IMPROVING UNDERSTANDING OF FEBRILE INFECTION RELATED EPILEPSY SYNDROME (FIRES)

Participant Information Sheet
(Participants aged 16+ with capacity to consent)

This form can be translated to Welsh upon request

Invitation

We would like to invite you to take part in a research study.

Before you decide if you would like to participate, take time to read the following information carefully and, if you wish, discuss it with others such as your family, friends, or colleagues.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

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 and young people, 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 children and young people 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 have I been invited?

You have been invited to take part in this study as your doctor has informed us that you are 16+ years old and have been diagnosed with FIRES.

What will happen to me if I take part?

1. You will be invited to take part in the study by signing a consent form that will be sent by email to you by our investigators. This form can be signed digitally and returned by email to the sender.
2. This consent will allow your doctor to send us your medical reports, and details of test results and treatments related to when you were diagnosed with FIRES. All information will be kept strictly confidential and anonymised and will not be accessible to anyone outside the research team.
3. If there is a stored CSF sample and you consent to its use in research, it will be sent to our laboratories.
4. We will ask if we can contact you directly regarding your 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 you will receive.

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

If you wish to withdraw your 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 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 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 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 and young people 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 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 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

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	Dr Marios Kaliakatsos Consultant Paediatric Neurology Great Ormond Street Hospital marios.kaliakatsos@gosh.nhs.uk Dr Suresh Pujar Consultant Paediatric Neurology Great Ormond Street Hospital suresh.pujar@gosh.nhs.uk Dr Dimitrios Champsas MD Student [Student email to be added]

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.

Aston University
BIRMINGHAM UK

Transparency Wording (NHS)

How will we use information about you?

We will need to use information from your medical records and samples that have already been collected for clinical reasons (Cerbrospinal fluid) for this research project.

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

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

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/
  - 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**].