred in a secure fashion, in line with our [data management policy](#). Any personal data used should be returned to ALSPAC on completion of the study.

5.2.3 Dealing with participants

ALSPAC participants are valuable long term committed study members who may withdraw from the study if they have a bad experience. The ALSPAC study team will always make initial contact with participants, even if the study is being conducted by an external team. PIs are reminded that they have a wider responsibility to ALSPAC when they or their staff are dealing with participants. If there are any problems or queries raised by participants, they should be referred to ALSPAC immediately.

The ALSPAC Participation Team will meet with the appropriate staff and provide an ALSPAC background briefing including some frequently asked questions. This is important because participants do not discriminate between different studies, and would expect any person contacting them on behalf of the study to be aware of all other relevant aspects of ALSPAC's work.

5.2.4 Disclosure and Barring Service (DBS) checks

Any staff who will be dealing with participants face-to-face will require a DBS check. The PI must ensure that any members of their team who are meeting participants are approved.

5.2.5 Sending study invitations

It is important that all data collection exercises are coordinated alongside other activities taking place within ALSPAC, particularly with respect to any contact made with participants. ALSPAC will agree a mailing/invitation schedule with each study, which may be affected by other activities taking place concurrently within ALSPAC.

5.2.6 Feeding back contact information

If new or updated contact information or other administrative information is obtained during the course of the new data collection exercise by the study team, this should be referred back to ALSPAC to update its participant contact management system. A record of all contacts made with participants is required, which will need feeding back to ALSPAC at regular intervals. This will include any phone contacts with participants.

5.2.7 Feedback of research findings

The ALSPAC [Disclosure Policy](#) states that information shall not, as a general rule, be disclosed to participants. This general policy should only be set aside when it is reasonably certain that the benefits of disclosure clearly outweigh any possible risks to the participants or their families.

5.2.8 Feedback of incidental findings

Researchers are expected to comply with the ALSPAC Incidental Findings policy. Feedback of incidental findings will be discussed at the new data collection planning stage.

5.2.9 Return of data

Any data generated through an approved project must be returned to the resource to encourage ongoing use by the research community. The PI is required to provide ALSPAC with a copy of *all* data collected and/or generated from ALSPAC participants, including scanned images, recordings etc., to be archived for future use. This may be required during the data collection period or once data collection has finished; this will be

agreed before data collection begins. Since data are collected using an anonymous ID unique to each study, it is impossible to link to any other data from the main resource until they are returned.

5.2.10 Backing up data

ALSPAC will arrange for data collected to be backed up on a regular basis on those studies where ALSPAC staff are collecting the data. In studies where the PI's team is collecting data backing up is their responsibility. However, ALSPAC will seek to take periodic copies of all data to reduce the risk of data loss. Clear arrangements to carry this out must be agreed before the start of the study if data collection is to be carried out off site or remotely to ALSPAC's standard data collection drive.

5.2.11 Feedback of project statistics/reporting to PIs

ALSPAC will provide regular reports on the progress of each study, the frequency of which will be agreed at the set-up meeting. ALSPAC will indicate at the earliest opportunity where there are risks or issues which need to be addressed.

5.3 After data collection

5.3.1 Participants' personal details

Once data collection is complete, all participant contact information a researcher may hold must be destroyed, having returned any updated contact details to ALSPAC.

5.3.2 Data collected

The PI is required to return a copy of the raw, unedited data collected to ALSPAC for archiving. Any processed datasets/derived variables and the syntax/scripts used in their creation should be returned to us once produced for inclusion in the resource. IDs will be converted to our centrally held ID.

5.3.3 Additional variables

Once data collection is complete any additional variables required to be added to those collected as part of the study can be arranged with an ALSPAC data buddy, who will be assigned to the study (see Section 3).

5.3.4 Data cleaning and built files

If data cleaning costs have been included in the grant award, ALSPAC will clean all data collected and provide a clean, built file for subsequent use. The delivery date of this file will be agreed in advance with the PI. ALSPAC will usually provide this service for data collected using ALSPAC staff on a PI's behalf. If the PI wishes to use their own staff to conduct data cleaning, it is their responsibility to provide ALSPAC with both raw and clean data files, along with the appropriate documentation in a timely manner.

5.3.5 Exclusive data access

Where a researcher (member of the ALSPAC team or an external collaborator) has secured funding for the collection and analysis of new data, they may apply for a period of exclusive access for a period of **up to 6 months** from the point at which a cleaned dataset is made available to them (please use the form available on our website for this purpose: [exclusive data request form](#)) The request must demonstrate a planned analysis associated with the new data collection that must be delivered to the specific funding scheme which is responsible for the collection of the data referred to.

