The University of Manchester

NNIBS study
(NF1 Non Invasive Brain Stimulation study-2)
Information sheet for parents- NF1 group

We would like to invite you 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 would involve for you. **One of our team will go through the information sheet with you and answer any questions you have.** This will take about 10-20 minutes.
Please talk to your family and friends about the study if you wish. If you have any questions about the study, please ask the doctor or research team.
This PIS should be read in conjunction with The University privacy notice (https://www.manchester.ac.uk/discover/privacy-information/data-protection/privacy-notices/)

Who will conduct the research?
The study is being run by Dr Shruti Garg from The University of Manchester. The Genetic Medicine department at Manchester University NHS Foundation Trust are organising the study. The funding comes from the Neurofibromatosis Therapeutic Acceleration Program at John Hopkins University, United States.

What is the purpose of the study?
Research suggests that up to 70% of children with NF1 have difficulties with learning such as problems with memory, attention and concentration. Currently there are no treatments for such difficulties. This study will examine the use a treatment known as transcranial Direct Current Stimulation or tDCS. This technique uses a small amount of electrical current which is applied to the scalp to alter the way the brain works. tDCS has been used before with children with ADHD, epilepsy , language difficulties and autism. We want to find out how this technique works using brain scanning (, commonly called MRI).

Why have we been asked to take part?
You have been invited to take part in this study because your child has NF1 and is aged between 11 and 17 years.

Do we have to take part?
It is up to you to decide whether you would like your child to join the study. If you agree to take part, we will then ask you to sign a consent form. For adolescents over 16 years old, we will also ask for their consent. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care your child receives.

What will happen if we take part?
The research team will explain the study to you in detail to help you make a decision about taking part in the study. All visits for the study will take part at the Clinical Research Facility, Grafton Street, University of Manchester. The study will involve two separate research visits and each visit will take up to 4 hours. Details of what will happen if you are interested in taking part are described below:

- A researcher will get in touch with you prior to the first research visit to explain the study and go through some questions about your child. This will be done to make sure that there are no problems with your child taking part.
- If you are happy to take part, you will be sent a recording of the MRI scanner noise. We will ask you to play the scanner noise to your child to prepare them for the research visit and get them used to the noise they will hear when they come on the research visit.

- On the day of the research visit, parents will be asked to complete some questionnaires, which will take about 30 minutes. A member of our research team will work with your child to complete some quizzes and computer games.

- We will then carry out the brain scanning. This is a completely safe procedure for children but it does involve children to lie still in the scanner. A play specialist or a researcher trained in working with children will explain the procedure to your child. Before getting into the scanner, we will put two clean, wet sponges to your child's scalp. Your child will be asked to play a computer game in the scanner, whilst at the same time a light electrical current (tDCS) is passed through the scalp through the wet sponges. The current will either be "real" (device turned on) or "fake" (device turned off). Your child will not be able to tell the difference between the "real" or "fake" stimulation, and you will not be told which type of stimulation you are receiving. The scanning process will take 60-70 minutes.

- After the scan, we will ask children to complete a questionnaire to tell us how they felt in the scanner.
- We will reimburse all travel expenses. All parents of the children participating in the study will also receive a £20 gift voucher as compensation for the time taken in the study. This will be given to you once your participation in the study has come to an end.

What are the possible risks of taking part?

We have used tDCS in children with NF1 before and have found that it is safe. The commonest side effect that children may experience may include some tingling or redness and itching at the site where the wet sponges have been applied. We will try our best to make the procedure is as comfortable as we can for your child. Other rarer side effects may include headache, neck and scalp pain, burning sensation, sleepiness, trouble concentrating and mood changes.

Safety of the children taking part is our utmost priority so if at any point the child feels uncomfortable and wants to discontinue, we will end the procedure safely and quickly.. There is a very small risk that patients undergoing tDCS could experience an epileptic seizure. However, there have been no seizures reported in 48 studies to date. To minimise the risk of this, we will go through a safety questionnaire with you before we undertake any procedures for the study. We will ask if your child has any history of epilepsy and this will inform our decision as to whether they might be suitable to enrol safely on the study.

Brain scans are routinely done in children with NF1. They are safe and involve the child spending about an hour in a large tunnel-like structure. There are always staff around to reassure the child and we work with families to create the best experience possible for the child. The staff are very experienced in preparing children and families for this experience. Nevertheless, some children can have difficulty in being in the closed space of the scanner, the noise of it or the need to keep still for a period of time. For this reason we will be doing careful preparation with both child and family for this experience.

Are there any benefits?

A study like this will tell us whether a simple and easy to use technique such as tDCS can be effective in helping children with NF1 who have learning difficulties. Your child might not receive any direct benefit but we hope that this will teach researchers more about how this technique is useful in children with NF1.

What will happen to my child's personal information?

