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Withdrawal of consent policy

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Contents

1 Introduction

The Avon Longitudinal study of Parents and Children (ALSPAC) is a long-term health research project that provides a resource to scientists throughout the world researching a wide range of health and social issues. Study participants are invited to attend for new data and sample collection studies and also to complete questionnaires and online tests. Administrative data such as NHS Primary (GP) and Secondary (Hospital) Care records and education records are also collected (known as record linkage). Study participants have the right to withdraw their consent from the study entirely (or partially) at any time without giving a reason.

The purpose of this policy is to:

- Provide staff with overarching principles that guide the approach to ALSPAC study participants withdrawing their consent
- Provide clear information on how ALSPAC will meet the requirements of the relevant legislation such as the Data Protection Act 2018 when handling requests from participants to withdraw consent
- Provide guidance to staff about the withdrawal of consent process and how requests to withdraw consent should be handled

2 Scope

This policy is for any member of staff who may have contact with an ALSPAC study participant who request to withdraw their consent, including line managers, members of the Senior Management Team (SMT) and ALSPAC Executive. This policy is for withdrawal of consent requests from adult participants only. This policy is for withdrawal of consent only (see definition in section 3), it does not cover requests to no longer be invited for specific activities e.g. invited to clinics, these types of requests will be managed by the participation team using Arcadia.

It is not possible to remove all historic data, or data contained within specific data sets that have been analysed and used by researchers. Biological samples can only be removed if they remain as stocks in the ALSPAC bioresource, some will have already been utilised if sent out for a particular study.

3 Definitions

ALSPAC defines withdrawal of consent as any request by:

1) any adult cohort member (over 18 years) to end their involvement in the study

2) any adult cohort member to end their child's (aged under 18) involvement in the study

This request would stop contact with the participant or prevent the use of existing data or samples or prevent the collection of new data or samples. It does not include the act of withdrawing consent for the collection of an item of data or biological sample during a data collection exercises (on the day or in the case of a biological sample at a later date). These are governed by separate SOPs relating to each active data collection, or to the withdrawal of consent for a particular sample

Later in this policy document (Section 4.2) the policy sets out how ALSPAC categorises the participant's individual requests.

4 Background information

4.1 Summary of relevant legislation

The collection, storage and processing of study data and samples is governed by several different pieces of legislation:

- The collection and processing/use of all study data is covered by; the DPA (Data Protection Act (2018), and the MCA (Mental Capacity Act (2018).
- The ALSPAC participant administrative record (but not the research data) is covered by the FOI (Freedom of Information Act (2000)).
- The collection, storage and use of human tissue is covered by the Human Tissue Act (2004)
- The collection and processing/use of data collected via linkage to health and administrative records come under the terms of the act(s) of parliament which legislate for the relevant department (who are the Data Owners)
- The collection and storage of personal data is covered by the GDPR (General data protection regulations)

Further information regarding relevant legislation is included in Appendix 1.

5 ALSPAC policy

5.1 Compliance with legislation

5.1.1 ALSPAC Legal position

After careful consideration ALSPAC is satisfied that it has valid, lawful reasons for storing and processing data. The key legislation that ALSPAC has considered in making this decision is summarised in Appendix 1.

As a research organisation ALSPAC has defined its lawful bases to hold and use personal data as "legitimate interests", "consent" and considers this to be a "public task".

In addition to the lawful bases (specified above) to hold and use personal data ALSPAC also specifies its special conditions for processing "special categories of data" as:

- the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject;
- processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

ALSPAC will apply the 3-step test to demonstrate "legitimate interests" for each new data collection undertaken.

5.1.2 GDPR

The GDPR guidelines on consent are applied in the following ways:

- Participants have the opportunity to provide their explicit consent for ALSPAC to collect, store and make available information about them (including data from genetic and other assays of the samples that were collected) for health-related research
- Participants are able to to give their consent for their health to be followed over many years through linkage to medical and other health-related records, as well as by being re-contacted by ALSPAC
- Consent is not provided as a precondition for a service or a benefit; participants are informed of their options and allowed to make an informed decision as to their study status free from coercion. A summary of this policy will be made available to participants via the study website
- A separate consent form from the information materials is provided for all new studies
- All participants are provided with the relevant information materials that describe how ALSPAC will use their information to support research that is in the public interest and that have gained approval from a recognised research ethics committee
- Informed consent is always taken by a fully trained member of staff. Withdrawal of consent is discussed during the informed consent process. The practicalities of withdrawing consent and the implications of doing so is made clear, including limitations of withdrawing consent for data or samples that have already be used
- All participants volunteer to take part in ALSPAC activities after having the chance to review the information materials and ask any questions that they have
- Participants can opt to re-join the study at any time.
- The consent forms make clear the specific purposes to which the data will be used
- ALSPAC will not provide data to researchers which can be used to identify participants. Instead, personal identifiers will be removed from the data provided to researchers and ALSPAC's legal agreement with these researchers requires them to restrict their use of data for their approved research and not to try and identify participants.

