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

Information Sheet and Consent Form for parents/guardians

V4.0, 16 Jan 2025

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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

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.

Our bodies are made up of millions of cells. Each cell contains DNA, which provides the cells with instructions on how to work. DNA also determines things like your hair and eye colour. Each piece of information is carried on a different section of DNA – these sections are called genes. The study of genes is called genetics.

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 impact whether or not different people get ill, or how badly, and can also impact how medications work for different people.

What is the purpose of the NIHR BioResource?

The **N**ational **I**nstitute for **H**ealth and Care **R**esearch (NIHR) BioResource has been set up to help support research into the role of genetics in a range of health and medical conditions. The NIHR BioResource comprises a panel of over 300,000 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 NIHR BioResource is funded by the National Institute for Health and Care Research (NIHR) which ultimately comes from the UK Government Department of Health & Social Care.

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

What is D-CYPHR?

Research into the origins of disease has revealed that most diseases start in childhood, but most health research is carried out in adults. We are therefore missing clues and opportunities to help prevent illness in children and in the adults they will become. We have created the **D**NA, **C**hildren + **Y**oung **P**eople's **H**ealth **R**esource (**D-CYPHR**) to help researchers better understand the genetics of childhood diseases.

D-CYPHR is led by the NIHR BioResource in partnership with the NHS, Anna Freud and the University of Cambridge. D-CYPHR is a research tissue bank especially for children aged 0-15. We want to make it easier for families to get involved with health and genetics research studies.

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 is why it is important to include children with and without health conditions in research. D-CYPHR now has around 9,000 volunteers who have joined and will help future health research.

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 young participants with and without health conditions, who are aged 0-15. By joining, your child could be helping researchers investigate childhood health.

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 D-CYPHR, 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:

Step 1: Register your interest in participating, you may have already done this.

Step 2: Sign consent forms:

- 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 (optional), as well as your name, and contact details.. Allow us to store them securely,
- allow us to collect, store and analyse health, social care, and education information about your child, for example through NHS England, local authorities, or educational sources. These records may be:
    - medical
    - education
    - social care

Why would researchers need access to these records?

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. This is why some researchers may request access to medical, educational or social care records.

Not every research study requires access to these records.

For research studies that do involve access to these records, we will only request information when needed and only information that is relevant to the research question. A couple of examples are listed below:

Example 1: A researcher is looking at how asthma is currently treated in the UK. They have identified a group of volunteers who have ticked 'yes' to asthma on their health and lifestyle questionnaire. The researcher may request to access the GP records for these children, to look at which inhalers they are currently prescribed.

Example 2: A researcher is looking at young people's mental health and how it impacts education. They have identified a group of volunteers who have reported depression or anxiety on their health and lifestyle questionnaire. This researcher may request information on the number of missed school days from the education records of these volunteers.

Access to medical/education/social care records will only be given to permitted staff, for example the administrative team handling the request and the approved researcher who made the request. Best ethical and legal practice will be followed to ensure your child's information will be handled in confidence.

Step 3: Complete a health and lifestyle questionnaire:

- 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 may also be given the option to each complete a second questionnaire about your child's free time, friends, school, and family. We may ask these questions because research shows that a person's genetic makeup can affect how they interact with different environments,

Step 4: Child donates a saliva sample:

- ask your child to provide a saliva sample. **DNA** will be isolated from their saliva sample and will be used to determine their genetic make-up,

- 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. You and your child can decide whether or not you would like to provide additional samples, and are under no obligation to do so,

- in the future, your child may be invited to provide other samples, such as blood samples. You will be provided with further information and you and your child can decide whether you would like to provide these additional samples at the time. You 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 you 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?

Watch the journey of a sample video and learn more.

We will isolate, analyse, and store a sample of your child's DNA from their donated saliva sample. 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 (nucleic acid present in all living cells), protein, and metabolites (a substance formed in or necessary for metabolism).

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 sent via tracked mail and will be stored in locked freezers. Only authorized staff members will have access to the freezers. The samples will be kept secure. Samples will be stored until your child reaches the age of 16, unless you request for them to be destroyed. When your child reaches the age of 16, we will ask them to decide for themselves if we can keep their samples, or if they would prefer for their samples to be destroyed.

4. DATA AND COMMUNICATION

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

De-identified (identifying information such as name removed) 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, but not their name.

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 child's 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. It is important to note that many health research studies may involve different partners, including academic, NHS and industry researchers. All managed access requests will go through an application process to be considered for access. Their application is reviewed by the NIHR BioResource Steering Committee/Scientific Advisory Board (SAB) and only applications that meet our strict criteria will be approved.

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 you and your child will be handled in confidence. Their samples will be labelled with a unique sample number before being transferred to the laboratory for testing. 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 our work 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 privacy notice (https://bioresource.nihr.ac.uk/media/04nhduml/privacy-notice-v2.pdf), 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.

We will be using information from you, and your child's healthcare, social care and education (if required) records in order to support research studies, and CUH will act as the data controller for the information we hold. We are responsible for looking after your information and using it properly.

Cambridge University Hospitals NHS Foundation Trust will keep identifiable information about you and your child for 10 years after the study has finished, and we may approach you to extend this.

