

Avon Longitudinal Study of Parents and Children Proposal System User Guide V1.0

This guide includes information about the process for applying to use the ALSPAC resource and how the approval process works. It is for researchers who are submitting a proposal through the ALSPAC Online Proposal System (OPS). All *bona fide* researchers can apply to use ALSPAC data for research that is in the public interest. Researchers wishing to gain access to ALSPAC data must agree to the terms and conditions of use as outlined in our <u>Access Policy</u>.

A *bona fide* researcher is defined as being a person with professional expertise to conduct *bona fide* research; and who has a formal affiliation with a *bona fide* research organisation that requires compliance with appropriate research governance and management systems as described in our Data Access Agreement (see a <u>sample here</u>). PhD and other student applications must be submitted by a *bona fide* researcher who is a supervisor (and the Primary Applicant must be a supervisor also).

We look forward to working with you!

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1. Before you apply

Please read this guide before completing your proposal. We <u>must</u> collect detailed information regarding your proposed project in order to fully review and approve any requests to use ALSPAC data.

Before you complete your proposal form, we encourage you to:

- Read the <u>Access Policy</u>.
- Check the documentation to ensure we have what you need:
 - Data collected from questionnaires and face to face clinics
 - Omics datasets
 - Third party <u>Linked data</u> you may wish to contact <u>alspac-linkage@bristol.ac.uk</u> in advance to discuss your requirements as strict access rules apply.
 - <u>Biological samples</u> please speak with the Bristol Bioresource Laboratory (<u>bbl-info@bristol.ac.uk</u>) <u>before</u> submitting your proposal.
 - Review the sample Data Access Agreement (DAA) and sample International Data Transfer Agreement (IDTA). These are legal documents and cannot be altered. We strongly recommend sharing these samples with your institution's legal team to confirm that your institution can sign the general T&Cs before starting your request. Data access is subject to UK data laws and cannot be used for commercial gain. Note: The DAA is *not* required for University of Bristol staff with a full employment contract.

2. Accessing the ALSPAC Online Proposal System

To begin the application process, please visit the <u>access page on our website</u> and click the 'Request A Proposal Form' button. You will be asked to provide your email address and your project title. Once this form is submitted, a message will be sent to the email address provided containing details of how to access your online proposal form. This email includes **important information** regarding access to your proposal form, including your **unique proposal homepage URL and access code** which can be used to access your Proposal Homepage (see section 3). Please keep these details safe and to hand – you will need them to return to your proposal form at any time.

You can share the URL and access code with anyone you wish, but **please be aware** that they can edit the forms up until the point that they are 'locked' for review by the ALSPAC access team. We recommend only sharing these details with colleagues who are contributing to the content of the proposal until the form is locked. Once locked, you can share it with anyone you want to view the proposal. You may wish to wait until the proposal is approved in case we need to unlock it and return it to you for an update prior to approval. A proposal PDF will also be available after submission (via your proposal homepage) if you prefer to download that for sharing instead.

3. Your Proposal Homepage

Your proposal homepage is unique to the proposal title you identified when submitting the new request via our <u>website</u>. The proposal title will be visible at the top of the page.

If you have multiple ALSPAC proposals, they will each have their own homepage and will have different URLs and access codes, which you will receive each time you request a proposal form (see section 2). Please keep track of your URLs and access codes so you can refer to them as needed (we can provide these again if you lose them). If you submitted a proposal using our old proposal system (2016 to summer 2024); we have migrated as much information as possible and can provide a URL and access code for it in the new system on request.

From the proposal homepage you can access the individual forms which make up the full proposal (see section 5) and you can see which forms apply and when they have been completed.

When your proposal is submitted, your home page will show:

- A summary of key details (primary applicant name and institution, and proposal type e.g. new data collection proposal, secondary data proposal, linked data proposal, and/or existing samples proposal).
- A 'Progress' page where you can access information about the review, progress throughout the life of the project i.e. amendments, and guidance if your proposal is approved and funded.
- A 'Full Proposal' page which collates the information you have provided across each form and can be printed as a PDF (via your browser).
- An 'Amendment Request' form (if your proposal is approved) should you need it. Guidance is included within the form itself and is not included in this guide, although there is a summary in section 8.

4. Applicants

All personnel involved in the project must be included on the proposal in the Safe People Form (2). You can add new personnel at any time after approval via an amendment request. Each applicant requesting to use individual-level data will be reviewed, and if approved, is required to: (i) be named on an Institutions Data Access Agreement (DAA) per proposal, and (ii) to complete a Data User Responsibilities Agreement (DURA) per proposal.

