

## Participant Information Sheet



**The Cleft Collective**  
Closing the Gap in Cleft Research  
A Healing Foundation Initiative

# The Cleft Collective Birth Cohort Study – Antenatal diagnosis

---

## You are being invited to take part in a research study about cleft lip and palate

---

- Before you decide whether to take part, it is important for you to understand why the research is being carried out and what it will involve.
- Please take some time to read the following information carefully and discuss it with others if you wish.
- You are free to decide whether or not to take part in this research study. If you choose not to take part this will not affect the care you receive.
- You are free to withdraw from the study at any time without giving a reason.
- Please ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information sheet. If you decide to take part you will be given a copy of this information and asked to sign a Consent Form.

---

## Important things that you need to know

---

- The Cleft Collective is the world's largest cleft lip and palate research programme.
- We are developing two Cohort Studies, based at the University of Bristol. This means that we will invite families to take part either after their child has received a diagnosis, or during the year of the child's fifth birthday. We will then follow each family as their child grows up and keep in touch along the way. This document gives you information about the **Birth Cohort Study**. This means that you would have received a diagnosis during pregnancy.
- A **Birth Cohort Study** is a study that follows the lives of a large group of people from birth to try and find answers to today's health problems.
- This research will help us find out more about the genetic and environmental causes of cleft, the best treatments for cleft and the impact of cleft on the family and the individual.
- We are asking families to give us biological samples, such as saliva, and to complete questionnaires.
- We are also asking families' permission to access their medical records.

---

## Contents

---

1. Why are we doing this study?
2. Why are we asking you to take part?
3. What will I need to do if I take part?
4. What will happen to my information?
5. What are the possible benefits and disadvantages of taking part?
6. Sharing the results and keeping in touch.
7. How is this study funded and managed?

---

## How to contact us

---

If you have any questions about this study, please speak to your cleft team, or contact The Cleft Collective research team at:

The Cleft Collective  
School of Oral and Dental  
Sciences  
University of Bristol  
Lower Maudlin Street  
Bristol, BS1 2LY  
United Kingdom

Website:  
[www.bristol.ac.uk/cleft-collective](http://www.bristol.ac.uk/cleft-collective)  
Email: [cleft-collective@bristol.ac.uk](mailto:cleft-collective@bristol.ac.uk)  
Telephone: +44 (0)117 34 24412  
Or join us on:  
Facebook:  
[www.facebook.com/CleftCollective](http://www.facebook.com/CleftCollective)  
Twitter: @CleftCollective

---

## **1. Why are we doing this study?**

---

Following your baby's recent diagnosis of cleft, you may be asking a number of questions:

- What caused my child's cleft?
- What are the best treatments for my child?
- Will my child be OK as she/he grows up?

For us to be able to answer these questions fully we need to understand more about the role that the environment and genetics play in the development of the cleft; about which treatments work best, when and for whom; and about how you and your child adapt to the cleft and its treatment.

Cleft lip and/or palate is a common condition which affects around one in 700 births per year in the UK. This research will help to identify areas where support is needed, as well as how to maximise any support that is put in place. The research will ultimately help to improve care for those who are born with a cleft and their families.

---

## **2. Why are we asking you to take part?**

---

You are being invited to participate because you have a child who has been diagnosed with a cleft.

---

## **3. What will I need to do if I take part?**

---

The diagrams provided with this information sheet explain the type of samples and information we would like to collect from you, your partner and your child(ren), why we need them, how we will collect them and when we will collect them. Please carry on reading for specific details.

### **Questionnaires**

We would like you to complete questionnaires at important time points as your child grows up. This may include questions about your family health history, your lifestyle, your wellbeing and your child's development.

### **Biological Samples**

We would also like your permission to collect biological samples such as saliva from you, your partner and your child(ren), at convenient time points during your child's cleft treatment. Other biological samples (tissue and blood) are also collected from the child for two reasons, firstly, the volume of saliva collected may be too small to obtain sufficient quantities of DNA and secondly, it allows for potential further analyses. These samples will be used to conduct biological research, including an analysis of the whole genome.

### **What is a 'genome'?**

Our 'genome' is the complete set of genetic information we have in our body and contains over three billion letters of DNA. Each person's genome contains all of the information on how to build that person. Our genome plays an important role in determining many of our characteristics and some genes can make

us more or less likely to develop diseases. Having DNA and other biological information from all members of the family enables us to look at all the different sets of genetic information, how they are inherited and how they may be linked to clefts.

### **Further Information on Cell Lines**

We would also like to use your child's biological samples to make cell lines. DNA from a single sample would run out before we can complete our research. By taking cells from blood and tissue and providing them with the correct nutrients and conditions, we can keep them alive and grow them in the laboratory. This means we can make more of your child's DNA to use when it is needed. We can also use cell lines for other tests which will help to tell us what affects the way cells from different people grow.

