



Participant Information Sheet

STARS Registry (Synapse Neurodevelopment TrAckeR ESNEFT)

We would like to invite you to enrol on our STARS Registry run by the Synapse Centre for Neurodevelopment team at ESNEFT. *Neurodevelopment is all to do with how the brain and the nervous system works.*

Please let us know if you would prefer an information sheet in larger font, or if you need additional support material.

We can also see whether an interpreter is available for people where English is not their first language (where possible).

Invitation to Self-Register

We are inviting you to take part in a health registry for children with neurodevelopmental conditions. The Synapse Centre for Neurodevelopment is a research centre at ESNEFT, which aims to improve our understanding of neurodevelopmental conditions that affect our local child population.

Our aim is to better understand neurodevelopmental conditions in our local area. Please take the time to read the following information carefully and discuss it with friends and family if you want to.

Why do we want to set up the STARS Registry?

Neurodevelopmental conditions are a group of conditions which involve brain development. For example, cerebral palsy and autism spectrum disorder (ASD) are classed as a neurodevelopment condition.

We would like to collect information on your child's development and any related symptoms they may have alongside their diagnosis. This information will help us:

- understand children with neurodevelopmental conditions needs
- design research studies to meet these needs
- identify studies that people are potentially eligible for, based on their symptoms or neurodevelopment condition generally



Why have I been asked to take part?

We are inviting all families with a child or children with a neurodevelopmental condition, and who are under the medical care of East Suffolk and North Essex NHS Foundation Trust, to self-enrol on the registry or attend a consent clinic, where we can help you put this information in.

What is involved?

Enrolling on the registry will involve consenting to share your child's data to the STARS registry (owned by ESNEFT). You will then be asked a number of questions related to your child's neurodevelopment condition and other health concerns or symptoms that they may have alongside this. We will request for you to update your data every year to ensure all your child's/children's information is up to date to ensure that we can monitor children's needs over time and also for an up to date record on research studies they might be eligible for.

Who has designed the registry and who maintains the registry?

Clinicians and healthcare researchers at East Suffolk and North Essex NHS Foundation Trust have designed this study in collaboration with patient representatives who have experience of family life with a child with a neurodevelopmental condition. The STARS registry platform has been provided by Amplitude Clinical Outcomes, who will also deliver technical support and maintenance. Ownership of your child's data will remain with you and your child. ESNEFT is known as the 'data controller' which means that we will ensure the data is processed in a way that is safe and secure. Amplitude Clinical Outcomes will not have access to your data.

Do you not already hold my child's information?

We do hold information at ESNEFT about your child's medical health, but we would like to find out more about other conditions or symptoms that they experience, that aren't routinely discussed or followed up.

Do I have to take part?

It is up to you to decide if you want to take part.

If you do decide to take part, you can withdraw at any time and without giving a reason and this will not affect you or your child's clinical care in any way. You can withdraw from the STARS registry either:



- withdrawing your consent on the STARs registry
- letting a member of the STARs registry team know, and they can withdraw you from the registry

Your information will be kept for as long as you decide to be part of the registry. If you decide you no longer want to be a member, you can contact us and we will remove your information. We would ask you whether you want all of the information permanently removed, or if you would like it anonymised (only gender and year of birth) alongside health information.

What will happen to my child's data?

We will only collect data on your child up until the age of 16 years old. We will retain the data you have provided up to this point, unless you would like to withdraw completely from the STARs registry. Data that would be retained would be anonymised so that we only had access to gender and year of birth, no other identifiable information. We will cross check the neurodevelopment diagnosis with our hospital records.

What do I have to do after I agree to take part?

Your clinical team may have introduced you to the registry. Alternatively, you may have seen it advertised locally. If you have any questions about the research, please contact the STARs registry team who will be happy to help.

Full consent to take part

If you are interested in self-registering, and you have had all of your questions answered, please scan the QR code on the next page. Or you can use the link below. The QR code or link will enable you to read the consent form and provide your informed consent to participate in the STARs registry.

We are also holding clinics where we can go through the STARs registry information with you and if you provide informed consent, then we can put your child's medical history in to the STARs registry with you.



If you would like to sign up to the STARS registry please scan the below QR code:



Registry web link:

<https://secure.amplitude-registry.com/ESNEFT-Synapse/patient-portal/?pce=true>

Information collected:

What information will we collect?

- Basic health information
- Your child's diagnosis/diagnoses
- Whether your child has any other difficulties, for example with sleep, language or migraines.
- Some questions on your child's educational needs.