Bearing in mind that researchers who collect new data will invariably have lead-in time associated with the project (as snapshots of the data can be provided prior to release), the reason for exclusive access must be clearly defined and justified in relation to the funded research. In order to comply with our funder's positions on exclusive access, which is to make all data available as quickly as possible, the Executive will consider each

request on a case-by-case basis. We will only grant a period of exclusive access if there is a clear reason for withholding data from other data users as describe above.

If a request is approved, then during the exclusive access period the ALSPAC Executive will still consider requests for access to the restricted data, but permission must be sought from the researcher who funded the data collection to release the data or to explore the potential for collaborative analysis. If the funding researcher declines to share/collaborate, the restricted data will not be available to others until after the period of exclusive access. After the embargo period all ALSPAC data will be released and made available to external researchers (within the usual constraints related to scientific legitimacy and disclosure risk).

6. Summary of researcher responsibilities

This section summarises the main responsibilities of any researcher wishing to work with the ALSPAC resource. The same rules apply to *all* researchers regardless of whether they are a member of ALSPAC staff, a new collaborator or a long-term collaborator.

6.1 Project proposals

It is important to note that the Executive do not consider overlap when approving projects, except where a request is made for finite samples. It is up to the researcher to determine whether any project they are proposing is not already being worked on by any other researcher and to be aware of any other researchers who may be working in their area of interest. The Executive may suggest possible collaborations, but the researcher is under no obligation: this is a suggestion rather than a pre-requisite of project approval. Summaries of all approved projects are available [online](#).

6.2 Funding

All projects must be appropriately funded.

Please submit your online proposal at least *one month* prior to any funder's deadline date: Our finance team need sufficient time to be able to provide you with any appropriate costings. We request that any negotiations with funders **MUST** include the Executive at all times

A researcher must send the Executive a copy of the final submitted grant, the award letter and any other relevant documentation when it is received; the Executive will arrange a set-up meeting once funding is approved to agree the objectives, timetable and staff required to meet the grant commitments. This will be followed by annual review meetings to ensure the milestones are being met. The PI must make every effort to attend these meetings. It is the researcher's responsibility to ensure there is no conflict between their funder's terms and conditions and ALSPAC's formal paperwork (Data Access Agreement, Data User Responsibilities Agreement and Material Transfer Agreement, where applicable).

6.3 Data access

Researchers must adhere to the ALSPAC Access Policy and data user responsibilities at all times. Researchers must also comply with the terms of the ALSPAC DAA and MTA where applicable. Current and future access is at risk if any researcher is found to be breaking these rules. In particular, data must **NOT** be shared with any other researchers without going through the Executive and the data buddy team. Serious breaches of data access rules will be prosecuted to the full extent of the civil or criminal law.

6.4 Information Security

Data users must maintain sufficient information security controls to protect the data from unauthorised use or access. The minimum information security requirements are described in Appendix Four. In particular, we are looking for a strong institutional commitment to Information Security (as evidenced by a comprehensive Information Security policy), a commitment to store and analyse the data in a secure system, and staff requirements to maintain confidentiality (as evidenced by an employment contract). Where we have any concerns around security, we reserve the right to complete a Data Privacy Impact Assessment (DPIA) which may increase the time required to approve a project.

Data users must not share, or provide access to, data with anyone outside of their approved user group (as defined in your project approval). If you need to add additional data users, please make an amendment to your project proposal through the online system.

It is possible that disclosure of a study participant may occur accidentally; researchers must not attempt to identify an individual. If a researcher does inadvertently identify a participant they inform the Executive as quickly as possible.

6.5 Confidentiality/security breaches

Any breaches of data security must be reported immediately to the Executive who will pass the issue on to the ALSPAC Chief Operating Officer for investigation. Examples of data security breaches include (but are not limited to):

- Any unauthorised person (i.e. has not signed a data access agreement for the relevant data set) gaining access to ALSPAC data;
- Sharing ALSPAC data with unauthorised persons;
- Failing to ensure data are sufficiently encrypted during transport;
- Sharing login details that permit access to ALSPAC data.

Please refer to Appendix Four for further information on our information security controls.

6.6 Destruction of data and return of derived variables

One month prior to the project end date provided on the Data Access Agreement, your data buddy will be in contact to check if you require an extension. If not, you will be expected to confirm deletion of your supplied dataset and return a copy of any variables you have derived from the data along with appropriate documentation (see Appendix Five). Failure to confirm deletion of the original dataset within 4 weeks of the end of your project may risk your future access to the resource.