4.1. Communications

We will contact you via email for (i) queries about your proposal (and any later amendments), (ii) proposal and amendment review outcomes, and (iii) when your project is due to end. The Primary Applicant will always be the main recipient of these emails.

We require <u>institutional email addresses</u> for all data users, including the student (if applicable); these applicants will be copied into most of the emails sent from our proposals system. If you also wish for non-data users to receive these emails, please add their email address where requested, otherwise, you can leave this blank. Emails relating to payments will be sent to the Primary Applicant and your finance contact if specified in the Safe Project Form (1). Please note this only relates to the first email originating from the ALSPAC proposal system. You are welcome to remove any recipients from the email thread as it develops by removing them as recipients when you respond to the email.

As your project progresses, your ALSPAC contact will reach out directly to whoever is the lead contact or who is most appropriate depending on the request at the time (e.g. we may reach out directly to an applicant handling the dataset if they have been in touch with us regarding the data previously). Where possible, having one main contact per proposal is optimal so that we can best manage your requirements. This is particularly important for complex projects. If your overall project is multifaceted, with different teams using different datasets, please submit separate proposals instead with a lead contact for each.

Please ensure email addresses are kept up to date. Please contact us immediately if you need to make changes. If an applicant leaves the project, their email address will be removed from the proposal after we are notified.

Please always include your proposal reference number (your B number which will be provided upon submission) **in your emails when contacting us.**

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4.2. Adding/removing co-applicants

New co-applicants must be formally added to a project via an Amendment Request (available from your proposal homepage after approval). It will be reviewed by the ALSPAC team prior to an approval decision. If data users at a new institution are added, a Data Access Agreement will be required and fees will apply. If you wish to remove an applicant or change their 'data user' status: Please get in touch with your data buddy (or <u>alspac-data@bristol.ac.uk</u>) to make this request.

4.3. Moving institutions

An Amendment Request (available from your proposal homepage after approval) must be submitted to update the details for anyone moving institution if they will still be involved in the project. If they plan to use the data at their new institution this must be discussed with us in advance as a new Data Access Agreement will be required **before** the data is transferred (this does not incur a cost). If the previous institution will no longer be involved, the datasets must be deleted from that institution's servers. If the applicant is no longer involved in the project, please let us know so we can update our records.

5. How to complete your Proposal Form

Our Proposal Form follows the **Five Safes Framework** and is comprised of several individual forms:

- 1. Safe Project
- 2. Safe People
- 3. Safe Data (New Collection, Secondary Data, Linked Data, Existing Samples)
- 4. Safe Setting
- 5. Safe Output

5.1. General completion guidance

- On your Proposal Homepage, click on each form to open it. They will each appear in a new tab.
- You will find a simple user guide at the top of each form (also linked below). It is very important that you carefully follow the guidance to provide us with the correct information. If the information provided is not sufficient, the proposal form will be returned to you to edit.

- The fields are numbered so that you can identify the guidance on each user guide. You may notice gaps in the numbering on the form you are completing. This happens where fields are *not* enabled depending on your earlier responses. Please do not worry about missing numbers; all fields that are required will be visible to you.
- Most fields require a response, as indicated by an asterisk *. You cannot submit a form without a response in these fields.
- Most free-text fields have a word limit. Please do not copy directly from grant applications as these often include much more detail than we need and can significantly increase the time taken to conduct the review. Please be aware that any copied text will be cut off at the word limit if it is exceeded.
- You do not have to complete all Safe Forms (1-5) in one go. You can click the Save & Return
 Later button at the bottom of each form if you need to save the form and come back to it later.
 Important if opting to use this function:
 - The system offers to email you a unique URL for the 'survey' that you are saving. This is different to your proposal homepage URL and no access code is required so please handle with care. The access code for your proposal homepage will be needed to get back to your homepage and to access the other forms.
 - Alternatively, you can choose not to receive the survey URL and refer to your proposal homepage URL and access code instead. You will always have access to each form via the homepage.
- If you see a line in place of a response; the response is pulled through from another form and will replace the line as the forms are completed.
- Once each form is complete, the date of completion will show on the homepage.
- When all Safe Forms (1-5) have been completed, you will be able to open the Submission Form
 (6). This must be completed by the Primary Applicant or an authorised delegate. This form must
 be completed in one go (you cannot 'save & return').
- Only fully completed and submitted proposals will move to the review process.