### **Cord blood**

We would like your permission to collect blood from your baby's umbilical cord after birth. The cord blood would be collected from the placenta after the cord has been cut. This process will not hurt your baby and will not delay any care that you receive immediately after the birth. This blood sample would then be sent to the laboratories for processing.

---

## **4. What will happen to my information?**

---

### **What happens to the samples?**

The samples will be delivered by post to a laboratory based at the University of Bristol where they will be processed and

stored securely and anonymously. Samples and data may be sent to other laboratories in the UK and worldwide as it is not always feasible for us to do all the tests in Bristol. However, we will always make sure that the samples remain anonymous. They will be labelled with a number and only The Cleft Collective team in Bristol will be able to link the data and samples back to any other information that you have given us.

Anonymous biological samples and data from your family may be shared with other researchers to promote research, in particular in relation to cleft. All researchers will need approval from a research ethics committee to make sure your rights are protected. These researchers will never have access to your personal data.

You will be asked to indicate on the consent form if you give permission for the storage and analysis of your samples in future, ethically approved cleft related research.

### **How long will the samples be stored for?**

Unless you request otherwise, we will store your biological samples indefinitely. The technologies for analysing samples are improving all of the time, so we would like to keep some of your samples to test when these new technologies are developed in the future. This may further enhance our understanding of cleft.

### **Accessing health records**

A great deal of information is collected and stored about all of us in our official government records. This information gives a detailed picture of many aspects of our life, such as our health, the

medications we are prescribed by doctors and our education. The Cleft Collective can use this information alongside the information you give us to improve our understanding into the causes of cleft and longer-term effects.

We would like to use these records for a number of reasons, including:

- Helping to make questionnaires shorter
- You may not be able to remember the answers to some of the questions we ask.

Information can only be released with your permission. In order to access the information, we will provide the minimum necessary personal details (such as your name and address) to the government departments and organisations holding the information. These details will only be used to identify your information. Before the departments and organisations send any information you have authorised back to us, your name and other details will be removed. None of your questionnaire responses will be disclosed to these sources for any other purpose. In the same way as the answers you give us in the questionnaires, the information from other sources will be kept completely confidential in accordance with the Data Protection Act. Further information on confidentiality and data protection is provided later on in this Information Sheet.

Health records include those held by your general practitioner (GP). For example:

- Details of visits to your doctor and any treatment you were given
- If you've ever been to hospital; why you were there and what happened whilst you were there
- Eye tests and dentist records.

All you need to do is agree to us accessing your health records on the consent form and we will do the rest. We will regularly request copies of your records from the relevant departments and organisations to look at any additional information that may have been added.

You can choose not to agree to us accessing your medical records without it affecting your involvement in the rest of the study. You are free to tell us to stop at any time without giving a reason.

We will link to your child's records in the same way as we link to your records. We can only do this with the consent of the parents or carer. We will request access to their Child Health Record which records their development and immunisations as well as records held by their Doctor (GP). We are not putting an expiry date on this consent as we do not know exactly when we will obtain and add the information. However, we will remind you of the permissions you have given from time to time, and you are free to withdraw your consent at any time. We would like to obtain information on your child from birth up to when they are an adult at which point they can consent for themselves.

We would also like to ask your permission to take copies of the records that are collected by your cleft team.

### **Accessing my child's education records**

School education records are collected by the Department for Education (<http://www.education.gov.uk/>). School education records are held in the National Pupil Database (NPD), a database for all children in maintained schools in England,

linking information about them to school learning aims and attainment.

The Cleft Collective would like to collect the routinely collected information on your child's education from the Department for Education. This is information about:

- Your child's achievements at school (Key Stage Assessments and GCSEs in England, Wales and Northern Ireland and 5-14 levels and Standard Grades in Scotland)
- The characteristics of pupils in your child's school (ethnicity, special educational needs, absences)

It will only be collected throughout their compulsory education (currently 4-16 years). We may be able to use this information to help us keep in touch with your family.

#### **Linking to the CRANE database**

The CRANE database is a record of information collected routinely after the birth of children born with cleft lip and/or palate throughout England and Wales. This information is stored electronically on a computer housed at The Royal College of Surgeons of England and is funded by the National Health Service. Information held on this database includes:

- Details of the type of cleft the child was born with
- Patient name, address, and postcode
- Whether there is a history of cleft lip or palate in the family

With your consent, we would like to access your child's information on the CRANE database; this will help us to get as much information as possible about your child's cleft without having to ask you directly. For more information about

CRANE, take a look at their website: <https://www.crane-database.org.uk>.