REC approval has been granted on the basis that ALSPAC will consent participants in their own right at age 18. This differs from the GDPR guidance on consent shown below:

- Any participant can withdraw for any reason at any time; a participant is independent of other participants within their family, each will have the right to consent/withdraw consent in their own right (subject to them being over 14 years old and having the capacity to make an informed decision)

5.1.3 HTA

The HTA codes of practice will be applied in the following ways:

- If a participant withdraws consent for samples to be used in any future projects the sample stocks held by ALSPAC will be destroyed. However, information and data will not be withdrawn from any existing projects.
- All ALSPAC consent forms and associated documentation relating to the collection of human tissue and relevant fieldwork protocols will be written in line with current HTA codes of practice and approved by a recognised Research Ethics Committee.

- All consenting and related processes will be audited regularly, as required by the Human Tissue Authority and for ISO27001 compliance.
- ALSPAC samples and data related to samples will be processed, stored and given out to approved researchers in a manner that is consistent with the legislation.
- Withdrawal will be discussed during the informed consent process. The practicalities of withdrawing consent and the implications of doing so will be made clear by fully trained fieldworkers.
- Data and samples will only made available to bone fide researchers undertaking health or other research that is in the public good.
- Information on the terms and conditions that researchers must sign up to access data and/or samples is available in the ALSPAC Access Policy.
- Once a participant has given consent to donate samples, no other person has the right to revoke it. Therefore, if a participant has died a friend or relative of the deceased participant cannot withdraw permission for the samples to be used.

5.2 Dealing with Requests to withdraw consent

Participants should be asked if they wish to take a break from the study for a period of time, when this is appropriate. This policy will be followed when the participant has made it clear that this is not an option and they wish to withdraw from the study. This contact will be conducted in an open, non-coercive manner where the participant is allowed to determine the outcome. A withdrawal of consent request will be reviewed and treated according to one of the three categories below, no other options will be provided. The participant will be informed of the action taken as a result of their request and the consequences of this action as specified.

5.2.1 Withdrawal of consent for any future contact

Criteria: Participant has withdrawn their consent for any future contact by ALSPAC. Consent remains to use existing data and samples, and continue to link to official records

Action: ALSPAC will no longer contact the participant directly but will still collect further information obtained by linkage to health and other administrative records and by analysis of samples. ALSPAC will confirm they have permission to retain and use data and samples provided previously.

Consequence: This level of withdrawal allows ALSPAC to continue to collect, store and process data (including the participants administrative record on Arcadia) and samples under its stated legal position but with no further contact with the participant.

5.2.2 Withdrawal of consent for any future contact AND for *new* data collection and data linkage

Criteria: Participant has withdrawn their consent for any future contact by ALSPAC and for the collection of any new data and samples

Action: ALSPAC will no longer contact the participant directly or obtain any further information by linkage to health and other administrative records. ALSPAC will confirm they have permission to retain and use data and samples provided previously.

Consequence: This level of withdrawal allows ALSPAC to continue to store and process data (including the participants administrative record on Arcadia) and samples under its stated legal position but with no further contact with the participant.

5.2.3 Complete withdrawal of consent

Criteria: Participant has withdrawn their consent for any future contact, for collection of new data and samples and for any further use of existing data or samples

Action: In addition to 5.2.1 and 5.2.2 above, any data and samples collected previously will no longer be available to researchers for new research. Deleting all active research data[1] will take place within a week of receiving the withdrawal of consent request. All main stocks of samples held in the ALSPAC bioresource, managed by the Bristol Bioresource Laboratories (BBL), will be destroyed within eight weeks of receiving the withdrawal of consent request. Samples that have been distributed for analysis will not be destroyed.

