

## Parent/Guardian Information Sheet

# The PANDA Study



## An evaluation of an alternative Dental Pathway

Dear Parent or Guardian,

I am writing to inform you of a research study we are conducting looking at children's dental services in Greater Manchester and would like your child to take part. Below is some information about the study. Please take some time to consider your child's participation. If you have any questions, please use the contact details listed at the end of this letter.

### Who will conduct the research?

Researchers at the University of Manchester and University of Liverpool alongside colleagues working in the NHS will carry out this research.

### What is the purpose of this study?

There are a large number of children who are referred for dental treatment through specialist services such as the Community Dental Service (CDS) or for treatment within a hospital setting. Unfortunately waiting times for Community Dental Service and hospital referrals have increased dramatically over the last few years. Given the long waiting list a potential alternative for treating children was introduced; a special kind of dental practice known as a "Child Friendly Dental Practice" (CFDP). These practices have been designed to allow them the time to manage children who may need additional support during their treatment. This option could reduce the demand on other services and allow them to deal with complex cases.

In order to understand how well these different services works, who they work for and in what circumstances we would like to explore these services and the impact they have on patients attending. We will do this by following the outcomes of patients who have attended these services and provide a guide so they can be set up across the country if successful.

### Am I suitable to take part?

Your child has attended the services we will be studying and we would like your permission to look at your child's dental/health data over the next two years so we can compare the outcomes for different people, attending different services. We will be asking around 800 children, aged between 4 and 16 years old who have been referred to the dental service you are attending, and their parents/guardians to take part.

As part of this study we are asking for your permission to access any data collected about your child's dental health. To do this we need to access information held by NHS Business Services Authority (which collect information about what treatment has been performed by the dentist you have attended) through hospitals/the NHS trust (collected by NHS Digital / Hospital Episode statistics), information collected by the Community Dental Service or

dentist you have seen for treatment and information described on any dental referral forms used within the referral process. We will link this to the information we have already collected about you. Access to this information will only be carried out for the study and there will no further access once the study ends. We will also ask you to answer some short questions by text message to understand how you feel about the service and other important points such as if your child has been in pain or needed antibiotics (a paper based survey will be available if you do not provide a mobile number).

Participation in this study is entirely voluntary. You may choose to withdraw from the study at any time and you do not have to give us a reason.

### **What would my child's involvement be?**

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

### ***Consent***

If you meet the eligibility criteria to take part in the study you can sign the consent form and complete the contact information sheet and demographic form. This consent will give us permission to access your child's dental data and connect it up to use within the research study.

#### **Data collection point 1 (within 1 month after consent)**

You will be asked to complete short survey via text message related to your child's treatment.

#### **Data collection point 2 (1 year after consent)**

You will be asked to complete short survey via text message related to your child's dental health.

#### **Data collection point 3 (2 years after consent)**

You will be asked to complete short survey via text message related to your child's dental health.

We will also ask a small number of participants to take part in an interview, if you agree to be one of these participants, we will interview you regarding you and your child's experience and the impact on them and their dental health, the interview will last 30-60 minutes and will be audio recorded. Your child can also participate but depending on their age we may ask them to produce a picture of their experience, how they felt before seeing the dentist, how they felt afterwards. Transcriptions will be retained for 5 years.

### **Length of Participation**

If you take part, we follow up with you and your child over a period of 2 years.

### **What risks are there to my child taking part?**

Any risk as a result of participation in this research study is extremely minimal. We are simply asking for permission to use data which is collected when your child attends for

treatment or appointments related to their dental health. All data is stored securely and according to NHS requirements.

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

You will be provided a £10 voucher at the end of the study if you answer the text message surveys.

**Data Protection and Confidentiality**

**What information will you collect about me and my child?**

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

- Name
- Address
- Contact details
- DOB of child
- Ethnicity
- Email address
- phone number
- NHS number (if applicable)

Individuals from the University of Manchester will access information which is collected as part of your child’s dental treatment and management. To do this we will need to provide your child’s personal identifiable data to the NHS, dentist, referral system in order to link your data and use for the study. This will be collected through clinical records, information submitted to NHS Business Service Authority, information collected through NHS digital and Hospital Episode Statistics, the NHS trust, information through the Referral system (RMSL), information collected by the Community Dental Service and information collected by General Dental Practitioners and those working within the Child Friendly Dental Practices. This will occur at the beginning of the study (when you first consent) and at the end of the study (2 years later) when the final health outcomes are collected. Access to this information will only be carried out for the study and there will no further access once the study ends

**Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection laws which protect your rights. This states we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is 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 several rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you. Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team. 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

(<https://documents.manchester.ac.uk/display.aspx?DocID=37095>).