5.2. Form specific completion guidance

Guidance is available at the top of each form and the links below. It is **very important** that you follow the guidance to ensure the information provided to us is correct. If the information provided in not sufficient, the proposal form will be returned to you to amend:

- Safe Project Form (1) User Guide
- Safe People Form (2) User Guide
- Safe Data Form New Collection (3A) User Guide
- Safe Data Form Secondary Data (3B) User Guide
- Safe Data Form Linked Data (3C) User Guide
- Safe Data Form Existing Samples (3D) User Guide
- Safe Setting Form (4) User Guide
- Safe Output Form (5) User Guide

5.3. Order of completion

Please start by completing Safe Project (1) first, followed by Safe People (2). There are fields on these forms that enable fields in later forms and therefore must be completed in this order. Once these forms have been completed you can complete forms 3-5 in any order you wish. Once all Safe Forms (1-5) are complete, the Submission Form (6) becomes available and the Primary Applicant (or an authorised delegate) must complete this to formally submit the proposal.

5.4. Referring to participant cohorts

Participants are organised into the following cohorts. Please use these cohort names to avoid confusion:

- G0 The original mother who was enrolled during pregnancy in the 90s
- **G0p** The partner of the G0 mother, this may be the G1 offspring's biological father, or another person as chosen by the mother.
- **G1** The offspring of the G0 mother, born in the 90s (i.e. the index children).
- **G1p** The partner of a G1 participant (only available for G2 related data and COVID datasets).
- **G2** The offspring of the G1 participant.

6. Submitting your proposal

When all the Safe Forms (1-5) are fully completed, the Primary Applicant (or an authorised delegate) can complete and submit the Submission Form (6). This form includes a 'declaration' to complete prior to submission. The name typed on the form serves as the signature.

Please note that student proposals **must** be <u>submitted</u> by a supervisor – however, the other forms can be completed by the student.

You will receive a confirmation email which should reach you within a few minutes. If you do not receive a confirmation within 48 hours, please check that your Submission Form (6) is showing as completed on your project home page and if it is then contact <u>alspac-data@bristol.ac.uk</u>.

When our review starts the forms will be locked. You can still access them at any time with your URL and access code, but you will not be able to make any changes. The proposal will remain locked from this point on, unless more information is required prior to approval, in which case the form will be unlocked and returned to you along with further guidance. Amendments post-approval can be facilitated by the ALSPAC Data Access Team.

We aim to respond to all proposals within 10 working days. We will be in touch if there are any queries. In some cases, such as new data collection, samples, linkage, and bespoke omics data requests, the review process will take longer and a member of ALSPAC will be in touch with you to discuss your request in more detail.

6.1. Tracking progress

After you have submitted your proposal, you will be able to see a progress record accessible via the homepage (called 'Progress'). This will show the status of the review and outcome (you will be alerted of the review outcome via email). From this page, you can also view a record of any updates and amendments throughout the course of the project.

6.2. Viewing your 'full proposal' and PDF

You will be able to access a page called 'Full Proposal', which collates the applicable details across all forms into one. You can save a PDF of this page using your browser if you wish.

7. Review and outcome

Once your proposal has been reviewed and any queries resolved, the ALSPAC Executive will contact you via email regarding the outcome. If your proposal is approved, you will receive a formal approval email with details of the next steps.

All approvals are conditional as there are a number of steps prior to granting data/sample access and/or starting a new data/sample collection, such as funding, completion of institutional and individual data user agreements, the review and agreement of your variable request, and external approvals, if applicable.

A member of ALSPAC or Bristol Biobank Resources (BBL) will be in touch for approved new data collections or existing biological sample proposals that are funded respectively. We usually expect that some time will be spent on the new collection or sample analysis before any existing secondary or linked data is requested (if required). When you are ready to consider your existing secondary data request, please speak to your ALSPAC contact about being referred to a member of the Data Access Team, or you can contact alspac-data@bristol.ac.uk. Agreements must be in place before any data – new or existing – can be shared and a member of the Data Access Team will facilitate this, so please let us know if you want to get this in place sooner.

For funded proposals requesting existing data and/or linked data only: Your approval email will ask you to contact the Data Access Team at alspac-data@bristol.ac.uk when you are ready to proceed. At that point, your proposal will be assigned to a member of the team who will support you throughout the life of your project.

Please be aware that if a significant amount of time passes between our approval and being ready to proceed with your project, costs already provided could be subject to change.

8. Amendments

Amendment requests can be submitted for approved proposals. To request an amendment, you will need to complete an 'Amendment Request' form which is available from your proposal homepage (after approval). Guidance is provided on the form.

The request will be reviewed the ALSPAC team, who may be in touch with you to discuss this further. When the request is 'agreed in principle', it will be put forward for a formal review.

