ALSPAC
School of Social and Community Medicine
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The Avon Longitudinal Study of Parents and Children (ALSPAC) Access Policy

Introduction

This document summarises the access policy of the Avon Longitudinal Study of Parents and Children (ALSPAC). Cohort profiles for the mother and the children are included in Appendix 1a and 1b. Briefly, pregnant women living in one of three Bristol-based health districts in the former County of Avon with an expected delivery date between April 1991 and December 1992 were eligible to be enrolled in the study. Around 14,000 pregnant women were initially recruited. Detailed information has been collected using self-administered questionnaires, data extraction from medical notes, linkage to routine information systems and at research clinics. Ethical approval for the study was obtained from the ALSPAC Ethics and Law Committee (IRB00003312) and Local Research Ethics Committees.

Management

Professor George Davey Smith is the Scientific Director of the study. The day-to-day running of the study is the responsibility of the ALSPAC executive. The executive currently comprises George Davey Smith (Scientific Director); John Henderson (co-Director); Debbie Lawlor (co-Director); John Macleod (co-Director); Lynn Molloy (Executive Director); and Sue Ring (Head of ALSPAC laboratories). The executive meets every two weeks to consider proposals and papers. The terms of reference of the ALSPAC Executive are contained in Appendix 2.

If you would like the executive to consider a proposal for the use of existing data or collection of new data or to approve a paper for submission please follow the guidance below and email your proposal or paper to the executive e-mail address: alspac-exec@bris.ac.uk.

An independent steering group (ISG) oversees the running of the resource. Professor Kay-Tee Khaw chairs the group and the group meets annually.

Sharing data with researchers

General issues

ALSPAC is run as resource for the research community. At the present time the resource is set up as a supported access resource rather than as an open access resource. However we anticipate that over the next few years more of the resource will become available via open access. The following sections describe the information available on the resource, the process of sharing different types of data and costs of sharing data.

Information on the resource

The study website describes the resource and the types of data available and should give you a good idea as to whether ALSPAC would be potentially valuable in addressing your research question (www.bristol.ac.uk/alspac). If you require more detailed information on the variables available please send an email to the ALSPAC executive (alspac-exec@bris.ac.uk) with the title 'Documentation request' expressing your wish to explore the ALSPAC resource for a potential research proposal. Your email should include enough information for the executive to identify you as a *bone fide* researcher i.e. your institution name, Department, your contact information and a brief explanation of your research interests.

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The study website does not provide you with the actual research data themselves, only descriptions of what is available. Access to research data must be requested using the procedure described above.

The process for working on genetic data is described below.

We encourage data sharing to maximise use of the resource so the executive may put you in touch with other groups working in the same area. The vast majority of the data are available for use on request and for these data we do not consider the issue of overlap. However, for recently acquired data, including questionnaire, clinic, genotyping and laboratory analysis data that have been collected via external funding the arrangements are different. These data will usually only be made available to test overlapping hypotheses one year after the data are cleaned and available for analysis unless a prior agreement has been obtained from the principal investigator of the project that funded the data collection.

Submitting a proposal

If you decide that you would like to work on the ALSPAC resource you should complete an ALSPAC Research Proposal Form describing your proposed research (see Appendix 3a) and email the completed form to the ALSPAC executive (alspac-exec@bris.ac.uk). This proposal form should have clearly stated aims and hypotheses and describe the relevant exposure, outcome and confounders that will be considered. The ALSPAC executive will reply within two weeks to inform you of the outcome and to provide advice on the next stages. In some cases, approval is withheld due to the lack of relevant data or biological samples. The executive will also estimate the cost of sharing data (see below). The executive also reserve the right to impose additional restrictions as appropriate.

Analysis of existing data

Once the proposal has been approved the executive will work out the costs of sharing data (see below) and you will be allocated a data buddy. Your data buddy will liaise with you over your proposal and the data you require. They will then provide the dataset. Special procedures are required for some types of data such as potentially identifying data and genotype data. These procedures are described in the sections below. When we approve your proposal we may suggest that you discuss your proposal with other researchers who have an intimate knowledge of the data you are requesting.

Potentially identifying data

Some of the data collected could allow study participants to be identified. These include personal details such as postcode and "free text" that could contain identifying information. The study team will not link these data directly to the published data resource. Instead a two-stage process is required if you wish to make use of potentially identifying data. Firstly, the potentially identifying data are sent to you as a separate file with an identifier but unmatched to any other data. Secondly, you then derive new variables that are less specific and could not be used to identify an individual and return these new variables along with accompanying documentation describing the derivation method(s) used to your data buddy so that these new variables can be added to the rest of your data request. If the study team have not handled a request like yours before they will ask the ALSPAC Ethics and Law Committee to review and approve your proposal. The ALSPAC Ethics and Law Committee may ask you to attend a meeting to explain your proposal. If your proposal requires detailed potentially identifying data to address a scientific question you may be required to complete a Data Transfer Agreement (DTA) similar to that described below for genotype data.

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Interpretable data

ALSPAC collects a variety of 'interpretable data', including a range of scanned images such as DXA scans, liver scans and brain MRIs. Should you wish to obtain access to interpretable data, rather than the variables we have already derived from them, you will be required to complete a DTA (Appendix 4).