As the University of Bristol owns the ALSPAC resource (see Appendix Five for further details), any derived variables (such as data obtained as part of a new data collection exercise, new sample analyses, or newly derived variables coming from secondary analyses) created as part of any research project will be incorporated in to the main resource and made available to all researchers. We would expect you to return the relevant data to your data buddy (for the IDs to be replaced) within 4 weeks of the end of your project. Failure to produce derived variables at this point may risk your future access to the resource.

6.7 Publication

6.7.1 Peer reviewed papers and other research output

All full papers must be [sent to the Executive](#) for approval along with a [completed papers checklist](#) prior to journal submission. Please note that if there are any **significant** changes to the paper after Executive approval, re-approval must be sought. This includes any research output being placed in the public domain (for example working papers or non-peer reviewed papers). The Executive will process all papers within two weeks of receipt. The Executive read all papers to check confidentiality is protected and to ensure that the paper will not bring the study into disrepute. The Executive reserves the right to require that any paper which could potentially breach the confidentiality of any ALSPAC participant(s) be withheld from submission for publication. The Executive will work with the authors to overcome such breaches.

The Executive also provide advice and feedback to authors where we feel this may be helpful, but their role is not to provide formal peer review: The applicants/authors are not duty bound to follow the advice provided. Under all circumstances the ALSPAC Executive reserve the right to submit letters or papers for publications in response to any paper to explain study procedures or to express a coherent scientific argument.

A checklist of requirements for ALSPAC papers along with some accompanying notes explaining these requirements and containing appropriate text to insert is available with the papers checklist. A completed checklist must be included with each paper submitted for approval. Please note, this also applies to working

papers and papers from research consortia. Researchers should let the Executive know when a paper is accepted and send through an electronic copy of the final published version.

A list of publications arising from the study can be found on the [study website](#).

For papers using data gathered from participants at 22 years and onwards, you should also include a citation to REDCap, as the tool that ALSPAC have used to collect the data. Please see the [REDCap website](#) for details.

6.7.1.1 Open access

6.7.1.1a Papers

ALSPAC fully supports the [Wellcome](#) and [RCUK](#) policies on open access. In summary, this means that if a) the specific research presented in a paper is wholly or partly funded by **Wellcome** or b) any contributing author is wholly or partly funded by Wellcome (via salary or fellowship/studentship) any publication must be made open access. It is the senior author's responsibility to ensure that any papers published comply with this policy. It is the responsibility of the grant-holder under part a) above, or the individual author(s) under part b) above to cover the costs of making a publication open access. Please see the [Wellcome website](#) for more information. If your research is wholly or partly funded by the one of the research councils in the **RCUK** you are required to make your research paper Open Access either via PURE, Bristol's open access institutional repository (for University of Bristol staff), or by publishing in a compliant journal. Please see the [RCUK website](#) for more information.

Please note that as Wellcome is a core funder of the study, any secondary analyses of ALSPAC data should also comply with the Wellcome open access policy. We therefore request that all articles are published in open access journals, if this is not possible, e.g. due to a lack of funds, please ensure articles are made freely available online through your Institution's website or other open access repository. You may wish to consult the [Journal Checker](#) tool to identify journals that are compliant with open access.

A number of charities provide open access support. Please refer to the [Charity Open Access Fund](#) for up to date information.

6.7.1.1b Journals

A number of journals request that datasets used in a publication are deposited in publicly available resources. The informed consent obtained from our participants and the data management policy will not permit this. We therefore request that the following statement be used by researchers in such cases: "The informed consent obtained from ALSPAC participants does not allow the data to be made freely available through any third party maintained public repository. However, data used for this submission can be made available on request to the ALSPAC Executive. The [ALSPAC data management plan](#) describes in detail the policy regarding data sharing, which is through a system of managed open access. Full instructions for applying for data access can be found here: <http://www.bristol.ac.uk/alspac/researchers/access/>. The ALSPAC study website contains details of all the data that are available (<http://www.bristol.ac.uk/alspac/researchers/our-data/>)".

6.7.1.1c Grant applications

Some funders request that data be made publicly available. We recommend the same statement above is used in such cases.

6.7.2 Theses

We request that we are provided with an electronic copy of any theses that use ALSPAC data as soon as possible after a degree is awarded.

