ALSPAC Withdrawal of Consent Policy

Version 2.1: Approved 07/02/2011

1. Introduction

Study members have the right to withdraw their consent for elements of the study or from the study entirely at any time. The administration of withdrawing consent is handled by the ALSPAC Participation Team, although other staff may be involved initially.

The Participation Team will address each situation on a case by case basis. They will respond to the cohort member who wishes to withdraw consent via the means deemed most appropriate (phone call or letter or face-to-face). They will explain the options available and aim to understand the reasons for withdrawal and the most appropriate eventual study status for the participant. This contact will be conducted in an open, non-coercive manner where the participant is allowed to determine the outcome.

In cases where there is a complaint, or an uncertain situation then the Participation team will refer the decision to ALSPACs governance bodies. ALSPAC sits within the University of Bristol governance structure. Any complaint or uncertainty will be through the tiers of the governance structure to the suitable level. In most cases this will be to the management level (ALSPAC Executive Committee) or the faculty level (in ALSPACs case this is represented by the ALSPAC Ethics & Law Committee). In some cases queries or complaints may be referred to University level advisors or committees.

2. Principles

The following principles govern this process:

- The study member should be informed of their options and allowed to make an informed decision as to their study status free from coercion.

- This policy will be made available in the ‘members’ area of the website and via the Participation team. Directions to these materials will be included in all consent materials and on the participant website.
• Each study member is independent of other members of their family. Each has the right to consent/withdraw consent in their own right (subject to them being over 16 years old and having the capacity to make an informed decision).

• Withdrawing consent from one element (i.e. willingness to complete questionnaires) of the study does not affect their overall study status or participation in other elements (i.e. willingness to attend focus visits).

• A study member can opt out of all new data collection but remain a member of the study and receive newsletters and other study feedback.

• The study member is always deemed eligible to participate and can opt to rejoin the study at any time.

3. Participation Options

   a. **Withdraw from certain area of activity (All are discrete options)**

      Designed to remove one or more element of the study.

      - Study member can opt out of any discrete element of the study (questionnaires, category of questionnaire, focus visit invitation, data collection via linkage to records, type of sample etc).
      - ALSPAC maintain permission to use other data, samples, continue data collection via linkage to records.
      - ALSPAC continue to send, or invite to, all other data collection tools.
b. **Participation ‘break’**

Designed to reduce pressure on participants in times of stress/high workload for them, for example during illness or family problems.

- Temporary halt to study participation.
- Temporary halt to Newsletters, results feedback and birthday.
- ALSPAC maintain permission to use data, samples, continue data collection via linkage to records.
- ALSPAC will resume sending materials/invitations after the period ends; this will be agreed in a follow up contact with the participant.

c. **‘Withdrawal from direct participation’**

Designed to allow the study families to keep up to date with findings and results from the work they had put in but to not send new data collection items.

- No questionnaires or participation invitations to be sent to study member.
- Study member to be sent Newsletters, results feedback and birthday cards.
- ALSPAC maintain permission to use data, samples, continue data collection via linkage to records.
- ALSPAC continue to maintain up-to-date contact and personal details on administrative database.

d. **‘Withdrawal from direct participation - with no further contact’**

Designed to allow the study families data to accrue via linkage and continue to be used for research, but also not to send any materials to the study members.

- No future contact with the study member.
- ALSPAC maintain permission to use data, samples.
- ALSPAC continue data collection via linkage to records.

e. **‘Withdrawal from study – maintaining permission to use existing data’**

The study member will withdraw from the study but permit ALSPAC to use the data they have provided to date.

- No future contact with the study member.
- No future data collection via linkage to records.
- ALSPAC maintain permission to use existing data and samples.
f. ‘Withdrawal from study – maintaining permission to some existing data’

The study member will withdraw from the study but permit ALSPAC to use some of the data they have provided to date. The study member can withdraw permission from some categories of data or samples.

- No future contact with the study member.
- No future data collection via linkage to records.
- ALSPAC maintain permission to use some existing data or samples.
- Study member withdraws permission for ALSPAC to use some existing data or samples.


g. ‘Withdrawal from study - no further use of all data’

The study member will withdraw from the study and withdraw permission for ALSPAC to use the data they have provided to date. Data from existing or past research cannot be recalled. It is necessary for some data to remain for audit purposes and that some data cannot be extracted for practical reasons (i.e. inclusion in backup and archive materials).

- No future contact with the study member.
- No future data collection via linkage to records.
- No researcher access to data previously collected (the study members data will be removed from the resource).
- ALSPAC will hold information about the study member on the administrative database for archival and audit purposes

4. Withdrawal of Consent Process Map

A process map is included to outline the withdrawal of consent procedure.
Withdrawal of Consent Process Map

**Participant notifies APT of intent to change study status**

**Notification via other ALSPAC staff**

**Participant prepared to discuss withdrawal of consent**

**Participant NOT prepared to discuss withdrawal of consent**

**Participation Team assess case:**
- Listen to study members request.
- Explain withdrawal options and process to study member.

**Where Required**

**Guidance sought from:**
- ALSPAC Executive Committee
- ALSPAC Ethics & Law Committee

**Participation Team assess case:**
- Determine the withdrawal option most suited to the study members request.
- Contact the study member to inform them of the action taken.

**Participants study status details changed on ALSPAC Administrative Database**

**Systems used to collect data via linkage amended, data owners notified where appropriate**

**Participants data & samples processed in accordance with withdrawal option**

**‘Thank You’ letter sent**
- Thanks study member for their participation
- Confirms withdrawal option has been complied with