

Participant Information Sheet (PIS) for Healthcare Professionals and Charity Workers

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You are being invited to take part in a research study that seeks to comprehend the experiences of expectant parents with NF1. The study aims to gather insights from healthcare professionals and charity workers who work with individuals with NF1 during pregnancy and the decision-making process. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➤ Who will conduct the research?

The study is being run by Dr Shruti Garg and her team from The University of Manchester in the School of Health Science. The Genetic Medicine department at Manchester University NHS Foundation Trust are organising the study.

➤ What is the purpose of the research?

As a research team, we are trying to understand the experiences of healthcare professionals and charity workers who provide support to individuals with NF1 during pregnancy.

Sometimes, children with Neurofibromatosis Type 1 (NF1) may have difficulties with learning and conditions like Autism Spectrum Disorder (ASD) and Attention Deficit Hyperactive Disorder (ADHD). While the experiences of expectant parents during pregnancy with an increased likelihood of neurodevelopmental conditions are not clear, how they get support from healthcare professionals and charities also needs to be explored. We hope this research study will help us support expectant parents with NF1 during their pregnancy and help us develop new support systems and interventions to improve the service-receiving experience of expectant parents with NF1. You are being asked to take part in this study due to your experience of working with people who have NF1, supporting them during pregnancy or their decision-making process. We plan to reach out to around 15 healthcare professionals to gain insights into the pregnancy experiences of expectant parents with NF1..

➤ Am I suitable to take part?

This study is for healthcare professionals and charity workers, including genetic counsellors, doctors and nurses working at the Genetics Service within Manchester Foundation Hospital and the charities (Childhood Tumour Trust and Nerve Tumour UK).

➤ Will the outcomes of the research be published?

The results of this study will be published in academic journals, on our website and social media pages. All data will be anonymised – which means that no one will be able to identify

you or your child. If you would like to be informed of the study findings, please let one of the research team know.

➤ **Disclosure and Barring Service (DBS) Check**

All researchers involved in this study have all undergone satisfactory DBS checks for working with adults and children, obtained through the University of Manchester and/or NHS Trust.

➤ **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 safety, rights, wellbeing and dignity. This study has been checked and approved by the Greater Manchester West ethics committee.

➤ **Who is funding the research project?**

The funding comes from Salford Royal NHS Trust and Manchester Academic Health Sciences Centre.

What would my involvement be?

➤ **What would I be asked to do if I took part?**

The study includes a video-recorded interview with our researcher. The research team will explain the study to you in detail to help you make a decision about taking part in the study. We will invite you to do a video interview.

The video interview will be done over Zoom to ask about your professional experiences of working with adults with NF1 who are considering pregnancy or are pregnant. The interview may take up to 60 minutes to complete. With your permission, we will video-record the interview. The audio recording will be treated as your personal data and treated according to data protection guidelines.

➤ **Will I be compensated for taking part?**

All participants in the study will receive a £20 gift voucher as appreciation for the time taken to partake in the study.

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

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

Audio recordings are essential for your participation in the study. It is important for us that you are comfortable with the recording process at all times, and you are free to stop recording at any time.

Data Protection and Confidentiality

➤ What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called “personal identifiable information”. Specifically, we will need to collect:

1. Name, date of birth, gender, ethnicity, year of experience of working with people with NF1
2. Audio-recording of the interviews that we carry out with you.

The data collected will be destroyed as soon as they are no longer required. However, if there is a need to clarify any of the points discussed during the interview, the interviewer may contact you within the next six months.

If you would like more general information on how researchers use data about patients, please visit: <http://www.hra.nhs.uk/information-about-patients/>

➤ Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

➤ What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](#).

➤ Will my participation in the study be confidential and my personal identifiable information be protected?

This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

Any information collected from you will be kept in the strictest confidence. The study team at the University of Manchester will have access to your personal information, and they will anonymise it as soon as the transcription process has been done, which is around 1 month time. Your name and any other identifying information will be removed and replaced with a random ID number.

The research team will have access to the key that links this ID number to your personal information. Your consent form will be retained for 5 years in a locked cabinet on UoM premises

for audit purposes. With your consent, we would also like to retain your contact details for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in. If you provide consent for this, your details will be safely stored on UoM servers in a digital folder only accessible to the study team and used only for the purposes described above.

The audio recording will be labelled using a unique study code and will be stored and transcribed within the University premises by a member of the study team. The transcribed document will be fully anonymised and any identifiable information will be removed from the transcribed script. Your participation in this research will be recorded in zoom and your personal data will be processed by zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent your anonymised information will be shared in order to support additional research in accordance with [The University of Manchester's Research Privacy Notice](#). This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.

At the end of the project, we will deposit fully anonymised interview transcripts, in an open data repository where those will be permanently stored. We will use the Figshare data repository at the University of Manchester Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Confidentiality will be maintained at all times during the study 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.

So that we can provide the shopping/Amazon voucher as a thank you for your time, your full name and email address will be shared with our Finance department who will send the voucher to you. Your full name and email address will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used for them for any other purpose.

Please also note that individuals from The University of Manchester 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. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

➤ **Contact details for complaints**

If you have a minor complaint, please contact the researcher(s) in the first instance.

Dr Shruti Garg

Tel. - 0161 3067967

Email –

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 –

This Project Has Been Approved by the XXX Research Ethics Committee

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

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, The 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 about complaints relating to your personal identifiable information](#)

Tel: 0303 123 1113

URL: <https://ico.org.uk/make-a-complaint/>

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s):

Dr Shruti Garg - Principal Investigator

Tel - 0161 3067967

Email – shruti.garg@manchester.ac.uk