6.7.3 Policy briefings

We encourage researchers to produce policy briefings wherever possible. We ask that these or similar documents are shared with us prior to release. This ensures we are aware of ongoing work and means our communications team can work with you to ensure details are correct and provide advice and support where necessary. Please submit any documents to alspac-exec@bristol.ac.uk.

6.7.4 Reports and other publications

Any reports to funders that will be made publicly available and describe the data must follow the same approval proposal as full papers (See section 6.6.1) and must be approved *prior* to sending to the funder. The reporting guidelines provided in the papers checklist must be adhered to for reports. We request that we are provided with an electronic copy of any reports and other publications that use ALSPAC data as soon as possible.

6.7.5 Conference proceedings and other presentations

ALSPAC do not need to see submissions to conferences unless this is the primary mode of publication in your discipline. For example, computer science. In such cases we request that abstracts are submitted to the ALSPAC Executive for approval as per peer-reviewed papers (see section 6.6.1). However, we request that any talks or posters presented at conferences or other meetings using data from ALSPAC must include an acknowledgement to the study and the participants along with the study logo. Please see the completed papers checklist for suggested wording.

6.7.6 Other output

Any other output that will be made available in the public domain must be approved by the ALSPAC Executive prior to it going live. For example, online tools for exploring data, metadata on third party websites etc.

6.8 The media

All press releases on research arising from the study must be written in conjunction with our communications team. We reserve the right to publish press releases on certain articles and expect the lead author of the article to agree the press release with the public relations team and to be available to deal with media enquiries and interviews. We may also ask authors to prepare a précis of important papers and/or lay-summaries to include in reports to funders and future applications for future core funding.

Appendix One: Example data access costs

Note that VAT will be charged where appropriate. Please see Appendix 2 for additional costs incurred for linked data.

Example 1:

Standard request of data available in the data warehouse and an additional DAA

Standard access Fee	£1750
DAA for one additional Institution	£355
Total Cost	£2105

Example 2:

Standard request of data available in the data warehouse, two additional DAAs, genetics and methylation data and 10 text data fields for coding

Standard access Fee	£1750
DAA for two additional Institution	£710
Genetics and methylation data	£750
10 text fields: Split stage protocol	£750
Total Cost	£3960

Example 3:

Standard request of data available in the data warehouse, G2 data, DXA images and child and maternal medication data (not standard data for disclosure reasons)

Standard access Fee	£1750
G2 data	£1250
Digital images (e.g. DXA scans at age 9)	£1250
Maternal and child medications	£500
Total Cost	£4750

Example 4:

Amendment to original request (any number of variables), to add GWAS data from mother and child

Standard amendment Fee	£500
GWAS data	£750
Total Cost	£1250

Appendix Two: Linkage data

Here we provide more detailed information on each of the different types of linkage data we currently hold.

For all these data, access arrangements are subject to change at the discretion of the data owner or due to change in legislation or ethical norms. There are limitations on how these data can be shared outside of ALSPAC, outside of the UK or European Economic Area (EEA).

1. Schools Data (provided by the Department for Education)

- This category includes data sourced from the National Pupil Database or from Local Authorities.
- Schools data are provided at a pupil and establishment level.
- Data are anonymised before release.
- Data are available for participants who have been sent a privacy notice describing our use of their data and have not dissented.
- If you require tailored data (e.g. specific subject grades at GCSE) additional disclosure controls will be required and such requests will be costed on a case by case basis.
- Schools data can only be used to investigate hypotheses which will promote the education or well-being of children

2. Further and Higher Education Data (provided by the Department for Business, Innovations and Skills)

- We have established proof-of-principle access to FE and HE records and are willing to consider applications based on accessing these records.
- This category includes data from the Individual Learner Record dataset (further education) and the Higher Education Statistics Agency (HESA) (higher education).
- Data are anonymised before release.
- Data are provided for consenting index children only.
- This data can only be used to investigate hypotheses which will promote the education or well-being of children

3. NHS (National Health Service) and ONS (Office for National Statistics) data

- This category includes data from the Death and Cancer registries.
- Currently there is no agreement to share these data with researchers outside of the University of Bristol.
- The ALSPAC Data Linkage team is able to provide *aggregated* data which has been subject to statistical disclosure checks (e.g. a count of how many ALSPAC mother have a registered breast cancer).
- The ALSPAC Data Linkage team may undertake analysis of these data 'in house'. This is subject to agreement, capacity and the recovery of direct costs.

