



# CHOIR



GREAT ORMOND STREET  
INSTITUTE OF CHILD HEALTH

Parent/Guardian Information sheet

CHOIR – Childhood Ocular Inflammatory Disease Research tissue biobank

Name of PI: Ameenat Lola Solebo

## **Introduction.**

You and your child are being invited to donate their samples to the CHOIR (Childhood Ocular Inflammatory Disease Research tissue biobank) because your child has an inflammatory eye disease.

Before you decide whether to take part, it is important that you understand why the samples are being collected, and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please feel free to ask us if there is anything that is not clear or if you would like more information.

This research is funded by different charities including Fight for Sight and the Kennedy Trust. It is taking place at different centres in the UK. It is partnered with the **UNICORN** (Uveitis in childhood national prospective cohort) study.

## **What are we researching and why are we doing this?**

We are collecting samples from children and young people who have inflammation in and around their eyes, including disorders such as uveitis, scleritis, orbital inflammation. This is in order to help researchers look for signals from those tissues and see whether those signals tell them what causes disease, which treatments work best, and what happens to children with different types of disease. These signals will be discovered by testing for different types of cells and proteins, and genetic testing. We will also look at stool ('poo') and saliva to see what kind of 'friendly bacteria' children or young people have inside them. We are doing this because it might help us plan treatment for future children, or help develop new treatments, or it might even help show how to prevent disease. We are also collecting samples from a 'control' group: children and young people who are related to a child or young person with an ocular inflammatory disease or who have a disorder that is associated with an increased risk of developing an ocular inflammatory disease. Using these 'control' samples allow us to understand what signals are coming from eye inflammation and which signals are coming from genes or from the environment. We are also asking if we can use cells from your child's donated samples to grow other cells that can be used for future studies.

## **Why have I and my child been asked to provide their samples?**

Your child has been asked to take part because they have an inflammatory eye disease – a disorder which involves inflammation inside or around their eyes.

## **What would taking part involve? /**

You and your child will be asked if we can take any or all of the following samples:

**Blood:** if your child's ever needs a blood test at the hospital for their condition, we would ask for an additional sample to be taken at the same time (so that we avoid another needle for your child).

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# CHOIR



**GREAT ORMOND STREET  
INSTITUTE OF CHILD HEALTH**

**Tears:** when your child comes in for a routine eye check, we will ask your permission to place a strip of blotting paper with an edge tucked inside the bottom corner of your child's lower eyelid. They will need to have an anaesthetic eye drop first. This will stop them creating too many tears and 'drowning' the strip. We would do this at the same time as they have their normal anaesthetic eye drop for their eye check in clinic. There will be no pain associated with the collection of tears using these strips.

**Stool:** we will give you a packet to take home with you that allows you to collect some of your child's stool ('poo') and return the sample to us in the post. We will also ask you to complete questionnaires about your child's lifestyle and what they eat, and to return them with the stool sample. These questionnaires take a total of 20 minutes to complete, and they will help us to analyse the signals from your child's poo.

**Saliva (spit):** we will collect saliva samples either by swabbing your child's mouth or getting them to spit into a tube.

**Intraocular** samples (from inside the eye): if your child needs eye surgery, we will ask for a sample of the fluid or iris muscle ('uvea') from inside the eye. We would only ever ask for samples that would otherwise be wasted as part of 'normal' surgery.

We are also asking for permission to access your child's medical records and the medical information their medical team collects about them, including images of their eyes.

We will also ask your child to give us formal permission for this research once they are able to do this (once they reach 16 years of age).

#### *Who owns the samples my child gives?*

The samples are considered a donation or a gift from you to research, and the CHOIR research group is responsible for the safekeeping, and appropriate use of the samples. The research sponsor (University College London Institute of Child Health, or UCL ICH) will own all the results from this project and will control who has access to it. The samples and data will be stored at UCL ICH.

#### **Voluntariness of giving samples and potential to withdraw**

It is up to you if you and your child takes part. If you agree to take part and donate samples, we will then ask you to sign a consent form. If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign an assent form with you, if they want to. If you decide not to give samples it will not affect your child's present or future treatment in any way, and you do not have to say why. You are free to withdraw at any time, without giving a reason and without affecting your child's medical care. As the data and samples generated during analysis in future studies are anonymous, we would not be able to remove any data or results of analyses that we had already processed prior to the time of your child's withdrawal. However no further samples would be taken, and you can request that any unused samples be destroyed.



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### **Benefits of taking part**

There may be no immediate benefit to your child from donating samples, but our research will help us and doctors to understand more about eye inflammation which will help the development of new treatments and help more children with this condition in the future. We are not able to feedback any information from any tests taken as part of this research to individual participants.

### **Potential disadvantages and risks of taking part**

No significant physical risk can be foreseen. Any samples will be taken at the same time as routine clinical tests. The discomfort of having samples taken will be no more than that incurred by having tests for medical care.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and granted a favourable opinion by London-City & East Research Ethics Committee

*Informational risks:* Some people are worried about being identified as being part of research. The chance is very small and we will do everything we can to prevent this happening by anonymising samples in the study.

### **Who will have access to my child's samples and data?**

All information that is collected about or from your child will be kept strictly confidential and in compliance with the General Data Protection Regulation 2018. All data and samples will be anonymised, this means they will be labelled with a code, not your child's name or other identifier. All of the information about the samples – paper and electronic – will be stored securely, according to national standards. Data will be kept for future approved studies if agreed to. ***It will be stored on protected computers, and destroyed securely once it is no longer needed.***

### **Will samples be shared with other researchers and from where?**

A lot of research can happen faster when scientists and doctors from around the world work together. Information about your child's samples may be shared with other approved researchers from other universities and hospitals based in the UK, Europe and Internationally for scientific and healthcare purposes if agreed to. All information will be shared in a way that means your child is not able to be identified. They will have to request access to the information first, and this will be assessed for appropriateness. Only those who are approved will have access to the information which answers their specific questions.