In order to undertake the research project we will need to collect the following personal information/data about your child:

1. Name, date of birth, address, gender
2. Details of the medical history, NHS number
3. Research assessments as described above

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your child's personal information. The legal basis upon which we are using your personal information is "public interest task" and "for research purposes" if sensitive information is collected. For more information about the way we process your child's personal information and comply with data protection law please see our Privacy Notice for Research Participants (http://documents.manchester.ac.uk/display.aspx?DocID=37095)

The University of Manchester, as Data Controller for this project, takes responsibility for the protection of the personal information that this study is collecting about your child. In order to comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained and your child's data will be looked after in the following way:

Any information collected from your child will be kept in the strictest confidence. The imaging data that will be collected will be added to the participant's medical record using the PACS (Picture Archiving and Communication System) system where we will transfer your un-anonymised personal details so that the radiologists connected to the study can review the scan and make sure everything looks ok. If there are any concerns about the scan findings, we will contact you and discuss this with you. We will also let your GP and you clinical team know after discussing the findings with you.

Each participant will be given a unique study code, which will be used to label the study information. All questionnaires and study data will be labelled with the study code. This anonymised data will be stored in a secure password-protected file on computers at the University of Manchester. Personal information will be stored separate to the study data in locked filing cabinets for 12 months after the end of the study. We may wish to contact you in the future about new research studies so, with your permission; we can keep your contact details on file for 12 months after the end of the study. All your personal details will be destroyed after 12 months. The research documents will be stored for 25 years at the secure Iron Mountain archiving facility, the agreed facility for studies run by the University of Manchester.

The data collected during this study could be used to support research in the future. We may use the data in future studies but also share it with other researchers working on other studies. All of the data will be anonymised before it is shared or used for future research so no one will be able to identify your child.

Confidentiality will be maintained at all times other than if the participant is identified as being at serious risk (such as child protection issues). In such cases, the information will be discussed with the Chief investigator and anonymously discussed with the child protection lead nurse at MFT. Local protocols will be followed in reporting this information to relevant professionals.

Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may

involve looking at identifiable data (including access to relevant sections of medical notes) but all individuals involved in auditing and monitoring the study, will have a strict duty of confidentiality to you as a research participant.

You have a number of rights under data protection law regarding your child's personal information. For example you can request a copy of the information we hold about your child. This is known as a Subject Access Request. If you would like to know more about your different rights, please consult our privacy notice for research and if you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL. at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office, Tel 0303 123 1113.

Will my child's participation in the study be confidential?

All the information we collect for the study will be kept confidential, which means that only the people in our research team will has access to this information. The data collected will be stored in a locked filing cabinet and labelled only with a study code, and information stored on computers will be protected by a password. Only in exceptional circumstances where an issue relating to the safety of a child has been identified will we share information with other health professionals at the hospital. After discussion with the Chief Investigator, we would follow the trust policies and liaise with the child protection lead nurse at the trust.

What happens if I do not want my child to take part or if I change my mind?

It is up to you to decide whether or not you child will take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to your child's care. However, it will not be possible to remove your child's data from the project once it has been anonymised and forms part of the dataset as we will not be able to identify your specific data. This does not affect your data protection rights.

Will my child's data be used for future research?

When you agree to take part in a research study, the research information about your child may be provided to researchers running research studies inother organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/.

This information will not identify your child and will not be combined with other information in a way that could identify them. The information will only be used for the purpose of health and care research, and cannot be used to contact you regarding any other matter or to affect your care. It will not be used to make decisions about future services available to your child.

Will I be paid for my child's participation in the research?

All parents of the children participating in the study will be reimbursed travel expenses and receive a £20 gift voucher as appreciation for the time taken to partake in the study.

What is the duration of the research?

The study involves two visits and will take upto 4 hours per visit.

Where will the research be conducted?
The research will take place at the Clinical Research Facility, Grafton Street, Manchester

Will the outcomes of the research be published?
The results will be posted on our website and social media pages and published in research journals. We can also send you a copy of the results on request.

Disclosure and Barring Service (DBS) Check
The researchers who may have access to children or vulnerable adults have undergone a satisfactory DBS check.

Who has reviewed the research project?
An independent group of people called a Research Ethics Committee, looks at all research in the NHS to protect your child's safety, rights, wellbeing and dignity. This study has been checked and approved by xxxx

What if I want to make a complaint?
In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or Manchester University NHS Foundation Trust but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Minor complaints:
If you have a minor complaint then you need to contact the researcher(s) in the first instance.

Dr Shruti Garg
Tel. - 0161 3060085
Email – shruti.garg@manchester.ac.uk

Formal complaints:

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:
The Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674.

What do I do now?
If you have any queries about the study or if you are interested in taking part then please let the research team know by returning the Indication of Interest form.

If you have any further information about the study, please contact:

Dr Shruti Garg - Principal Investigator
Tel - 0161 3060085
Email – shruti.garg@manchester.ac.uk

If you have any problems relating to the service you have been provided with through the NHS, please contact:

Patient Advice and Liaison Service (PALS)
Tel – 0800 015 1462
Email – pals@manchester.nhs.uk
This Project Has Been Approved by the XXX Research Ethics Committee

Thank you for reading through this information sheet and considering participating in our study.