4. NHS Primary Care Data

- Primary care data, via Electronic Patient Records (EPRs) is available from ALSPAC or, potentially, through ALSPACs existing linkage to the [Central Practice Research Datalink \(CPRD\) \(subject to separate agreement with CPRD\)](#).
- CPRD: ALSPAC has linked to the CPRD database. Coverage is limited (by CPRDs population coverage) to ~500 enrolled index children. CPRD expect to increase this coverage over time. Access to these data is conducted using the CPRD Safe Setting (in London), this requires all analysis to take place in London. The ALSPAC Data Linkage team will arrange for a dataset of ALSPAC variables to be 'merged' into a copy of CPRD. This process is subject to statistical disclosure control checks which may lead to changes being made to the data to reduce the possibility of disclosing the identities of study participants/CPRD cases.

- ALSPAC Collected EPRs: ALSPAC have collected the index children’s EPRs directly from participants’ practices and have extracted at least some life-course data on ~80% of enrolled index participants. These data are available to request by UK-based researchers. These data are subject to stringent anonymisation processes. These may, depending on results of project-level privacy impact assessments, result in the application of controls such as data transformations that could result in significant data change in some or all variables. These data are made available to researchers via ALSPACs SeRP (Trusted Research Environment).
- The ALSPAC Data Linkage team may undertake analysis of these data ‘in house’. This is subject to agreement, capacity and the recovery of direct costs.

5. NHS Secondary Care Data

- ALSPAC have linked to the Hospital Episodes Statistics (HES) dataset and the Mental Health Services Data Set.
- These data are subject to stringent anonymisation processes. These may, depending on results of project-level privacy impact assessments, result in the application of controls such as data transformations that which could result in significant data change in some or all variables or the access of the records in a dedicated secure research environment (which can be accessed remotely).
- Currently there is no agreement to share these data with third party researchers who are not University of Bristol staff (this does not include honorary members of staff).
- The ALSPAC Data Linkage team may undertake analysis of these data ‘in house’. This is subject to agreement, capacity and the recovery of direct costs.

6. Geospatial Records

- ALSPAC have linked participants to a range of natural and social environment records that are indexed by reference to a place (e.g. a participant’s home or school) rather than a participant.
- Access to geospatial data is subject to controls designed to maintain the confidentiality of participants.
- The ALSPAC Data Linkage team can be contacted to discuss requests for new geospatial linkages.

7. Data access costs for linkage data

The below table and examples overlap outline data access costs for projects seeking to use linked health and education data via ALSPACs Secure eResearch Platform (SeRP):

Item	Details	Cost
UKSeRP costs		
UKSeRP base cost – year 1	All projects require this and covers use of the system for 1 year	£1000
User cost – year 1	This is per user and covers 1 year; all projects require at least 1 user	£500
Disclosure control – year 1	All projects require this. It covers 2 bulk* output disclosure checks. Additional output checks may incur further charges	£600
UKSeRP additional years	Each additional year is costed based on calculation from first year costs. E.g. year 2 of a 1 user project = $(1000+500)/2 + 600 = 1350$	$(UKSeRP \text{ base cost} + \text{User cost})/2 + \text{Disclosure control}$
File building		

Item	Details	Cost
Building education data		£600
Building GP data		£600
Building HES data		£600
Building MHSDS data		£600
Building registry data		£600
Ethics		
NHS REC amendment	Required for all projects using linked health records	£360
HRA CAG application	Only required for projects seeking to use linked health records where outcome/exposure is particularly sensitive e.g. mental/sexual health	£1200

* Each check can contain multiple items (e.g. summary tables, graphs)

Costing examples

Example 1:

Request for access to linked education data for 1 user for 1 year:

UKSeRP base cost – year 1	£1000
User cost – year 1	£500
Disclosure control – year 1	£600
Building education data	£600
Total cost	£2700

Example 2:

Request for access to linked health (GP, HES) data for 1 user for 1 year with particularly sensitive (mental health) outcome/exposure:

UKSeRP base cost – year 1	£1000
User cost – year 1	£500
Disclosure control – year 1	£600
Building GP data	£600
Building HES data	£600
NHS REC amendment	£360
HRA CAG application	£1200
Total cost	£4860

Example 3:

Request for access to linked health (GP, HES) data for 2 users for 2 years, where outcome/exposure not deemed particularly sensitive e.g. physical health:

UKSeRP base cost – year 1		£1000
User cost – year 1	(500*2)	£1000
Disclosure control – year 1		£600
UKSeRP additional years	(1000+1000)/2+600	£1600
Building GP data		£600
Building HES data		£600
NHS REC amendment		£360
Total cost		£5760