Consequences: If a participant also requests that all research data (archived in addition to active) is deleted, ALSPAC will endeavour to remove all data from electronic archives and from any paper storage within 8 weeks. ALSPAC cannot guarantee to delete all archived data but will ensure the participants contributions will not be used again.

Some research samples may be in circulation, ALSPAC will ensure that any data generated from these can no longer be linked to other data collected from the same individual.

Participant details logged on the ALSPAC contact management system will not be deleted. The participant log will be flagged notifying staff that the participant has withdrawn consent and therefore no further contact will be made with them to avoid unnecessary contact and to ensure their information is not added back into the system (e.g. derived variables being returned from completed projects/information abstracted from legacy paper records). These contact details will be kept on the contact management system as a record of their involvement in ALSPAC including where their data and/or samples have been used for completed research projects up to the point of withdrawal.

5.2.4 Reversal of withdrawal of consent

Participants in any of the categories above will also be made aware that if they wanted to re-join the study at any time in the future, they would be able to do this (for future data collections) and should contact ALSPAC to make their wishes known.

5.3 Monitoring of Withdrawal of Consent Requests

All requests will be logged centrally. Each request will be referred for consideration at an Exec. Meeting. Quarterly, the Exec will receive the Withdrawal of Consent log and check that progress of withdrawals is occurring in line with this policy, and with current legislation, including

g HTA requirements.

5.4 Staff Training

ALSPAC aims to provide a professional service to participants in all circumstances. ALSPAC aims to comply with legislation relevant to this policy by carrying out effective recruitment of staff.

[1] 'Active research data' refers to all active and accessible (available in standard storage or through exhaustive searching) research data held by ALSPAC

Training will be provided to ALSPAC staff to ensure compliance with this policy and with the legislation relevant to this policy.

- All staff working with participants will be made aware of this policy and trained in the procedures relating to the policy
- Line managers, SMT and the Executive will provide support to staff by listening to concerns from staff dealing with participants and advising on further action where necessary
- Fieldwork staff will be appropriately trained for taking informed consent and to ensure all aspects of withdrawal are covered during this process
- Administrative staff will be appropriately trained for taking and processing requests for withdrawal from the study. Staff will ensure this process is "easy" for participants to access and complete
- All ALSPAC staff will complete annual information security training; ALSPAC has attained ISO 27001 accreditation for its data management system
- All staff involved with taking consent, obtaining biological samples, processing and storage of samples (i.e. those working under the remit of the Oakfield House HTA licence) are required to undertake HTA training.

6 Definitions & Abbreviations

ALSPAC	Avon Longitudinal Study of Parents and Children (also known as Children of the 90s)
ALSPAC Board	Responsible for the strategic oversight of ALSPAC including policies and procedures
ALSPAC Executive	Have overall responsibility for the management of the ALSPAC study
SMT	ALSPAC senior management team, responsible for the day to day running of the study
SOPs	Standard operating procedures
ALEC	ALSPAC law and ethics committee
LREC	NHS local research ethics committee
HTA	Human Tissue Authority
GDPR	General Data Protection Regulation
DPA	Data protection act
MCA	Mental capacity act
BBL	Bristol Bioresource laboratory

7 Roles & Responsibilities (Actors)

Who	What and why
Participation team	Will oversee the process of withdrawal of consent requests, which may come by a variety of routes, following the Standard Operating Procedure mentioned in section 7. Will respond to the participant who wishes to withdraw consent via the means

	deemed most appropriate (phone call or letter or face-to-face). This contact will be conducted in an open, non-coercive manner where the participant is allowed to determine the outcome
ALSPAC Board	Oversight of this policy
ALSPAC Executive	Will receive notification of all requests to withdraw consent and will review the log on a quarterly basis. Have overall responsibility to ensure compliance with this policy and provide expert opinions on how to deal with specific cases.
SMT	Members of the senior management team are responsible for ensuring all their staff members are made aware of this policy and that it is implemented within their teams. To provide support to members of their team who express concerns about a withdrawal of consent request.
ALSPAC staff	It is the responsibility of all staff to make themselves aware of this policy and implement it in conjunction with the SOP for withdrawal of consent.