When the request is approved, you will receive a confirmation email. A record of the amendment (or any other minor changes) will be visible at the bottom of the Progress and Full Proposal PDF pages, (available on your proposal homepage) once the amendment has been fully processed.

Please see our <u>Access Policy</u> for further details including changes of scope, data re-use, and student projects. You may wish to contact us before submitting your request, either via your data buddy, lead contact, or <u>alspac-data@bristol.ac.uk</u>. Please be aware that some amendments may prompt us to ask you for a new proposal instead.

9. Proposals submitted pre-September 2024

Proposals submitted prior to September 2024 on our previous system have been migrated to the new system and will now have their own unique proposal homepage, access code, and associated Amendment Request form. We aim to share this new information with Primary Applicants for **active** proposals. You can request these details from us if you need them. The proposals reference number (B number) will remain the same.

Migration of amendments are more complicated; however, we will be working hard to copy over as much information as possible. The old system will still be available to ALSPAC staff until the process is complete.

Please see our FAQ in Appendix 1 which outlines what has changed and how to submit a new proposal or amendment.

10. Support

Please see our website in the first instance: https://www.bristol.ac.uk/alspac/researchers/.

For queries about:

- Data and data access processes (including costs and agreements), contact <u>alspac-</u> <u>data@bristol.ac.uk</u>.
- Biological samples, contact <u>bbl-info@bristol.ac.uk</u>.
- Omics data, contact <u>alspac-omics@bristol.ac.uk</u>.
- Linked data, contact <u>alspac-linkage@bristol.ac.uk</u>.

11. Version History

V1 – 6th January 2025 – First release.

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Appendix 1: FAQs - change of system (6th January 2025)

Q: I'm used to the old proposal system... what's changed?

A: Briefly, the main changes are as follows:

- We are now using REDCap to collect proposal details.
- You do not need to create a user account; each proposal will have its own URL and access code which open a 'proposal homepage'. You must keep a record of these safe and only share them with people who need access.
- Your homepage links to five forms following the principles of the '5 Safes': Safe Project, Safe People, Safe Data, Safe Setting, Safe Output. Plus, a 'Submission' form.
 - There is guidance for completing your proposal (see the links above).
 - The forms include much of the same fields as the original system, plus a few more.
 - We hope the new forms and guidance will help you to provide the correct level of information required for us to sufficiently review your requirements.
- Amendments are logged via the proposal homepage and will be reflected on the proposal itself, meaning all changes over time are visible in one place and the proposal reflects the current state of the project.

Q: I'm used to the old proposal system... how do I submit a proposal now?

A: The first step to submit a new proposal has not changed; From this webpage https://www.bristol.ac.uk/alspac/researchers/access/, click on the button to 'Submit a research proposal'.

Next, you will be asked to provide your email address and the title of your proposed project. Upon submission of this form, you should receive an email to the address provided with a unique URL and access code to open your 'Proposal Homepage'. This should be kept safe and only shared with those you wish to share the proposal form with. Each proposal will have its own homepage and access code and you will need to keep these on hand.

Your homepage links to five forms following the principles of the '5 Safes': Safe Project, Safe People, Safe Data, Safe Setting, Safe Output. There is guidance for completing your proposal forms (see the links above). The forms include much of the same fields as the original system, plus a few more. We hope the new forms and guidance will help you to provide the correct level of information for us to be able to properly review your requirements.

After the five forms are completed, you will be able to access the 'Submission' form to formally submit your application. You can access the forms at any time using your homepage URL and access code. The forms will be 'locked' when we start our review (typically within a week of submission) and will remain locked for the life of the project (unless we need more detail from you prior to approval).

Q: I'm used to the old proposal system... how do I submit an amendment now?

A: Once your proposal is approved, you will see an Amendment Request Form available at the top of your homepage. Guidance is provided on the form. All amendment requests will be visible on the one form and approved amendments will be updated on the proposal form itself with a record of what has changed. This means that the proposal forms will reflect the current status of the project in one location.

Q: What's happened to proposals that were submitted on the old proposals system?

A: All proposals have been migrated into the new system.

The migration will be in two stages: Stage 1 - the basic level of information that can easily be migrated from the old to new system (e.g. project title, Primary Applicant details, start and end dates, funder details etc.), plus fields that have been move directly into text fields (e.g. secondary data topics required); Stage 2 - information that cannot be directly migrated across (e.g. co-applicant details that are now separated into data user and non-data user categories). We hope to transfer all the required information as soon as possible – but don't worry, ALSPAC staff will have access to the old system until everything is moved.

All proposals imported into the system will have its own unique homepage URL and access code. We can share these with you on request.