

D-CYPHR | The DNA, Children + Young People's Health Resource

Information pack for parents/guardians



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If you require this information to be translated into another language or in a different format, please speak to a member of the BioResource team.

1. INTRODUCTION

Around 30% of the population are said to be living with a long-term health condition such as diabetes, heart disease or mental health conditions. Living with a chronic disease can have a major impact on a person's quality of life and on their family. Genetics can play an important part in many of these diseases and impacts the severity of the condition, the medications that might work for different people and how best to prevent people getting ill in the first place. The National Institute for Health and Care Research (NIHR) BioResource has been set up to help support research into the role of genetics in a range of health and medical conditions. The BioResource has focused primarily on adult volunteers up to this point, but research into the origins of disease has revealed that most diseases start in childhood. We are therefore missing clues and opportunities to help prevent illness in children and in the adults they will become. We have created the DNA, Children + Young People's Health Resource (D-CYPHR) to help researchers better understand the genetics of childhood diseases.

Thank you for taking the time to consider your child joining D-CYPHR as a health research volunteer. Please read the following information carefully and make sure to ask us if there is anything that is not clear, or if you would like more information.

What is the purpose of the NIHR BioResource?

The NIHR BioResource comprises a panel of more than 200,000 volunteers, with and without health conditions, who are willing to take part in health research. The National Coordinating Centre is based in Cambridge, with local BioResource centres located across the country. The BioResource has a grant from the National Institute for Health and Care Research (NIHR) which ultimately comes from the UK Government Department of Health & Social Care and we are closely linked with the University of Cambridge.

The NIHR BioResource is supporting studies looking at how genes and other factors influence disease. By gaining more information on the genes involved in disease we can begin to identify better treatments, diagnostic tools, and care.

A critical part of any research study is to have a group of people who don't have diagnosed illnesses, as they are used as a comparison for those who do. Understanding the genetic and lifestyle or environmental differences between those who develop a certain disease and those who do not is an important way for us to try and understand the causes of that disease. Those who develop a health condition in childhood are also more likely to have a genetic explanation for that condition. This means

It is particularly important to identify a group of children without that condition who are willing to participate in the BioResource so researchers can study a wide range of illnesses in children.

2. TAKING PART

Who can join the DNA, Children + Young People's Health Resource?

The DNA, Children + Young People's Health Resource (D-CYPHR) is recruiting volunteers with and without health conditions. D-CYPHR is now open to families with children aged 0-15. Although not eligible for D-CYPHR, young people over the age of 16 can join the [adult BioResource](#). By joining, your child will be helping researchers investigate and understand why some individuals have a disease.

Does my child have to join D-CYPHR?

Your decision to join is completely up to you and your child. If your child does not join, the decision will not affect the healthcare they receive in any way. If your child does join the BioResource, they are free to withdraw at any time and without providing a reason.

What will happen if my child joins D-CYPHR?

If you and your child agree that your child can join, we will ask you to:

- read and sign a consent form on behalf of your child. Children who are able to will be asked to sign an assent form as well (online or paper),
- provide basic information including your child's name, date of birth, NHS number, your name, and contact details for yourself and your child (if appropriate), and allow us to store them securely,
- we will ask your child to provide a saliva sample (via a saliva sample tube). DNA will be isolated from their sample and will be used to determine their genetic make-up,
- you and your child will be asked to complete a questionnaire about your child's health and lifestyle (online or paper),
- you and your child will be given the option to complete a second questionnaire about your child's free time, friends, school, and family,

- allow us to collect, store and analyse health, care, and education information about your child (including accessing their medical, education and social care records, for example through NHS England (previously known as NHS Digital), local authorities, or educational sources).

We know that, as well as our genes, health is impacted by our environment. When we talk about ‘environment’ we mean the things that make up a young person’s day to day experiences – it could include where they live, the structure of their family, or the kind of school they go to. Research is showing that a person’s genetic makeup can affect how they cope with different environments, and we want to explore how this works for young people,

- in the future, your child may be invited to provide further saliva samples, either for other studies or if the initial sample you provided was insufficient for certain types of testing,
- in the future, your child may be invited to provide other samples, such as blood samples. You and your child can decide whether you would like to provide these additional samples, and are under no obligation to do so,
- agree to be contacted in the future to be invited to take part in other research studies. We will use your child’s saliva sample, and additional information, to invite your child to research studies that are looking for volunteers. You and your child can decide whether or not your child would like to be involved at the time, and are under no obligation to do so.

3. SAMPLES

What will happen to the samples my child gives?

