Research Study Title: **PiCCoLO**
(Paediatric Chronic pain Clinic LOngitudinal cohort)

Participant Information Sheet for Young People aged 12-15

Can you help with research?

We are asking whether you and your parents would be interested in providing information about your health for a research study.
Before you decide whether to join, it's really important to understand what the study is all about, why we're doing it, and what it would involve for you. So, take some time to read through this leaflet carefully and chat about it with your family.

Summary of important things you need to know:

- In this research study we will use information from you and your medical records. We will only use information that we need for the study.
- Everyone will keep your data safe and secure. At the end of the study we will save some of the data in case we need to check it and for future research if you agree.
- We will make sure no one can work out who you are from the reports we write. Please read the following pages for more information.

- If you are interested, one of our research team will go through the information sheets with you and your parent or carer, so we can answer any questions you have. You do not have to take part, your treatment at the hospital will stay the same.
- You will not need to do any extra tests or hospital visits for this research.

If anything isn't clear or if you have more questions, feel free to ask us or ask your parents to give us a call. We're here to discuss it with you and your parents.

Thanks for taking the time to read this!

PART 1: STUDY INFORMATION

Why are we doing this research?

We are trying to find out more about the effects of chronic pain on children and young people's health, and how this changes over time.

What is chronic pain?

Chronic Pain is when you have any kind of pain in your body that lasts longer than about 3 months.

Why have I been invited to take part?

You have been invited because you have been referred to the pain clinic at GOSH. We are hoping that if we can learn more about the effect of pain and its treatment, we will be able to help other young people who experience pain too.

What will happen to me if I take part?

- You would be one of many hundreds of children and young people helping us with this study.
- Your parent or caregiver will also be with you when you come to see us at Great Ormond Street Hospital.

Usual Care at Pain Clinic:

- At your Pain Clinic hospital appointment, you will see a pain team that includes a Pain Consultant, Clinical Nurse Specialist, Physiotherapist and Psychologist.
- The Team will enter information about you, your pain, other illnesses, treatments or tests you have had into your hospital record.
- You will also fill in some questionnaires about your pain, your activities and school, and how you feel. This helps the team understand more about your pain.

Where will the research be done?

- After your clinic, one of the research team will ask you and your parent/carer if you want to join the study.
- If you agree, you and your parent/carer will be asked to sign a form. If you haven't had a chance to read this information sheet before the day of your appointment but have talked about the study with the researcher and would like to give consent on the day, you can change your mind over the next 2 days and let us know that you don't want to join the study, and we won't look at your data. You can also stop being in the study at any time later on, for any reason.
- If you turn 16 while you are in the study, we will send you an updated Information Sheet, and ask you to fill in a new form to say that you still agree to the study. This can be done over the phone.
- We will also ask if you and your parent/carer are happy to be contacted at 2 later times (3 and 5 years) to answer questions over the phone or via video so

we can see how you are doing. You are free to say no to these extra questionnaires.

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. Your data will only have a code number.
- We will keep all information about you safe and secure.
- We will store your information with your code number in a database managed by a digital research team at GOSH.
- Once we have finished the study, we will keep the data so we can check the results. All the data will be kept safe for 25 years, following rules about data protection.

What are my choices about how my information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we have about you.
- If you agree to take part in this study, you will have the option for your data to also be used in other research.

What will happen to the results of this study?

- The results will be published in medical journals and presented at scientific meetings so that other healthcare providers can learn from this work.
- We will write our reports in a way that no-one can work out that you took part in the study.
- If you want to receive a newsletter with an anonymous summary of the results, you can let us know.

Are there any risks in taking part?

We will not be asking you to do any extra tests outside of what usually happens in a clinical appointment. You may feel a bit upset or have new questions when you are asked about your pain. If you are still being seen at the Pain Clinic, you will. be able to get in touch with your named pain nurse specialist. For the 3- and 5-year follow-up questionnaires, if you are no longer under the care of the Pain Service team, we will encourage your parents/carers to contact your GP. We will also send you a copy of the GOSH Pain Education booklet that has information and links to websites that can help with distress or worry.

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. The results will also help us find out things that could increase the risk of having long-lasting pain 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?

It is highly unlikely that taking part in this study could harm you and it will not affect your hospital care. If there is a problem, tell us and we will try to sort it out straight away. You and your mum, dad, or carer can contact the project co-ordinator:

Name: Suellen Walker
Position: Consultant
Hospital/Department: Great Ormond Street Hospital
Tel: 020 7905 2382
Or the Patient Advice Liaison Service (PALS):
Email: pals@gosh.nhs.uk; Tel: 020 7829 7862

Where can I find out more about how my information is used?

You can find out more about how we use your information by scanning this QR code to watch a video:

You can also ask one of the research team by sending an email to:
Suellen.Walker@gosh.nhs.uk OR
Anna.Fieldwalker@gosh.nhs.uk
Or you can ring us at the Hummingbird Ward on 02078138268

Who has reviewed the study?

All research in the NHS is first checked by a group of people called the Research Ethics Committee. They make sure that the research is safe and fair. This study has been reviewed by the West of Scotland REC 4 Committee.

Who has funded the research?

The study is funded by Great Ormond Street Hospital Charity.

Who should I ask if I have further questions?

If you have questions, talk to your parents first. You can also ask your parents to contact the research team at Great Ormond Street Hospital.

Thank you very much for your interest in this study.