

## **The Cleft Collective 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 Collective Research 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, letter, email). This will also take account of what the participant has specified in terms of how they would like to be contacted on their consent 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 project manager or the chief investigators. If necessary, in some cases queries or complaints can be referred to University level advisors or committees.

#### **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.
- This policy will be mentioned in the 'Frequently Asked Questions' section on The Cleft Collective website.
- Each participant 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 give biological samples).

- A participant may 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 if they have previously opted out.

### **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 (examples include questionnaires, donating biological samples, data collection via linkage to records).
- The Cleft Collective maintains permission to use other data, samples, continue data collection via linkage to records (if consented).
- The Cleft Collective continue to send, or invite to, all other data collection tools, (e.g. if participant opts out of donating biological samples, they can still be sent questionnaires)

#### **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 and results feedback.
- The Cleft Collective maintains permission to use data, samples, continue data collection via linkage to records (if consented).
- The Cleft Collective will resume sending materials etc after the period ends, this will be agreed in advance with the participant. The participant can choose to extend/shorten this time period at any time.

#### **c. 'Withdrawal from direct participation'**

Designed to allow the participants to keep up to date with findings and results, but not to be sent new data collection items:

- No questionnaires or participation invitations to be sent to participant.
- Participants to be sent various information including newsletters and results feedback .
- The Cleft Collective maintains permission to use data, samples, continue data collection via linkage to records (if consented).
- The Cleft Collective continues 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 participants' data to accrue via linkage and continue to be used for research, but new data collection materials and newsletters are no longer to be sent to the participant:

- No future contact with the participant.
- The Cleft Collective maintains permission to use data and samples provided to date.
- The Cleft Collective continues data collection via linkage to records (if consented).

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

The participant will withdraw from the study but permit The Cleft Collective to use the data they have provided to date:

- No future contact with the study member.
- The Cleft Collective maintains permission to use data and samples provided to date.
- No future data collection via linkage to records.

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

The participant will withdraw from the study and withdraw permission for The Cleft Collective 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 backup and archive materials):

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