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

In accordance with the data protection law, The University of Manchester is the Data Controller for this project. This means we are responsible for making sure your personal information is secure, confidential and used only in the way you have been told it will be

used. We would not share information with other people or organisations about you or pass on your contact details without your permission. All researchers and staff members are trained in data protection, and your data will be looked after in the following way:

The study team will store identifying information (name and contact details) securely and separately from study data. Your or your child's data will be marked with an ID number and not your name. The key for linking the ID number to you or your Child's identity will be accessible only to the research team. The data itself will be pseudo- anonymised as your unique ID number connects to the identifiable data provided by yourself. Data will be stored on University of Manchester approved and securely backed up servers or computers and data will be stored in encrypted files, folders, computers, or devices. We will also ask for your permission to keep your contact details on file and contact you about future studies you might be interested in.

Your consent form (including your name and signature) will be retained separately for 2 years after the end of the study, only the research team will have access to these (after this period the data will be fully anonymised and you will no longer be able to withdraw your data and information from the study). After the end of the project, data will be kept for 5 years and will be securely transferred to an alternative safe storage solution.

This will be the DHU Research Data Storage (RDS) system, also known as Isilon. Any data collected through the NHS will be stored at the University of Manchester, and within storage developed to keep NHS data safe and according to NHS data requirements.

*If you would like more general information on how researchers use data about patients, please visit: [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)*

### **Sharing data:**

With your consent your anonymised information will be shared in order to support additional research in accordance with the [UK Policy Framework](#).

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 dental 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.

### **Potential disclosures**

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 and your child as a research participant.

Researchers may be required to disclose information by law in certain circumstance, just as a health professional would, for example if there are any suspicions of child neglect or abuse.

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.

### **Will the outcomes of the research be published?**

The information from this study will be published in a peer reviewed journal. We will create an animated video and present this through social media/online to explain the results and will also feedback the results to parents/guardians through the post if they wish.

### **Who has reviewed the research project?**

The project has been reviewed by East Midlands – Nottingham 2, REC reference 23/EM/0093.

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

Any researcher who will have access to children will have undergone an appropriate level of DBS check

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

This project is funded through the National Institute for Health Research (NIHR151661).

### **Who is running this study and what if I have a question?**

Dr Michaela Goodwin is the Chief Investigator of the study and works at the Division of Dentistry, University of Manchester her contact details are at the end of this email.

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

It is up to you if you want your child to take part in this study. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You are free to withdraw your child from the study at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your child's data from the project once it has been anonymised as we will not be able to identify the 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.

In the unlikely 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 the NHS trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### **What if I want to make a complaint?**

#### **Minor complaints**

If you have a complaint that you wish to direct to members of the local team, please contact:

Name: Michaela Goodwin

Email: Michaela.goodwin@manchester.ac.uk

Telephone number: +44 (0)161 2324711

#### **Formal Complaints**

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.

Or by emailing: [research.complaints@manchester.ac.uk](mailto: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](mailto: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 <https://ico.org.uk/make-a-complaint/>

### Contact Details

If you have any queries or questions about the information provided, please contact –

Name: Michaela Goodwin  
Email: [Michaela.goodwin@manchester.ac.uk](mailto:Michaela.goodwin@manchester.ac.uk)  
Telephone number: +44 (0)161 2324711

### What do I do now?

If you are happy for your child to take part in this study, please complete the attached consent form and contact sheet and return it to the dentist who provided it or you can return via the post to:

The Dental Health Unit  
Williams House  
Manchester Science Park  
Lloyd Street North, Manchester  
M15 6SE

I would like to thank you for reading this information sheet and considering your child's inclusion in the study.

Yours sincerely,



Dr Michaela Goodwin