Appendix Three: Split-stage protocol

Split-stage protocol for derived data

The split-stage protocol comprises of the following stages:

1. ALSPAC send the potentially identifying data (e.g. postcodes) in an encrypted file to the approved researcher group. This will be a stand-alone file with a unique case identifier, but unmatched to any other data.
2. The researcher then derives any new variables using their specialist skills or equipment (e.g. modelling postcode to satellite collected air pollution data). The researcher will ensure the derived values are less specific than the source variables and they could not be used as a proxy-ID to identify an individual. These new variables are then encrypted and returned to ALSPAC, along with accompanying documentation describing the derivation method(s) used to the appropriate data buddy.
3. When ALSPAC have confirmed they have received and opened the file, the researcher is then required to delete all copies of the information provided in stage 1.
4. ALSPAC will remove the potentially identifying information (e.g. postcode), then combine the derived variable with the remainder of the information in the data request. ALSPAC reserve the right to further process the derived data to ensure an appropriate level of disclosure control (ALSPAC will discuss this with researchers in the event of this occurring). This new data file will have a different case ID to the file issued in stage 1. ALSPAC will encrypt and send this file to the researcher after receiving written confirmation that stage 3 has been completed.

The extract mechanism by which the split-stage protocol is administered may vary, depending on which potentially identifiable information is being requested. Examples are provided below for illustration. The exact mechanism implemented is determined per project, at ALSPACs discretion.

IMPORTANT: Researchers are not permitted to join, or attempt to join, the information provided in stage 1 with the information provided in stage 4.

Example 1: Free text data

Both questionnaires and clinic datasheets contain free text fields, where additional information not contained within the given tick box responses can be provided by the respondent. These data are not routinely coded and included in built/release files as different researchers may choose to use the data in different ways according to their specific needs. However, there is a risk that participants have also included personal identifiers in these free-text fields.

Researchers, subject to approval by the ALSPAC Executive Committee, may be provided (there is a standard cost-recovery charge per text field; see section 1.3.1) with these data using the Split-Stage Protocol. It will be provided once the appropriate charges have been paid.

(Stage 1) the researchers will be provided the text data with a unique 'TextID'

(Stage 2) the researcher will code the text variables

(Stage 3) return an encrypted copy of the derived – coded – variables to ALSPAC. Upon receipt, the researcher will destroy all copies of the free-text data.

(Stage 4) ALSPAC will combine the coded variables with the remaining requested data, add the project 'Collaborator ID' case identifier and send this data file to the researchers.

Example 2: Date of birth

Complete dates of birth and other dates (e.g. clinic date or questionnaire completion date) are not usually made available; only month and year are released as standard. The age of any data collection sweep is always computed and made available. Exact dates of birth will not be given to research collaborators. We recognise that there are times when this information is important for deriving variables such as season of birth variation in a particular measure.

In these circumstances, we will work with the researcher to produce their derived variables using a modified version of the Split-Stage Protocol, as follows:

(Stage 1) the researcher will be provided with a limited dataset containing a collaborator ID, pseudo date of birth, and any other essential data

(Stage 2) the researcher will use this dataset to write syntax that correctly generates any derived variables

(Stage 3) the researcher will send this syntax to the study team (in SPSS or Stata format)

(Stage 4) the ALSPAC data team will run the syntax using the genuine full date of birth to create the derived variables.

In situations where researchers provide a strong justification for needing complete date of birth throughout their main analyses (e.g. as a primary exposure, outcome or key co-variable) and the justification is agreed by the Executive, a similar process to that described above will apply. Here the researcher would have to provide complete syntax for all their analyses in a form that the ALSPAC team can use and the researcher would be provided with a full set of results. The real costs of doing this additional work will have to be paid in advance by the researcher and will vary on a case by case basis depending on the amount of work required by the ALSPAC team.

Example 3: Clinically interpretable data

ALSPAC collects a variety of 'clinically interpretable data', for example: DXA bone mineral density scans, liver scans and brain MRIs. In many cases, these interpretable data may be potentially identifying in their raw format yet require the specialist expertise of a clinician to interpret them properly. The specific nature of the Split-Stage Protocol is likely to differ from project to project; however, the principles – where potentially identifiable information is processed in isolation from other ALSPAC information – is likely to be applied.

Example 4: Spatial data

Complete postcode data are not usually made available; rather the very broad first digits of postcodes are released, or information derived from these (e.g. household quintile of Indices of Multiple Deprivation at the time of data completion). However, we recognise that there are times when this information is important for deriving variables, such as for spatial research projects.

