

Cleft@18-23 Withdrawal of Consent Policy

1. Introduction
2. Principles
3. Participation Options

1. Introduction

Participants who have been enrolled in the study 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 the responsibility of The Cleft@18-23 Study Team who will address each situation on a case-by-case basis. They will respond to the participant who wishes to withdraw consent, through the means deemed most appropriate (phone call, email). This will also take account of what the participant has specified in terms of how they would like to be contacted on their initial contact form.

The research team member 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 team member will refer the decision to the Programme Manager or the Chief Investigator. If necessary, in some cases queries or complaints can be referred to the research governance team from the University of Bristol.

2. Principles

The following principles govern this process:

- The participant should be informed of their options and allowed to make an informed decision as to their study status free from any coercion.
- Information about how to withdraw from the study will be on the Cleft@18-23 website.
- A participant may withdraw their consent for the use of their data but remain a member of the study and receive newsletters and other study feedback.
- The study member is deemed eligible to participate and can join the study in the future (future work packages) if they have previously opted out. This will be dependent upon the needs of the work packages and appropriate consent processes.

3. Participation Options

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

Designed to remove one or more element of the study:

- Participant can opt out of any discrete element of the study (either data collected at the research clinic or data collection via linkage to records).
- Cleft@18-23 maintains permission to use other data and continue data collection via linkage to records (if consented).
- Cleft@18-23 will continue to send newsletters and results feedback or invite to participate in future research (if consented).

b. 'Withdrawal - no further contact'

Designed to allow the participants' data via linkage and from research clinic appointments to continue to be used for research, but newsletters and results feedback are no longer to be sent to the participant:

- No future contact with the participant.
- Cleft@18-23 maintains permission to use data provided to date.
- Cleft@18-23 continues data collection via linkage to records (if consented).

c. 'Withdrawal from study – maintaining permission to use existing data'

The participant will withdraw from the study but permit Cleft@18-23 to use the data they have provided to date:

- No future contact with the study member.
- Cleft@18-23 maintains permission to use data provided to date.
- No data collection via linkage to records (if not already complete).

d. 'Withdrawal from study - no further use of all data'

The participant will withdraw from the study and withdraw permission for Cleft@18-23 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 some data cannot be extracted for practical reasons (i.e. inclusion in analysis as anonymised data, backup and archive materials):

- No future contact with the study member.
- No researcher access to previously collected data and samples (the Cleft@18-23 team will make every effort to remove the participant's data from the resource).
- No future data collection via linkage to records.
- Cleft@18-23 will hold Information about the study member on the administrative database for archival and audit purposes

Contact Details

Email: cleft-1823@bristol.ac.uk

Office phone: 0117 3310025

Mobile: 07484 515858