How will we collect the information:

- We will collect the information through the STARS registry.
- The information is collected through a series of questions on our STARS registry platform
- Information can be collected in person with one of our research team or from the comfort of your own home through a link to the STARS registry



What will happen to the data in the STARS Registry?

Your child's data will be analysed by the Synapse Centre team at ESNEFT. This will be to improve our understanding of the conditions affecting our local child population and therefore where to focus future research.

You may also be contacted to enquire whether you are interested in taking part in any future research projects. ***Just because you have consented to be part of this study, does not mean you have to say yes to any future studies.***

We will publish the results of this research in scientific journals, and present the information at conferences. We will write our reports and presentations in a way that participants cannot be identified. You and your child's information will be kept safe.

Are there any benefits from taking part in this study?

There are no direct benefits to individual participants for taking part. However, we hope the data collected in the registry will lead to research in the areas that will help children with a neurodevelopment condition, guided by the STARS registry findings.

What are the possible risks and burdens of taking part?

This study does not pose any significant risk to your health as no interventions or treatments are being performed as part of the study.

If I participate will my child's medical information be kept confidential?

We will need to use information from your child's medical records at ESNEFT in order for you to enrol onto the registry. This is so that we can make sure the information on the registry is the same as your child's medical records. Only the Synapse Centre for Neurodevelopment research team will access your child's medical information.

In addition, we will require details including: your child's name, date of birth, address and postcode, their NHS number, and your telephone number, and your email address for administrative purposes.

All your data will be kept safe and secure on the STARS registry.

East Suffolk and North Essex NHS Foundation Trust (ESNEFT) is the data controller and therefore we are responsible for your data, and will treat your data confidentiality in line with the Data Protection Act (2018) and General Data Protection Regulation guidelines.



If you have any concerns or queries over yours or your child's medical data and information, please contact FOI@esneft.nhs.uk

Can I see the study information stored about me?

To safeguard your rights, we will use the minimum possible personally identifiable information. To ensure that your child's information is kept secure, we will assign them a participant number, therefore pseudonymising their information before any data analysis. This means that instead of your child's information being under their own name, it will be linked to a code number so that no one knows the information is about them.

You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients/
- www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to FOI@esneft.nhs.uk (ESNEFT Data Protection team)
- or by ringing the Research and Development team on 01473 703885

What if I have a complaint or concerns about the study?

If you have any further questions, have any concerns or wish to make a complaint, please speak to the Synapse Centre for Neurodevelopment team who will do their best to help.

If you are not satisfied with this and continue to have concerns about any aspect of the way you have been approached or treated during this study, the usual National Health Service complaints mechanisms are available to you, such as the Patient Advice and Liaison Service (PALS).

Contact details are provided in the contact information section at the bottom of this information sheet. Taking part in the study would not affect your legal rights.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Health Research Authority and the Research Ethics Committee: **North East - Newcastle & North Tyneside 1 Research Ethics Committee.**



Who is organising and funding the research?

The sponsor of the registry is the East Suffolk and North Essex NHS Foundation Trust.

The STARS registry has received funding for the pilot phase (initial 2 months) from the National Institute of Health and Care Research via the Clinical Research Network.

The sponsor may decide to discontinue the registry at any time and if this happens we shall explain to you why this has happened. This will not affect your on-going clinical care.

We will still use pseudonymised data we have collected up until this time point for our analysis (unless you have withdrawn from taking part in the STARS registry).

I have some further questions, who can I ask?

You can find further information by contacting the team below:

STARS registry data custodian: Dr. Ben Marlow (Dr Ben Marlow (MBiochem MBBS MRCPCH PGCME)

Consultant Paediatrician (Neurodevelopment) ESNEFT

Clinical Director – The Synapse Centre for Neurodevelopment www.synapsecentre.co.uk

Clinical Lead for Paediatrics SNEE ICB)



Principal Investigator:

Dr Benjamin Marlow

Email address: synapsecentre@esneft.nhs.uk

TEL: 01473 703885

If you wish to make a complaint, please contact:

PALS/Independent Advisor Name: pals@esneft.nhs.uk

Participant Information Sheet for parents; STARS Registry, IRAS ID: 303847 v1.3 16/07/24



THE SYNAPSE CENTRE
FOR NEURODEVELOPMENT
ESNEFT

PALS/Independent Advisor Phone: 0800 328 7624

OR

Frances Farnworth, Assistant Director of Research, R&D office, East Suffolk and North Essex
NHS Foundation Trust

Telephone number: 01473 703885

Thank you for taking the time to read this information.