We want to know how genes influence disease. Genes are made up of DNA. We will isolate, analyse, and store a sample of your child’s DNA from their donated saliva sample and, using advanced laboratory techniques available now or to be developed in the future, we will determine your child’s genetic make-up. This may include determining the sequence of all or part of your child’s DNA code. For those children that decide to provide a blood sample in the future, we may also isolate and test other components of their blood such as cells, RNA, protein, and metabolites. Researchers may seek access to your child’s samples and related data, but their personal details will never be released to researchers without your knowledge and permission. Your child’s samples will be kept in a secure location.

4. DATA AND COMMUNICATION

What will happen to any data produced from the samples my child gives?

De-personalised data about your child will be stored in an electronic archive and made available to researchers. This data may include part of or your child's entire DNA code but will not identify them. It may also include the results of other tests performed with your child's samples and other information from the research database that does not identify your child personally, e.g. their age in years, their gender.

Researchers will have to make a request to access this data and explain how they will use it, e.g. which research question they are trying to answer. This type of system is referred to as 'managed access'. Genuine researchers will be given access to the data for their research, and they will be reminded of their obligation to keep your data safe by accepting the terms of a data transfer/access agreement.

'Managed access' requests could come from researchers who are working in the public and charitable sector (Universities, Research Institutes) or in commercial companies, either in the UK or overseas.

Researchers share the results of their studies by means of reports or publications, which includes placing information/data on the internet, in press articles, in project leaflets, and through other media. **Under no circumstances will information that identifies your child personally be disclosed in any of these documents.**

Will our details be kept confidential?

Yes. Best ethical and legal practice will be followed to ensure that all information collected about your child will be handled in confidence. Their samples will be labelled with a unique sample study number before being transferred to the laboratory for testing and information from genetic and other tests will be stored separately from their personal details. Access to their personal details will only be available to necessary members of NIHR BioResource staff, IT staff that manage our databases and, if required, regulatory organisations who check that this study is being carried out correctly. Information from these tests will not be used or made available for any purpose other than for research. Your child will not be identified personally in any report or publication.

Transparency Statement under General Data Protection Regulation (GDPR)

Here, we explain how we comply with the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679). Please also read our <https://bioresource.nihr.ac.uk/about-us/governance-and-ethics/privacy-notice/>, which explains what we do with the information we hold about you, how you can request access to this personal data, and other data rights.

[Cambridge University Hospitals NHS Foundation Trust \(CUH\)](#) is responsible for managing the NIHR BioResource Research Tissue Bank.

How will we use information about you?

We, the NIHR BioResource, will need to use information from you and your child, from your child's medical records, including from their GP, hospital records and other health-related central records, their social care records and education records for this research project.

This information will include your child's:

- Full name
- NHS number
- Date of birth
- Contact details including address, and any phone number and email address (if appropriate)
- Name and contact details of your child's GP
- Health-related information e.g. on your child's lifestyle, disease history, medication etc.
- Genetic information that will be generated from your child's saliva or any blood samples or provided by e.g. NHS health-related central records, disease registries etc.
- Social care information
- Education records

And your own:

- Full name
- Date of Birth
- Contact details including address, phone number and email address

People will use this information to do the research or to check your child's records to make sure that the research is being done properly.

People who do not need to know who you and your child are will not be able to see your and their names, date of birth or contact details, nor your child's NHS number (which are your "personal identifiable information"). Your child's data will have a code number instead.

We will keep all information about you and your child safe and secure.

Some of your child's information, but not their personal identifiable information, will be sent to other countries worldwide. They must follow our rules about keeping your child's information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

What are your choices about how your child's information is used?

You and your child can choose for your child to stop being part of the study at any time, without giving a reason, but we will keep information about you and your child that we already have.

No further contact withdrawal

Please request this if you and your child choose to stop further contact with us but would be happy for us to continue research with their sample. If you choose a 'no further contact withdrawal', we will continue collecting of information about your child's health from central NHS records, their hospital, their GP, and also information from social care and educational records. However, we will stop contacting you to invite your child to take part in further research studies.

No further use withdrawal

Please request this if you would like us to stop looking at your child's information after the point of your withdrawal. We will destroy your child's remaining sample and will stop any further contact with you. However, we are unable to remove any information that has already been collected about your child up until the point of your 'no further use' withdrawal.

We need to manage your child's records in specific ways for the research to be reliable. This means that we will be able to let you see the data we hold about your child. We will be able to change some of the information we hold about you and your child (for example your contact details and contact preferences) if you ask us to; however, we won't be able to let you change other data we hold about your child (such as your child's genetic information for example).

Where can you find out more about how your information is used?