#### **How do we make sure your data stays confidential and protected?**

All the information we have about you, and the samples we take from you, will be stored securely and confidentially, as is required by law in the Data Protection and Human Tissue Acts. A unique ID number will be the only way the information can be linked to you. Only the Bristol Cleft Collective research team will be able to link you to the unique ID number; this is important so that we can contact you in the future. Please note that the analyses carried out do **not** include paternity testing, or any analysis that might have an effect on your life insurance.

If you decide to take part, we would like to inform your GP, but please be assured that they will not have access to any information you provide us with. We will ask you to give us your GP's name and contact details if you agree to take part.

The information we need to exchange with the relevant government departments to access medical and educational records (if you consent to this) will be encrypted and sent via secure transfer systems.

You will be asked to indicate on the consent form if you give permission for your data to be stored and analysed in future, ethically approved cleft related research. Only anonymous samples and data will be shared with researchers. They will not have access to your personal information.

---

## **5. What are the possible benefits and disadvantages of taking part?**

---

There may be no direct advantage to you or your child in taking part. However, you will be helping us to provide improved knowledge and support for all those affected by cleft lip and/or palate in the coming years.

We do not see any major disadvantages to you taking part in the study. However, the study will require some of your time. The research will not interfere with your child's cleft treatment as it will take place alongside your child's normal treatment, or can be done from your home.

Very occasionally our analyses may uncover a specific genetic cause for the cleft. If so, we will inform the Clinical Genetic Service linked to your Cleft Centre who will offer you the opportunity to discuss this and answer your questions.

It is also possible that the research may find a genetic change which we think you should be informed about because it has other important health implications, separate to the cleft, for your baby or your family. As above, we would then contact your Clinical Genetic Service asking them to talk to you about what it means and decide with you if anything further is necessary.

You can choose not to be given any genetic information from the study if you prefer by initialling the relevant box on the consent form.

All information provided from the study will be in line with guidance to be produced by The Wellcome Trust and the Medical Research Council in 2013.

Please note that we will only provide this feedback if the biological cause is of relevance to your family and has been identified with very high confidence, and confirmed by an expert team.

---

## **6. Sharing the results and keeping in touch.**

---

### **What will happen to the results of the research?**

The anonymous findings of this research will be reported in professional publications, meetings and conferences. Results may also be shared with charities and with members of the general public, but you will not be personally identified in any report, presentation or publication.

We will also report anonymous summaries of the research findings via The Cleft Collective website ([www.bristol.ac.uk/cleft-collective](http://www.bristol.ac.uk/cleft-collective)) and via newsletters that will be emailed/posted to you unless you choose not to receive them.

### **Keeping in touch**

An important part of The Cleft Collective is to keep in touch with those who have agreed to take part. This will tell us more about your child's treatment journey and about how your child is developing. We initially have funding for this project for five years; however, if we can secure further funding then we would like the study to continue indefinitely so that we can collect more information from you and your family. To help us keep in touch, we will use information held by the National Health Service (England and Scotland), The NHS Information Centre and the NHS

central register and the Health and Social Care (Northern Ireland). This information includes when you move house or leave the NHS. If at any time you decide you do not want us to contact you again, you just have to tell us.

You may also be offered other opportunities to take part in related cleft studies should you wish to.

---

## **7. How is this study funded and managed?**

---

The Cleft Collective Cohort Studies are run by the University of Bristol and the University of the West of England. Expert scientists oversee this research; the lead scientists are Professor Jonathan Sandy and Professor Nichola Rumsey.

This research project was reviewed and approved by:

- The Healing Foundation before they agreed to provide the funding
- The NRES Committee South West – Central Bristol; an independent group who look at all research involving NHS patients and who are there to protect your safety, rights, well-being and dignity

We also ask parents of children born with a cleft to give us their advice on aspects of this study and our study materials, for example, this information sheet.

The research is funded for five years from May 2012 by the Healing Foundation (registered charity no. 1078666); the Vocational Training Charitable Trust (registered charity no. 295192); the University of Bristol and the University of the West of England. These funding bodies are not involved in research for

commercial purposes. The research is also supported by the Cleft Lip and Palate Association and involves all of the cleft teams around the UK.

---

### **Contact for further information**

If you have any questions about this study and what you are being asked to consider, or if you have any queries/concerns at any point now or in the future, please contact the researchers at The Cleft Collective research centre in Bristol (details provided on front sheet).

If you have a complaint and you do not wish to speak to The Cleft Collective Team, you can contact your cleft team.

If you feel distressed and would like extra support at any time, you can contact:

- Your cleft team – most cleft teams have a Psychologist, but another member of the team may also be able to help you.
- The Cleft Lip and Palate Association (CLAPA) – the only UK-wide voluntary organisation set up to specifically help those affected by cleft lip and palate.

Web: [www.clapa.com](http://www.clapa.com)

Phone: 020 7833 4883

Email: [info@clapa.com](mailto:info@clapa.com)

- Your GP (doctor)

Thank you for reading this information sheet. Please keep it for future reference.