In some rare cases, these interpretable data may be potentially identifying. In this case, we will draw up a bespoke agreement for the data you require and you may also need to seek the approval of the ALSPAC Law and Ethics Committee using the proposal form at http://www.bristol.ac.uk/alspac/researchers/data-access/ethics/. Please note that this process may take several weeks.

Genotype data

Research using SNP genotype data requires a legally-binding agreement between the University of Bristol and your host institution. This agreement is called a Data Transfer Agreement (DTA). For University of Bristol staff based outside the School of Social and Community Medicine a Data Service Level Agreement (DSLA) is required. These forms differ in terms of the signatories required, not the access level received. A project specific appendix must be agreed before the agreements are signed.

Genotype data cannot be released until fully completed forms have been received. Copies of the DTA and DSLA are included as Appendices 4 and 7 as pdf files to show the information that is required. Once your proposal is approved we will provide word files with the specific appendix for you to complete, sign and return to us.

Genome Wide data is held by ALSPAC and, due to its potential for disclosure of identity, current ethical constraints require these data to be analysed only in Bristol. We are working towards secure remote access that will enable direct access to these data in the future. ALSPAC is collaborating with several GWAS consortia with Bristol based researcher/s as members of the consortium. For further information about these projects or if you would like ALSPAC to contribute to a new consortium please contact the ALSPAC Executive (alspac-exec@bris.ac.uk) who will put you in touch with relevant researchers.

Genome wide sequencing for 2000 individuals is being generated as part of the UK10K project which can be accessed as outlined on the UK10K website (http::://www.uk10k.org).

Bristol statisticians can also run bespoke analysis and provide summary data for approved projects on a non-collaborative basis. In such cases the group requesting the data will need to cover the cost of analysis. Such projects will be processed in order of receipt.

Assays on biological samples and genotyping

To use existing biological samples or to carry out specific genotyping on ALSPAC DNA you need to complete the Research Proposal Form (Appendix 3a) 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. Please send the completed form to the ALSPAC executive (alspac-exec@bris.ac.uk). If you would like further information about samples or laboratory procedures please contact the ALSPAC laboratory (alspac-exec@bris.ac.uk). Decisions on the use of biological samples will consider the amount of the stored sample required, the amount in storage and the perceived scientific value of the proposed study.

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For genetic studies involving simple SNP analysis researchers are encouraged both to carry out genotyping on the whole cohort and to use K Biosciences (http://www.kbioscience.co.uk) rather than genotyping in their own laboratories. The company holds sets of ALSPAC DNA 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 K Biosciences must be placed via the ALSPAC laboratory.

Samples, including DNA, are provided under the terms of a Material Transfer Agreement (MTA) or in the case of University of Bristol staff a Material Service Level Agreement (MSLA). 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. A sample MTA and SLA are contained in Appendix 5 and Appendix 6 as pdf files to show the information that is required. Please note that for samples that are classified as relevant material under the Human Tissue Act (HTA) the HTA MTA should be used instead (see Appendix 5b). Once your proposal is approved we will provide word files with the specific appendix for you to complete, sign and return to us.

Collection of new data

The ALSPAC study team collect new data from the study families using self-completed postal and on-line questionnaires and at ALSPAC study clinics. Data collection may be on the whole cohort or on a specific sub sample (a sub study – see section below). The current plan for new data collection between 2012 and 2015 can be seen in Appendix 10. These questionnaires and clinics require funding (see section below) so where you have suggestions for new data collection you need to complete a Research Proposal Form (Appendix 3a describing your proposed research ensuring you complete the specific sections on new data collection and send the completed form to the ALSPAC executive (alspac-exec@bris.ac.uk). Please note that not all new data collection will necessarily be approved - participant overload and other practical and ethical considerations will be taken into account when reaching a decision. Please note that you will need to gain approval for your proposal from either the ALSPAC Ethics & Law Committee or a NHS REC depending upon the nature of the study. Researchers are encouraged to apply for funding for data collection two years in advance of the proposed start date for data collection to secure a commitment to include these data. Please note that our usual position is that we do not divulge individual results to study participants and consent to take part in the study has been granted on this basis. Our policy guidance regarding divulging biomedical information to individual participants can be seen in Appendix 8. More details are available in the ALSPAC Data Collection Policy (Appendix 11).

Sub studies

In order to avoid overloading study participants, an individual participant should not normally be taking part in more than one sub-study at any given time. If, for sound scientific reasons, investigators request that we include a given participant in more than one sub-study concurrently, careful consideration will be given to the potential burden on that individual by the ALSPAC Executive and where necessary further ethical scrutiny will be requested.

Reflecting our commitment to maintaining participant confidentiality ALSPAC requires all researchers undertaking new data collection on individuals recalled for assessment on the basis of a particular characteristic to take all steps necessary to ensure that disclosure of this characteristic in relation to an identified individual is avoided. You may therefore be required to include controls in your study in order to mask the characteristics of participants to researchers, staff and participants. The number of controls required and any additional steps needed to maintain confidentiality will vary between studies. All ALSPAC studies involving new data collection must be approved by an appropriate ethical authority.