You can find out more about how we use your child's information

- at <https://hra.nhs.uk/information-about-patients/>
- our privacy notice, available from <https://bioresource.nihr.ac.uk/about-us/gdpr/>, which includes the Data Protection Officer contact details
- by asking one of the research team
- by sending an email to nbr@bioresource.nihr.ac.uk
- by ringing us on 0800 090 2233

Invitation to future studies

The BioResource supports many different research studies. We may, on the basis of the data held in the research database, contact you to ask whether your child would like to take part in a research study. You will be provided with information regarding each of these studies and will be free to decide whether or not your child would participate.

Some research will not require any further input from your child as the sample data generated from their saliva sample, and information you provided/granted us access to when your child joined, can be used for research purposes.

How often will I be contacted?

We closely monitor the number of times you are approached to invite your child to future studies. We greatly appreciate the effort made by volunteers and are happy to cover travel/parking costs incurred by volunteers participating in studies. If you would like updates about the progress of the BioResource you can sign up to our newsletter.

5. RISKS AND BENEFITS OF JOINING

What are the risks and disadvantages of joining D-CYPHR?

Joining D-CYPHR will involve your child donating a small saliva sample. If your child decides to provide a sample of blood in the future, qualified, experienced staff will collect it. Blood sampling can cause

some discomfort when the needle is placed in the vein to draw blood. There is also a possibility that a small bruise may develop.

What are the benefits of joining D-CYPHR?

Like any donation, there is no direct personal benefit to your child - this is a gift, and we are incredibly grateful to everyone who volunteers. Your family will be contributing to science and to the future of healthcare.

6. RESULTS

Can my child and I know the results obtained from their study samples?

The NIHR BioResource does not intend to undertake analysis of data generated by genotyping or sequencing of DNA samples collected at the time of enrolment to identify variants that may have clinical significance, and hence does not plan to provide feedback of genetic findings. We will notify you if this changes.

Will any of the results obtained with my child's sample predict the risk of disease?

We cannot answer this question. Many of the studies that will be carried out using these samples aim to discover variations in the genetic code (so-called genetic markers) that might predict the risk of certain diseases. However, it may be years before we can confirm how important or accurate these markers are and determine the associated risk.

If your child is contacted to take part in a future study, this does not mean that your child's health is at risk. All individuals carry risk and protective DNA variants in their genes, and we are a long way from understanding how they balance each other and what combination of markers interacting with other factors such as age or gender cause disease.

What happens if an invention is made using my child's sample?

Your child's donated samples and related information are given as an absolute gift, i.e. without receiving a payment and without conditions. The BioResource is operating on a non-commercial basis, meaning it will not sell your child's sample to make a profit and will not allow anyone else who is working with the sample to do so either. However, if samples are made available to other research institutions or to commercial companies, a fee may be charged to cover the operational costs.

In the future, your child's sample may help researchers in the public and commercial sector to make an invention, for example, develop a new product to diagnose or treat disease. If an invention results from the research undertaken with your child's sample, you will not receive any compensation or payment. BioResource partners in the public sector may work together with commercial companies to develop inventions for the benefit of patient and donor care, and we hope that such products are brought into use to improve healthcare in the future.

7. WITHDRAWAL PROCESS

What if I no longer want my child to be a member of D-CYPHR?

Volunteers are free to withdraw at any time without giving a reason. As detailed in section 4 of this document, if you choose to withdraw your child, there are two types of withdrawal you can choose from ('no further contact' or 'no further use')

- You will be asked to specify whether you would like us to destroy the sample(s) your child has donated ('no further use' withdrawal) and which are stored at the central archive.
- It will not be possible to destroy samples already prepared or already distributed for testing.
- Yours and your child's personal information will be retained in an archive so that a record remains of your initial consent and the withdrawal process.
- Should you wish, by choosing 'no further use' withdrawal no further data will be retrieved from your child's health-related, social care and education records and no new data from laboratory measurements will be added to the research databases; pre-existing data will not be used in further analysis wherever possible.
- Pre-existing data and data that has already been distributed to other researchers cannot be destroyed.
- Once confirmation of your decision for your child to withdraw is received, you and your child will not be contacted again by the BioResource.

- If the BioResource is unable to confirm your decision of whether you want your child to withdraw from further contact only, or also from further use of their samples and data, your child's sample(s) and data will be retained for future use, but you and they will not be contacted again.

What will happen when my child reaches the age of 16?

Within the context of research, your child will be considered an adult when they turn 16. As such, we will write to you asking if they would like to continue to participate in the NIHR BioResource. They will be provided with an adult Participant Information Sheet which is very similar to this one and they will be invited to complete a Consent Form to confirm their decision to continue. They will also be provided with the option of withdrawing if they so choose.

8. FUNDING & SPONSORSHIP

Who funds and sponsors the NIHR BioResource?