In these circumstances, we will work with the researcher to produce their derived variables using a modified version of the Split-Stage Protocol, as follows:

(Stage 1) the researcher will be provided with a limited dataset containing postcode and any other essential data. To protect the identities of participants the genuine participant postcodes will be masked by including other, randomly selected, genuine postcodes and synthetically created essential data.

(Stage 2) the researcher will use this dataset to write syntax that correct generates any derived variables

(Stage 3) the researcher will send encrypted copies of the derived variables to the study team, and, upon receipt, delete all copies of the original Stage 1 data

(Stage 4) the ALSPAC data team attach the derived variables to the remaining requested ALSPAC information, change the case ID and return this file to the researchers. The derived variables will be checked for disclosure risk and may be processed to a less granular level (the means to achieve this will be discussed and agreed in advance).

IMPORTANT note for projects requesting spatial data:

- The ALSPAC team will **not** provide exact address or complete postcode data under any circumstances, due to issues of identifiability. Instead a range of derived administrative boundary variables are available as outlined in the data dictionary. Each project proposal will be judged uniquely on its own merits and disclosure risk.
- Previous provision of, and the availability of, geographical data are not a guarantee of data provision.
- Requests for specific geographies may be denied in cases where it is believed participants' disclosure may be at risk.
- As a condition of submitting a proposal that includes ALSPAC spatial data a researcher will be required to include detailed information on the reasoning and methodology behind the requested geography to justify the choice, and specify why the selected spatial resolution is appropriate for the research question, for instance, in the case of high resolution geographies being requested, the Executive require justification as to why smaller resolution data are not acceptable.
- It is important to note that at the highest resolution held by ALSPAC (Lower Super Output Area) many data cases will be reverted to missing due to low unit population counts, therefore selecting variables with the highest resolution possible so that further information can be derived when unnecessary can be counter-productive to research.
- The ad-hoc method of address data management has permitted a database with extremely high temporal accuracy. However due to historical database errors, and individual level differences in reporting address movement, there will inevitably be a small number of cases that have no address data at certain time points. These missing cases should not greatly affect research that uses additional ALSPAC data as there is understandably a very high correlation between address accuracy and questionnaire/clinic responses.

Split-stage protocol for study administration

In some exceptional data collection instances, it may be necessary for non-ALSPAC staff to be involved in the administration of the data collection. In turn, this may mean researchers accessing participant names and contact details (e.g. a qualitative researcher arranging interviews that they will conduct, and subsequently analyse). In these circumstances, a modified version of the split-stage protocol will apply with important additional stages:

Stage 1: Following project approval and negotiation with ALSPAC staff, the researcher (with input from ALSPAC) will be expected to produce a fair processing information and consent pack for study participants (this is likely to need ethical review and approval). The information must explicitly describe the fact that the researcher does not work for ALSPAC and to seek opt-in consent for ALSPAC to provide contact information to the researcher.

Stage 2: ALSPAC staff will administer the consent campaign (subject to cost recovery fees being paid).

Stage 3: Subject to required contractual agreements being entered into, ALSPAC will provide the researcher with the names and contact details of consenting participants. These will be used solely for the purposes agreed in the project proposal.

Stage 4: The researcher will collect the information required for the project. The researcher will ensure that research information is kept securely, and separately from the names and contact details (it is required that these are kept within separate electronic file systems and only accessible on a need to know basis to staff named in the project proposal). ALSPAC can provide a case ID to assist with this data separation. Once data collection is complete, the researcher will process the data and then return an encrypted copy, along with sufficiently detailed documentation, to ALSPAC. Upon confirmation of receipt, the researcher will securely destroy all copies of the name and contact information (ALSPAC will maintain a key to link participants back to their data if required).

Stage 5: ALSPAC will combine the collection information with other ALSPAC information, assign a new collaborator case ID number and will then send an encrypted copy of this final dataset to the researcher.

The above description is for illustration only; details are likely to vary on a project by project basis.

Appendix Four: Information Security Controls

This is taken from the ALSPAC Data Access Agreement

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 Institute is responsible for ensuring the Recipient Investigator(s) are trained in research governance good practice and Information Security and the terms, conditions and responsibilities within the Data Protection Act 1998 or any other Applicable Law;
 - (i) 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;
 - (j) 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.

Appendix Five: Types of Data

This is taken from the ALSPAC Data Access Agreement

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 Liked 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.