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New data and derived variables

All data collected as part of a new data collection exercise will be made available to all researchers as part of the main resource; usually one year after the data has been cleaned. Any derived variables created as part of a project must be returned to your data buddy with appropriate documentation and this will also be made available to all researchers. This also applies to existing data where new variables have been created that will be of interest to other researchers.

Costs and grants

ALSPAC receives funding from the Wellcome Trust, the Medical Research Council and the University of Bristol to support core activities. These do not extend to support for individual projects and researchers will be expected to meet additional costs. These 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 the study team will then let you know how much it will cost. If you are submitting a grant to cover the costs of the agreed research you must send the final copy of the grant including the finances for approval at least two weeks before the submission date. Proposals received less than two weeks before the submission deadline will not usually be approved. The executive are happy to provide a letter of support once your research has been approved and the budget has been agreed. For proposals to collect new data a member of the ALSPAC executive (or a Bristol based scientist nominated by the ALSPAC Executive) must be included as a co-applicant so they can act as guarantor for the proposed new data. You should send the executive a copy of the award letter when you receive this and the executive will then arrange a set up meeting followed by annual review meetings to agree the objectives, timetable and staff required to meet the grant commitments.

After approval

From the 1st July 2011 we have been publishing copies of approved proposals on our website so people are aware of approved and ongoing work. We also reserve the right to make available analyses on our website or in correspondence to journals that have not been included in submitted papers.

Contact with study members

Only members of the ALSPAC study team or researchers who are honorary members of the study team will be allowed to contact study participants directly.

Confidentiality

Protecting the confidentiality of the study families is a primary concern of the ALSPAC 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. Anyone accessing the data will be required to sign confidentiality agreements.

PR policy

All press releases on research arising from the study should be seen and approved by the ALSPAC executive (alspac-exec@bris.ac.uk). We may decide to press release certain articles and will expect the lead author on the paper to agree the press release with the ALSPAC 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 to include in reports to funders and future applications for future core support.

Authorship and publication

Authorship on papers should follow standard practice. All full papers must be sent to the ALSPAC Executive for approval (alspac-exec@bris.ac.uk) along with a completed papers checklist (Appendix 9a) *prior* to journal submission. The executive expect to 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 also provide advice and feedback to authors where we feel this may be helpful but our role is not to provide formal peer review.

A checklist of requirements for ALSPAC papers along with some accompanying notes explaining these requirements and containing appropriate text to insert is contained in Appendix 9b. A completed checklist must be included with each paper submitted for approval. Researchers should let the executive know when a paper is accepted and send through an electronic copy of the final published version. If your work on the resource was funded by the Wellcome Trust or other bodies that require open access to publications arising from their funding it is the authors' responsibility to ensure papers are freely available. A list of publications arising from the study can be found on the study website **(http://www.bristol.ac.uk/alspac/)**

Intellectual property

Intellectual property rights belong to the University of Bristol. We will consider dividing intellectual property rights where researchers outside of the University of Bristol will be making a particular contribution. Any such division must be considered and agreed before the research starts. Further information on the University of Bristol policy on intellectual property can be found on: **(http://www.bris.ac.uk/hr/terms/generalterms.html#a11)**

Acknowledgements

We have agreed a standard acknowledgements section that should be included as is or in a modified form to fit the journal requirements for all papers:

"We are extremely grateful to all the families who took part in this study, the midwives for their help in recruiting them, and the whole ALSPAC team, which includes interviewers, computer and laboratory technicians, clerical workers, research scientists, volunteers, managers, receptionists and nurses. The UK Medical Research Council, the Wellcome Trust and the University of Bristol provide core support for ALSPAC. This publication is the work of the authors and <insert names> will serve as guarantors for the contents of this paper and does not reflect the views of the ALSPAC executive. This research was specifically funded by <INSERT DETAILS FOR SPECIFIC PROJECT WHERE APPROPRIATE, including Welcome Trust grant number>."

Feedback

This policy was last updated in June 2013. We welcome feedback, comments and suggestions. Please send to (**alspac-exec@bris.ac.uk**).

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Appendices

Appendix 1a	Cohort Profile: The 'Children of the 90s'; the index offspring of The Avon Longitudinal Study of Parents and Children (ALSPAC)
Appendix 1b	Cohort Profile: The Avon Longitudinal Study of Parents and Children: ALSPAC mothers cohort
Appendix 2	Terms of reference for the ALSPAC Executive
Appendix 3a	Research proposal form
Appendix 3b	Proposal amendment form
Appendix 4	Data Transfer Agreement
Appendix 5a	Material Transfer Agreement
Appendix 5b	HTA MTA
Appendix 6	Material SLA
Appendix 7	Data SLA
Appendix 8	Policy guidance regarding divulging biomedical information to individual participants
Appendix 9a	Publishing papers checklist
Appendix 9b	Supporting acknowledgements and study sample information for papers checklist
Appendix 10	ALSPAC New data collection plan 2013 – 2019
Appendix 11	ALSPAC data collection policy