Research Study Title: **Paediatric Chronic pain Clinic Longitudinal Cohort (PiCCoLO)**

PARTICIPANT INFORMATION SHEET FOR CHILDREN

To be shown and read by parent/carer if required

Can you help?

We are asking whether you and your parents would be interested in providing information about your health.

Before you decide if you would like to join, it is really important that you understand what the study is about, why it is being done, and what it would involve for you. So please read and think about this leaflet carefully. Also talk about it with your family.

In this study we will use information collected during your visits to pain clinic and put into your hospital record. We will only use information that we need for the study. At the end of the study we will save the data in case we need to check it, and to include it in other studies if you agree. We will make sure no one can work out who you are from the reports we write. The next few pages have more information.

If something isn't clear or you have more questions you can ask your parents to give us a call and we can discuss it with you and your parents.

Thank you for reading this.

PART 1: STUDY INFORMATION

Study title

How does chronic pain affect children and young people?

What is research?

Research is a way of carefully looking to find out the answer to an important question.

Why are we doing this research?

We are trying to find out more about the effects of chronic pain in children.

What is *chronic pain*?

Chronic pain is when something in your body hurts for a long time, usually for more than 3 months.

Why have I been invited?

You have been invited because your doctor has asked the specialists in the pain clinic to see you. We want to learn more about the effect of pain and its treatment, so that we can help other children who experience pain too. You would be one of at least 1000 children and young people helping us with this study.

What will happen to me if I take part?

Your mum or dad or the person who looks after you and brought you to the hospital will also be with you when you talk to us.

As part of your usual hospital visit, you will fill in some questionnaires about your pain, how you feel, things you do to help when you have pain, and how well you sleep. The Pain Team use this information to understand more about your pain and how best to manage it. If you agree to join the study, we will also collect this information from your hospital records. We will not ask you to do any extra tests or hospital visits.

After your appointment, someone from the research team will be around to answer questions about the study, either in person or online. If you and your parent/carer agree, you will be asked to do some forms showing you understand what will happen and you agree to take part. This can be done in person at the first appointment, over the phone, or using a secure videocall. If you didn't have time to look at this information sheet before your appointment, you can still agree to take part in the study, but if you change your mind in the next 2 days, just let us know, and we won't look at any of your hospital notes. You can also stop being part of the study later on if you want to.

If you turn 12 during the study, we will send you a new Information Sheet and ask you to sign a new form agreeing to the study. This can be done over the phone with you and your mum, dad or carer.

Where will the research be done?

The information will be collected during your usual clinic visit. This will include your age, information about any illnesses you have, your pain, treatments that have been used, and the questionnaires you and your parent/carer did at clinic or online.

To see how things change over time, we will ask to get in touch with you and your mum, dad or carer two more times, 3 and 5 years after your first visit. We will also ask you some questions over the phone or on video. You can say no to this if you want.

How will you use information about me?

- We will need to use information collected at your pain clinic visits and from your medical records for this research project. This will include your hospital number.
- People who do not need to know who you are will not be able to see your name or contact details. We will use a code number rather than your name for the study files.
- We will keep all information about you safe and secure.
- Once we have finished the study, we will keep the data so we can check the results. Data about you and from your questionnaires will be measured at GOSH and will only be looked at by the researchers who are working on the study.
- All the information will be kept safe for 25 years, to fit with rules for protecting research data.

Can I choose how the information is used?

You can stop being in the study whenever you want, and you don't have to tell us why.

We will keep the information we already have about you, as this helps to know the research is done in the right way.

If you say it's okay, we might use this information in later research studies too.

You can find out more about how your information is used by watching the video linked to the QR code here.

Is there anything else to be worried about when taking part?

There are no risks to you from being part of this study. We will not be asking you to do any extra tests outside of what usually happens in a clinical appointment.

If you are worried about your pain or feel upset when you are answering questions, we will make sure you are looked after by the hospital team and named nurse if you need them. If you are no longer a patient in the Pain Service and you feel upset when answering questions later on, we will ask your parents to talk to your doctor. We will also send you our Pain Education booklet that has information and links to websites that can help.

Will taking part in this study help me?

The study will not help you right now. It will help us to understand more about pain, and how it affects people as they grow up, to see which treatments work better in future studies.

Thank you for reading so far. If you are still interested please go to Part 2.

PART 2: FURTHER INFORMATION

This is more detailed information that you need to know if you are taking part.

What if there is a problem?

If there is a problem you should talk to your parents first or any of the researchers who will tell them what they need to do about it.

What if I don't want to do the research anymore?

Just tell your mum, dad, carer, doctor, or nurse at any time. They will not be cross with you. You will still have the same care whilst you are at hospital, and leaving the research project will not affect how you are treated now or in the future at GOSH.

What happens when the research study stops?

We will collect all the information together and we will look at what it tells us about how pain affects children.

Who is organising the research?

The study is being organised by the Pain Research Team at Great Ormond Street Hospital NHS Trust.

Who has paid for the research?

The study is funded by Great Ormond Street Hospital Charity.

Who has checked if the study is OK to do?

Before any research is allowed to go ahead it has to be checked by a group of people called the Research Ethics Committee. They make sure that the research is fair. This study has been reviewed by the West of Scotland REC 4 Committee.

Who should I ask if I have more questions?

If you have questions, talk to your parents or caregiver first. You can also ask your parents or carer to ask the research team at Great Ormond Street Hospital, or the people at the hospital who look after you.

Thank you very much for reading this – please ask any questions if you need to.