8 Related documents and references

ALSPAC Access policy http://www.bristol.ac.uk/media-library/sites/alspac/documents/researchers/data-access/ALSPAC_Access_Policy.pdf

Data Protection Act 2018 http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted

Mental Health Capacity Act 2018 https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/

Freedom of Information Act 2000 https://www.legislation.gov.uk/ukpga/2000/36/contents

Human Tissue Act 2004 https://www.legislation.gov.uk/ukpga/2004/30/contents

Human Tissue Authority. Code of Practice A: Guiding Principles and the Fundamental Principle of Consent https://www.hta.gov.uk/sites/default/files/HTA%20Code%20A_1.pdf

Human Tissue Authority. Code of Practice E: Research. https://www.hta.gov.uk/sites/default/files/Code%20E.pdf

SOP-ADM-xxxx Process following withdrawal of consent request from a participant

9 Appendix 1

Summary of Key Legislation

9.1.1 General Data Protection Regulation (GDPR)

In 2018 the General Data Protection Regulation (GDPR) came into force. A legal requirement of GDPR is that a research organisation must have a defined lawful basis to hold and use personal data. Personal data is defined as any information that relates to an identified or identifiable individual, such as name.

9.1.2 Legitimate interests

Legitimate interests are defined in the GPDR as '"processing which is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child". In this case, ALSPAC is defined as the "data controller". In the GDPR, there is a 3-step test to demonstrate "legitimate interests". These are:

- the purpose test: what are ALSPAC's legitimate interests?
- the necessity test: is the processing necessary for the legitimate interests?
- the balancing test: ALSPAC has to weigh up the participant's interests

9.1.3 Public task

This is a lawful basis for processing personal data:

- 'in the exercise of official authority'. This covers public functions and powers that are set out in law; or
- to perform a specific task in the public interest that is set out in law.
- It is most relevant to public authorities, but it can apply to any organisation that exercises official authority or carries out tasks in the public interest.
- You do not need a specific statutory power to process personal data, but your underlying task, function or power must have a clear basis in law.
- The processing must be necessary. If you could reasonably perform your tasks or exercise your powers in a less intrusive way, this lawful basis does not apply.
- This decision must be documented in order to be able to rely on this basis to help BD demonstrate compliance if required.
- should be able to specify the relevant task, function or power, and identify its statutory or common law basis.

9.1.4 Consent

Under the GDPR, explicit consent needs to satisfy each of the following 6 criteria:

- Consent needs to be **freely given**.
- Consent needs to be **specific**, per purpose.
- Consent needs to be **informed**.
- Consent needs to be an **unambiguous indication**.
- Consent is an act: it needs to be **given by a statement or by a clear act**.
- Consent needs to be **distinguishable from other matters**.

9.1.5 Special category data

Special category data is personal data which the GDPR says is more sensitive, and so needs more protection. In order to lawfully process special category data, both a lawful basis under Article 6 and a separate condition for processing special category data under Article 9

must be specified. These do not have to be linked. There are ten conditions for processing special category data in the GDPR itself, but the Data Protection Act 2018 introduces additional conditions and safeguards. Conditions for processing special category data must be determined before processing begins under the GDPR, and this should be documented. GDPR includes genetic data and some biometric data in the definition of special category data.

There must be a lawful basis for processing under Article 6, in exactly the same way as for any other personal data. In addition this processing must also satisfy a specific condition under Article 9. This is because special category data is more sensitive, and so needs more protection. For example, information about an individual's:

- race;
- ethnic origin;
- politics;
- religion;
- trade union membership;
- genetics;
- biometrics (where used for ID purposes);
- health;
- sex life; or
- sexual orientation.

In particular, this type of data could create more significant risks to a person's fundamental rights and freedoms. For example, by putting them at risk of unlawful discrimination. The GDPR specifies that "research purposes" include "studies conducted in the public interest in the area of public health".

9.1.6 Human Tissue Act

The Human Tissue Authority's approach to the storage and use of biological samples is based on the fundamental principle of consent (Code A – Guiding principles and the fundamental principle of consent). The Human Tissue Act and the Human Tissue Authority's Codes of Practice require that consent must be in place to store and use tissue from the living. Anyone removing, storing or using material in circumstances for which the Human Tissue Act requires consent, must be satisfied that consent is in place. The HTA has set Standards on consent for those working in licensed establishments. The Standards and associated guidance include how the consent process should be governed, the information that should be provided to those from whom consent is sought and the training that staff should receive. In respect to withdrawal of consent the HTA code of practice states:

- Consent may be withdrawn at any time, whether it is generic or specific.
- Withdrawal should be discussed at the outset when consent is being sought. The practicalities of withdrawing consent and the implications of doing so should be made clear.
- Withdrawal of consent cannot be acted upon where tissue has already been used.