### **Will genetic testing be done on samples?**

Yes, we expect that researchers will be examining genetic aspects of eye inflammation, so DNA will be stored and analysed. ***They are likely to use a type of genetic testing called 'whole genome sequencing', which gives us the information about almost the whole of the DNA carried in an individual.***



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### **Will information from the genetic testing be returned to us?**

*Researchers will not be returning the genetic test results to you.* The importance or implications of those research findings may not be known for some time. It is very important to realize that those results are research findings and not a clinical test.

### **Your child's data may be stored in an open access database.**

Samples may be sent to external laboratories for analysis. Only approved laboratories and researchers will analyse your samples. Samples may be kept as there may be new ways to of doing testing in the future and the results will be held in a secure database.

When this testing occurs coded data may be placed in international archives of data from people with different types of inflammatory disease. This data will be completely unconnected to your child's name or other identifiable data and stored for an indefinite period of time. Access to this anonymised information will only be given to bona fide researchers around the world who will use the information for good scientific reasons and if you agree. Access to the anonymised information stored in this archive will only be accepted via applications from appropriately qualified researchers who sign a legally-binding Data Access Agreement in which they commit to:

- a) Use the data only for research purposes;
- b) Protect the data confidentiality;
- c) Provide appropriate data security;
- d) Not attempt to identify individual participants from whom data were obtained;
- e) Not redistribute the data or any subset or derivative that could be used to identify the research participant.

For the anonymous genetic information data to be useful to the research community, some information about your child and their medical problem/treatment such as age, sex, medical condition will be linked to this. There is a remote possibility that your child could be identified by looking at genetic information, but only if this information is matched to other genetic data held in databases which also store personal, identifiable data. We regard this event as extremely unlikely, but it is important that you are aware of this risk.

### **Will my child's data be shared with commercial industry?**

The samples and data collected as part of this research may be shared with approved commercial (for profit) organisations if you agree. The research shared will be de identified, so no one will be able to tell the data is from your child and your personal information will remain safe and confidential with the research team.

You or your child will not benefit financially if a product or test as a result of research on their samples leads to the successful development of a new medical treatment or test.

### **What will be done with the results of research from these samples?**

Results from future studies based on these samples research may be published in peer reviewed scientific and medical journals and/or presented at conferences to the scientific community. This will be reported in a way that will not identify you or your child and is important to share the results to help research advance as quickly as possible. We will also provide the participating families with summaries in a newsletter once a year.

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INSTITUTE OF CHILD HEALTH

### **Are there any arrangements for compensation?**

No special compensation arrangements have been made for this project.

In the event of any harm occurring to you due to participation in the study, normal University Clinical Trials Liability compensation arrangements apply.

### **Will we be contacted again?**

If you agree to take part on behalf of your child, when they are old enough and able to give consent themselves we will be asking them to agree on their own behalf for permission to collect samples. At that time they will make their own decision.

In the future we may contact you or your child to take part in future research. It is up to you and child if wish to take part in these studies. We may also contact you to update you on the results of research from their samples

### **What if we have questions or worries?**

If you or your child have a concern about any aspect of sample donation please discuss them in the first instance with the principal researcher Ameenat Lola Solebo, a.solebo@ucl.ac.uk, who will do their best to answer your questions.

If the problems are not resolved, or you wish to comment in any other way, please contact the ***Patient Advice and Liaison Service (PALS) at Great Ormond Street Hospital are available on telephone number 020 7829 7862.*** If you wish to complain formally regarding how this research is run, please contact the hospital complaints department on ***020 7405 9200.***

**Thank you for taking the time to read this information sheet and considering donating samples. If you and your child decide to give us samples, you will be given this information sheet and signed consent and assent forms to keep.**



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CHOIR



### GDPR statement:

University College London Great Ormond Street Institute of Child Health (ICH) is the sponsor for this research based in England. We will be using information from you and/or your medical records in order to undertake this research and will act as the data controller for this research. This means that we are responsible for looking after your information and using it properly. ICH will keep identifiable information about you for 5 years after the research has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the research, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

### **How will we use information about you?**

We will need to use information from your child and from your child's medical records for this research project.

This information will include your child's:

- Name
- NHS number
- Hospital number
- Date of birth
- Ethnicity
- Post code
- Phone number (parent contact details)



# CHOIR



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We and the research sponsor, UCL, will use this information to do the research or to check your 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 or contact details. Your data will have a code number instead. Some of your child's information will be shared with other researchers in Europe. They will not have access to your child's personal details – only the code number. They must follow our rules about keeping your child's information safe.

We will keep all information about you safe and secure.

Once we have finished the research, 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 you took part in the research.

### **What are your choices about how your information is used?**

- You can stop being part of the research at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this research, you will have the option to take part in future projects.

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

You can find out more about how we use your information

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- by asking one of the research team
- by sending an email to [dataprotection@gosh.org](mailto:dataprotection@gosh.org)

### **Who can I contact if I have a complaint?**

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer.



**CHOIR**



**GREAT ORMOND STREET  
INSTITUTE OF CHILD HEALTH**

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) ([www.ico.org.uk](http://www.ico.org.uk) or 0303 123 1113).

You can find out more about how we use your information by contacting the UCL GDPR team: [gdpr@ucl.ac.uk](mailto:gdpr@ucl.ac.uk)