The NIHR BioResource is funded by the National Institute for Health and Care Research (NIHR). The study has been reviewed and approved by East of England - Cambridge Central Research Ethics Committee.

Cambridge University NHS Foundation Trust is the establishment responsible for the management of the NIHR BioResource – Research Tissue Bank.

9. CONTACT INFORMATION

If you want more information before deciding or have any queries, please feel free to contact the NIHR BioResource team on freephone 0800 090 2233 or e-mail us on dcyphr@bioresource.nihr.ac.uk or nbr@bioresource.nihr.ac.uk or visit our website at <https://bioresource.nihr.ac.uk/>.

Thank you for taking the time to read the information sheet and considering taking part in the DNA, Children + Young People's Health Resource.

If you were sent this information sheet in the post, complete the consent form on the next page.



PARENT/GUARDIAN CONSENT FORM FOR CHILD D-CYPHR

This form can be completed online

If you agree for your child to take part in D-CYPHR please:

- initial boxes 1, 2, 3 & 4
- print, date and sign your name and the name of your child at the end of this form

1. TAKING PART

I confirm that I have read and understood the Information Leaflet version ___ dated ___/___/___, for D-CYPHR. I have had the opportunity to ask questions and these have been answered.

I understand the following:

- **I can decide for my child to join D-CYPHR, part of the NIHR BioResource or not.**
My child’s routine healthcare or legal rights will not be affected in any way if they don’t take part.
- **If my child joins, he/she can withdraw at any time.**
If my child withdraws, I understand that some research may have already taken place using their data, and this can’t be undone.

I agree to the following:

- I, the undersigned, am the parent or legal guardian of the child named at the end of this form, and I have the authority to sign this Consent Form on behalf of the child.
- I agree for my child to join D-CYPHR.
- I can be contacted by the BioResource to:
 - ask me and my child to complete questionnaires, including a health & lifestyle questionnaire for my child.
 - invite my child to participate in other studies including donating further samples.
 - send me communications on behalf of my child (e.g. newsletters, invitations to events).

Box 1:

Initial here to show you agree.	
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2. SAMPLES

I agree to:

- My child giving saliva samples for research. I understand that my child’s samples may be transferred between research institutions.
- My child possibly being asked in the future to provide a blood sample; they will be free to choose whether to do this or not
- My child’s samples being tested as outlined in the Parent/Guardian Information Sheet, and this may include the reading of my child’s entire genetic code.
- Long-term de-personalised storage of my child’s samples (including cells and DNA) for health-related research, with storage to continue in the event of my child’s incapacity or death.
- That these samples are a gift to the NIHR BioResource and all rights to these samples are relinquished.

Box 2:

Initial here to show you agree.	
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3. DATA

I agree that:

- The NIHR BioResource may access my child’s health, education and social care-related records, such as through NHS England (previously NHS Digital), hospital/GP records, local authority or educational sources, analyse and store this information long-term, even in the event of my child’s incapacity or death. I understand that information from his/her medical notes and other health-related records may be used to provide information about their health status.
- Data produced by studying my child’s samples may be included in publications and/or placed in electronic archives (with no connection to my child’s name or other personal identifiers). I understand that this archive will only be accessible to researchers on application, to ensure the results are only used to advance scientific and medical understanding.
- My child’s personal and contact details (e.g. name, date of birth, NHS number, address, email, phone number etc.) can be collected and stored on secure databases by the NIHR BioResource. I agree that my personal and contact details (e.g. address, email, phone number, date of birth etc.) can be stored on secure databases by the NIHR BioResource. These details can be used to request my child’s health, social care and educational records, for communications by the study team and for possible invitations for my child to participate in physical and mental health-related research studies.

DATA (continued)

I understand that:

- My child may be invited to participate in other studies based on data held or accessed about them, and/or analysis (including of DNA markers) of samples they have donated. Both my child and I will be provided with full, age-appropriate information about these studies, when and if we are contacted. I understand that I am free to decide whether or not my child will take part in these studies.
- This research may include work conducted by commercial companies, and that neither I nor my child will benefit financially if this research leads to new medical tests, treatments or inventions.

Box 3:

Initial here to show you agree.	
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4. RESULTS

I understand that:

- The NIHR BioResource will not routinely feedback any genetic or other test results, as my child's samples are taken for research purposes.

Box 4:

Initial here to show you understand.	
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First Name and Surname of Parent/Guardian (BLOCK CAPITALS)	Date of Birth	Parent Signature	Date

First Name and Surname of Child (BLOCK CAPITALS)	Child's Date of Birth		Date

First Name and Surname of Person receiving consent (BLOCK CAPITALS)		Signature	Date