

IMPROVING UNDERSTANDING OF FEBRILE INFECTION RELATED EPILEPSY SYNDROME (FIRES)

Participant Information Sheet (Parents/Carers/Guardians of children 2-15 years old)

This form can be translated to Welsh upon request

Invitation

You are being invited to consider giving permission for your child to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask me if there is anything that is not clear or if you would like more information. Thank you for reading this.

What is the purpose of the study?

The purpose of our study is to improve the outcomes of children and young people affected by the epilepsy syndrome known as “FIRES” or febrile infection-related epilepsy syndrome. FIRES is exactly what it sounds like, an explosive onset of difficult to treat seizures. FIRES is a rare type of epilepsy, and there are no specific treatments that are universally effective. In children, we often don’t know the cause but the cerebro-spinal fluid (CSF), the fluid that bathes the brain, often reveals high levels of molecules associated with inflammation.

Our study aims to identify children and young people in the UK with this condition, collect clinical information to learn more about the current treatments to inform future care. Some families will also be approached to donate CSF samples for laboratory studies. We will only use samples that have been taken during routine clinical care, no additional tests will be required. The research is being undertaken as part of an educational project led by Dr Dimitrios Champsas, supervised by Dr Sukhvir Wright.

Why has your child been invited?

Your child has been invited to take part in this study as your doctor has informed us they are under 16 years old and have been diagnosed with FIRES.

What will happen to your child if they take part?

1. If you consent for your child’s participation to the study, this will allow your doctor to send us your child’s medical reports, and details of test results and treatments related to when your child was diagnosed with FIRES. All information will be kept strictly confidential and anonymised and will not be accessible to anyone outside the research team.

2. If there is a stored CSF sample from your child and you consent to its use in research, it will be sent to our laboratories.
3. We will ask if we can contact you directly regarding your child's treatment and outcome in the future.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part and this decision does not affect the treatment your child will receive.

If you do decide to participate, you will be asked to provide informed consent.

If you wish to withdraw your child's data after participation then you have up to 15 days to do so by contacting the your doctor and giving your name. After this point, your data will be anonymised and it will not be possible to withdraw it.

Will my taking part in this study be kept confidential?

Yes. A code will be attached to all the data you provide to maintain anonymity. Analysis of your child's data will be undertaken using coded data.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device (hard drive). To ensure the quality of the research Aston University may need to access your child's data to check that the data has been recorded accurately e.g. for the purposes of audit.

What are the possible benefits of taking part?

There is no direct benefit for you or child taking part in this study. However, we hope that the findings of this research will lead to new treatments that would improve the treatment options available and outcomes for children affected by FIRES.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/or presented at conferences. If the results of the study are published, your child's identity will remain anonymous.

A lay summary of the results of the study can be forwarded to you when the study has been completed. Should you wish to receive a copy, please provide your email address on the consent form or contact a member of the research team.

The anonymised results may be used for research by other research teams.

What will happen to any samples that I provide?

The samples will be stored using your unique identification code and used in accordance with the Human Tissue Act, which ensures appropriate management of all human materials.

With your permission any samples remaining at the end of the study will be retained in an anonymised form for future research. Any future research involving the samples will require review by a research ethics committee before it commences.

Who is funding the research?

The study is being funded by Aston University and is in collaboration with Great Ormond Street Hospital, London.

Who is organising this study and how is my data being used?

Aston University is organising this study and acting as data controller for the study. Research data will be used only for the purposes of the study or related uses identified in this Information Sheet.

Who has reviewed the study?

This study was given a favorable ethical opinion by the **Wales REC 5** Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your child's participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or via the University switchboard on +44 (0)121 204 3000.

Research Team

<p>Dr Sukhvir Wright Wellcome Trust Clinical Research Career Development Fellow Institute of Health and Neurodevelopment, School of Life and Health Sciences, Aston University and Honorary Consultant Neurologist Birmingham Children's Hospital s.wright5@aston.ac.uk</p>	<p>Dr Marios Kaliakatsos Consultant Paediatric Neurology Great Ormond Street Hospital marios.kaliakatsos@gosh.nhs.uk</p> <p>Dr Suresh Pujar Consultant Paediatric Neurology Great Ormond Street Hospital suresh.pujar@gosh.nhs.uk</p> <p>Dr Dimitrios Champsas MD Student [Student email to be added]</p>
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Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.



Transparency Wording (NHS)

How will we use information about you?

We will need to use information from your child's medical records and stored samples (cerebrospinal fluid collected for clinical reasons) for this research project.

This information will not include any identifiers (initials/ NHS number/ name/ contact details

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.

We will keep all information about your child 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 your child being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you agree your child 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/
- our webpage available at www.aston.ac.uk/dataprotection
- by asking one of the research team
- by sending an email to dp_officer@aston.ac.uk, or
- by ringing us on 07311888336