GREAT ORMOND STREET
INSTITUTE OF CHILD HEALTH

UNICORNS

Uveitis in childhood prospective national cohort study

We would like to invite you and your child to take part in our research study. Before you decide we would like you to understand why the research is being done and what it will involve.

Please read this information. Ask us (**using the contact details at the end of the form**) if there is anything that is not clear or if you want to know more. Take time to decide whether or not you want your child to take part.

Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you and your child if you take part.

Part 2 gives you more detailed information about the conduct of the study.

PART ONE

1. The aim of the study.

We want to collect information about children with uveitis in the UK in order to understand what happens to children with the disease, and **why**.

2. Why is the study being done?

There are still some unanswered questions about why children get uveitis and why some children with uveitis have worse outcomes than others. By analysing data on a large number of children, we hope to provide information that will help doctors and parents make decisions about their child's care.

3. Why are we being asked to take part?

We are asking you to take part because we would like to include all children and young people who have been diagnosed with uveitis.

4. Do I have to take part in this study?

No. It is up to you and your child (wherever possible) to decide to join the study. After reading this information sheet, if you agree to take part, please sign the consent form. If your child is able to understand the research and is happy to take part and can write their name, they can sign an assent form with you, if they want to.

5. What will happen if we decide to take part?

This national research study is being done through a group of consultant ophthalmologists (eye doctors) in the UK. We are seeking your permission to allow

your child's ophthalmologist to let us have information that they already routinely collect during your child's appointments. We will also ask for you to tell us more about your child when you start in the study and every year after that, using electronic or paper-based questionnaires. This would involve the following:

a) If you and your son/daughter agree to take part, we would like you to complete the attached consent forms to let us know. You can use the freepost envelopes provided to post the forms back. If we haven't heard from you by 4 weeks from now, we will write to you to remind you about the study.
b) We would ask you to complete questionnaires which ask about your child's general health (eg, sleep), overall well-being, and quality of life, as we want to understand how uveitis is affecting your child. The questionnaires each take approximately 5 – 10minutes to complete, and in total, they should take no more than 35 minutes to complete.
c) We would schedule a telephone call with you (this would last for between 10 and 60 minutes, depending on how long you wanted to talk to us) to go through the questionnaires
d) We will also ask for your permission hold onto your family's details and approach your child directly when they become an adult, so that we can get their permission to use their information from other hospitals at a later date.

We hope that taking part in our study should be a positive experience for your son/daughter allowing him/her to tell us in detail about how uveitis has affected them. However, we recognise that there is the potential for you or your son/daughter to find some aspects of this difficult. We would like to reassure you that our study team is experienced and appropriately trained and able to deal sensitively with any difficulties that might arise. We also remind you that you are free to withdraw from the study at any point.

This information will be pooled together with information about other children undergoing treatment at other hospitals in the UK. It will then be analysed statistically to understand better which factors predict the best outcomes. Your child's treatment will not be affected or altered in any way by being involved in the study. We will let your GP know that your child is taking part in this study.

e) We will also, **separately**, ask if it is OK for us to come back to you later to talk about a **second** study, **UNICORN-Bio**, which involves getting a sample of your child's blood, tears, spit, or stool (poo). We will aim to analyse these fluids to try to find chemical signals or genes which can identify children with particular types of uveitis. **You do not have to take part in this second study if you do not want to share these kinds of samples with us.**

PART TWO

6. Who will have access to my child's records?

Only the research team involved in this study and representatives from Regulatory Authorities or from the NHS Trust where it is relevant to you and your child taking part in this research (e.g. Research Ethics Committee that has approved this study) would have access to your child's medical notes and the actual data collected during the study.

Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible. Only authorised members of the research team will have access to your personal information. The anonymised data set will be kept for [10 years] after the end of the project, after which it will be reviewed to determine whether it would be appropriate to delete it.

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 study, 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.

You can find out more about how we use your information by reading the attached sheet on patient data, or by contacting the researchers (details below).

7. Who are the researchers involved in this study?

- Dr Lola Solebo, Study Chief Investigator, Senior Lecturer and Honorary Consultant Ophthalmologist, UCL Institute of Child Health and Great Ormond Street Hospital for Children NHS Foundation Trust
- Professor Jugnoo Rahi, UCL Institute of Child Health and Great Ormond Street Hospital for Children NHS Foundation Trust
- Professor Andrew Dick, UCL Institute of Child Health and Bristol University Hospitals

We also have the support of over 60 consultants who look after children with uveitis across the UK, including your child's eye doctor.

8. What will happen with the findings of the study?

We plan to publish the findings of the study in scientific journals, and share them at scientific meetings, so that we can let other professionals know what we have learned from this study. However, we will pool information in our reports, so that it will not be possible to identify any individual person who takes part. Everything you and your son/daughter tell us will be strictly confidential. We will ask the hospitals to display findings from the study in their clinics for families to see.

9. What are the potential benefits?

This study is unlikely to bring any immediate benefits to your son/daughter, although many children and young people have found it a very positive experience to share their thoughts with us. However, we hope that it will improve our understanding of children and young people's experience of uveitis, and what happens to them and why, and help us to improve the treatment and services provided for them in the future.

10. Will any laboratory or genetic tests be done?
No laboratory or genetic tests will be done as part of this study

11. What if new information becomes available?
If there are any changes made to the way the study is being done, we will let all the families involved know.

12. Who is organising and funding the research?
The study is organised by Lola Solebo, and funded by the National Institute of Health Research.

13. Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee.

14. How can we find out more about research?
We have included an information sheet about the use of patient data in this study pack.

15. Who do I speak to if problems arise?
If you have any questions or complaints about the way in which this study has been, or is being conducted, please, in the first instance, discuss them with the researchers named below. For independent advice you can also contact the Research and Development Department at UCL Institute of Child Health and Great Ormond Street Hospital (phone number 020 7405 9200

16. Details of how to contact the researchers:
You can contact any of main researcher:

Dr Lola Solebo (Study Chief Investigator), UCL Institute of Child Health, 30 Guilford Street, London WC1N 1EH, Tel: 020 7905 2250, Email: a.solebo@ucl.ac.uk

If you and your child decide to take part in this study, please keep this information sheet and the family copies of the signed consent and assent forms. Please use the freepost envelopes provided to post the study consent forms back to us.

Thank you for taking the time to read this information sheet.

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Information on the use of patient data

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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)

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 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 you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study 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 study, you will have the option to take part in future research using your data saved from this study.

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/
- by asking one of the research team
- by sending an email to 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.

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 or 0303 123 1113).