Appendix Six: Policy updates

This appendix will detail the changes made to this policy since the release of v5.0 in April 2014.

v.5.1 Released May 2014

Statement added to Section 1.3 clarifying that costs for education data are subject to change

Project amendments clarified in Sections 1.3.2 and 1.3.3

Sections 1.3.4 and 1.3.5 have been added

Final bullet point added to Section 2

Paragraph added to Section 2.2 regarding posting lay summaries of projects using linkage data on the ALSPAC website

Statement added to Section 5.1.8 regarding paperwork for new data collection must be signed off internally

Statement added to Section 6.1.1.1 regarding journals and depositing data.

Section 6.5 – Clarification added for returning derived variables

v.5.2 Released September 2014

Clarification on open access policy in Section 6.6.1.1

Statement added to Section 6.1.1.1 regarding funders and depositing data.

Including all research output in Section 6.6.1

Clarification of obtaining sequencing data in Section 2.3

v.5.3 Released October 2014

Clarifying charges in Table 1 for non-standard data

v.5.4 Released December 2014

Adding details on other charities supporting open access publication – Section 6.1.1.1a

v.5.5 Released February 2015

Clarifying the use of schools and higher education data – Appendix Two

v.6.0 Released April 2015

Updated cost recovery charges

Clarifying the data management fee and exchange rates in Section 1.3.3.3.

v.6.1 Released June 2015

Updated to accommodate new online project proposal system.

Updated to include costs for new data collection in Section 1.3.6.

v.7.0 Released September 2016

Updated cost recovery charges

Clarified the scope of set-up meetings in Section 5.1.2

Changed Wellcome Trust to Wellcome to reflect their new name

v.7.1 Released November 2017

Updated Section 1.4 to reflect changes to the management of ALSPAC

Updated Section 2 to give information about the various ways of interrogating our data

Changed Sections 4 and 5.1.11 to refer to recently formed Bristol Bioresource Laboratory (BBL)

Added information in Section 6.6 about referencing study on posters, including logo and citing REDCap

Addition of Appendix Three on the split-stage protocol

v.8.0 Released May 2018

Updated throughout to reflect the introduction of the Data Access Agreement, including the addition of Appendices Four and Five.

Updated section 5.3.5 regarding exclusive access to data.

v.8.1 Released June 2018

Updated section 6.6.4 and added section 6.6.5 to reflect alternative outputs produced by researchers

v.8.2 Released July 2018

Updated section 5.3.5 regarding exclusive data access

v. 8.3 Released February 2019

Updated sections 1.4.3 and 1.4.4 to reflect changes to the Board and ISAB

Updated the weblink to ARIES summary data (section 2.3)

Updated section 5.2 regarding feedback of study findings

Updated section 5.3.5 regarding exclusive data access

Updated section 6.6.3 regarding reports to funders

Updated section 2.2 removing reference to a Data Transfer Agreement, since the DAA now applies to all data sharing

v 9.0 Released April 2019

Added section 2.1.1 on G2 data

Updated costings table to remove charges for geographical data, amended charges for imaging data and added charges for G2 data

Added section 6.4 on Information security

Added section 6.7.3 on Policy briefings

v. 9.1 Released July 2019

Updated section 1.3.6 regarding notice periods for submitting grants for new data collection.

Added costs to section 1.3.3 for grants that do not require access to existing data

Clarified in Section 1.1 that research must be in the public interest

v.9.2. Released October 2019

Added costs to Table 1 for individual DAAs and ID swaps for linkage and other data

Updated section 1.2 to note that a DPIA may affect approval times

Updated section 6.4 to clarify information around security requirements and note that a DPIA may be required.

v.10.0. Released January 2020

Updated section 1.3.3 to clarify Data management fee

Updated section 3.2 to provide options when the DAA cannot be signed

Providing more detailed information on student projects in section 1.2

v.11.0 Released April 2020

Overhaul of cost recovery charges – Section 1.3, Table 1 and Appendix 1 updated

v.12.0 released June 2020

Updated section 1.3.1 to include details of data in hand required for new project

Section 1.3.5 removed following restructure of cost recovery charges

Added section 2.2.2 on secure remote servers

Section 5.3.5 Clarifying the position on requesting exclusive access to new data

v.13.0 released February 2021

Updated costs and details around accessing linked health and education records

Updated broken data dictionary links

Section 1.3 Clarifying the responsibility of researchers to check costs after grant submission

Section 5.3.5 Clarifying exclusive access requests.

Section 6.7.1.1 Reflecting the change in Wellcome's open access policy