How will we use information about you?

During your child's participation 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 (where necessary) for this research project.

This information will include your child's:

- full name
- NHS/CHI 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, for example, NHS health-related central records, disease registries etc.
- social care and education information

And your own:

- full name
- date of Birth
- contact details including address, phone number and email address

Staff 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 are will not be able to see your child's name, NHS/CHI number, date of birth or contact details (which are their "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.

Scientific information about your child, but not their personal identifiable information, may be sent to researchers in other countries worldwide. They must follow our rules about keeping your information safe.

If and when the NIHR BioResource finishes, we will keep some of the data so we can check the results. We will write our reports in a way that ensures no-one can work out that you or your child took part in the NIHR BioResource.

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

- You can stop being part of D-CYPHR (and the NIHR BioResource) at any time, without giving a reason;
- If you choose to stop taking part in the NIHR BioResource, you have two options as outlined in the 'Withdrawal process' section. Further information on leaving the BioResource can be found here: https://bioresource.nihr.ac.uk/participants/members/leave-us/;
- You may request a copy of the information we hold about you and your child;
- We need to manage your child's records in specific ways for the research to be reliable. 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 (such as your child's genetic information).

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 Patient data and research leaflet - Health Research Authority
- 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.

We are open to support many different kinds of childhood health study, here are a couple of examples:

- Our families have supported a trial of SPARX-UK, mixing cognitive behavioural therapy and gameplay. It is exploring how to help young people with depression and anxiety.
- Children aged 6 – 16 are helping a study looking at how much energy children expend – their metabolism. Children wear two small devices, one on their chest and one on their wrist for 2 days during their usual activities.

We hope to be able to support hundreds more research studies in the future.

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. Today there are around 1.7 million children and young people in England with a long-term health condition, and one in six children could have a probable mental health condition. Your contribution will be helping valuable research.

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. The saliva sample is collected for research purposes only therefore the NIHR BioResource 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?

You and your child are free to withdraw at any time without giving a reason. If you choose to withdraw your child, there are two types of withdrawal you can choose from (‘no further contact’ or ‘no further use’):

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 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.

- 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.

10. Consent Form

This form can be completed online

PARENT/GUARDIAN CONSENT FORM FOR CHILD D-CYPHR

Please initial box

1. ☐ I confirm that I have read (or had read to me) the information sheet version 4.0, dated 16JAN2025. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.

2. ☐ I understand that my decision for **my child** to participate in D-CYPHR is **voluntary**. If my child joins, they are **free to withdraw at any time.** If my child does withdraw from D-CYPHR they do not have to give a reason. Joining D-CYPHR and then withdrawing will not affect my child's medical care or legal rights. [see section 7, p14]

3. ☐ I agree that the BioResource may access **my child's** medical, health, social care, and educational (if required) records held by public bodies, and to analyse and store this information long-term. I understand that this may include the provision of information about my child's health status. I understand that in order to access these records, identifiable personal details – like name, NHS number, date of birth will be sent to these public bodies. [see section 2, p6]

4. ☐ I agree to **my child** giving saliva for health related research. I understand that my child's samples may be shared to support future research, including commercial studies. I understand my child's samples will be tested, and that this may include the reading of the entire genetic code. I understand my child's sample will be stored long-term. [see section 3, p8]

5. ☐ I agree to provide **my own** personal and contact details. I agree to be contacted by the BioResource to invite **my child** to participate in other research studies. [see section 2, p6]

6. ☐ I agree to provide information for **my child**. For example, through the completion of questionnaires. [see section 2, p6]

7. ☐ I understand that relevant sections of **my child's** medical/health related, social care and education (if required) records and data collected during the research may be looked at by approved individuals for auditing and monitoring purposes. I give permission for this. [see section 4, p11]

8. ☐ I understand **my child's** samples and de-personalised data may be shared with researchers through a 'managed access' process. [see section 4, p8]

9. ☐ I understand that **my child's** samples are taken for research, and the BioResource will not feed back any genetic or other test results. [see section 6, p13]

10. ☐ **I agree for <u>my child</u> to join D-CYPHR – part of the NIHR BioResource Research Tissue Bank.**

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First Name and Surname of **Child** (BLOCK CAPITALS)	**Child's** Date of Birth		Date
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First Name and Surname of **Parent/Guardian** (BLOCK CAPITALS)	Date of Birth	Parent Signature	Date

FOR D-CYPHR OFFICE USE ONLY

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First Name and Surname of **Person receiving consent** Signature Date

(BLOCK CAPITALS)

FOR WITNESS AND/OR TRANSLATOR USE ONLY

WITNESS/TRANSLATOR STATEMENT: If participant is not able to read the text and/or sign for themselves but has capacity to give consent OR if the Participant Information Sheet and Consent Form has been translated.

Witness/translator [to delete either as appropriate]:

I witnessed accurate reading of the consent form to the potential participant, who could ask any questions and received satisfactory answers

or

I was present during the meeting between [insert name] and the participant. I translated for the participant the Participant Information Sheet and the Consent Form.

I confirm that they gave their consent freely.

………………………………………………………. ……………………… ……………..

Witness/translator: First Name and Surname Signature Date

(BLOCK CAPITALS)