ODD SOCKS STUDY

Participant Information Sheet

For participants who turn 16 years old <u>during</u> the main study

Chief Investigator: Nicholas Peterson

You have recently been treated for a broken ankle and were enrolled in the ODD SOCKS study with the consent of your parent/guardian. Now that you have turned 16 years of age, we would like to confirm that you are happy to continue to be part of the study.

Before you decide to continue in the study, it is important that you understand why we are doing it and what it would involve for you. Please visit the study website www.ODDSocks.org and watch the video which explains the study.

Feel free to talk about it with other people if you want. If there is anything that is not clear, or if you would like more information, please ask someone from the research or clinical team.

Alder Hey Children's NHS Foundation Trust

UNIVERSITY OF OXFORD

NIHR | National Institute for Health and Care Research

1) WHAT IS THE ODD SOCKS STUDY?

The ODD SOCKS Study is a research study trying to improve the treatment of children who have broken their ankle involving the growth plate. Hundreds of children sustain this injury in the UK each year. Doctors treat these injuries in different ways. Some doctors advise to rest the leg in a cast or splint and allow it to heal by itself, whilst others advise surgery to fix the bone. Despite the relatively large number of these injuries, doctors are currently not sure whether one way of treating them is better than the other because it has never been researched.

In this study we compare the two most common treatments used throughout the UK:

1. Resting the leg in a plaster cast for up to 6 weeks, to allow it to heal by itself.
2. Surgery to fix the bone back into its natural position. This will usually involve inserting screws to hold the bone in position and resting the leg in a splint or cast for up to 6 weeks.

We plan to include 192 children who all have a fracture like your child. This number is based on previous scientific research. By including this many children, we will be able to reach a firm conclusion at the end of the research.

2) WHAT DOES THE STUDY INVOLVE?

This section gives an overview of all the activities that happen when someone takes part in the study. You, together with your parents, might have already completed most of these activities or you might just be at start of your recovery. By signing the consent form, you will only give consent for those activities that have not been completed.

During your continued recovery, the hospital team will see you in clinic at regular intervals according to their normal procedures. During some of the clinic visits you may have an x-ray if the doctors think this is necessary. After 2-years you will have x-rays of your ankle for the ODD SOCKS study - this may be an additional investigation beyond routine care. We will also have brief contact with you and your parent/guardian by text message and/or email for study specific follow up. This study specific follow up takes place 6 weeks, 3 months, 6 months, 1 year and 2 years after joining the study. We ask questions about how much pain you have, what activities you can do and how you are feeling in general. We also would like to know about visits to the hospital, whether you had to miss school and if you or your parents had any extra costs because of your injury (for instance due to days absent from school/ college/ work etc). It is important that you try and answer the questionnaires as soon as possible after they are received (it should take about 5-10 minutes). If the questionnaire is not completed, we will give you a reminder after a few days (by text or e-mail). If it is not completed after one week or we have any questions about your answers, we may call you to ask the questions over the telephone. We are able to offer a £10 e-voucher at the end of the study as a 'Thank you' and to compensate you for costs incurred through completing the questionnaires (i.e. mobile phone data). You will receive further information on how to claim this upon completion of the 24-month questionnaire.

If you decide not to continue to be part of this study, this will not change the level of care that you will receive. Even if you decide to continue now, you can change your mind at any time and can contact the research team by email at ODDSocks@ndorms.ox.ac.uk. The study results will

be available to you online at www.ODDSocks.org at the end of the study. All results will be anonymised, so no one will be able to identify you from them.

3) WILL THERE BE EXTRA TESTS?

You may have two extra x-ray images as part of this study.

The x-rays will show us how your ankle has healed after the injury and allow us to compare healing in the two groups. The amount of radiation in total from these x-rays is roughly the same as the radiation you would be exposed to when flying in a plane for about an hour.

All other tests and assessments will be the same as for people who do not participate in the study.

4) WHAT ARE THE RISKS AND BENEFITS OF TAKING PART?

Now that your ankle has been treated, any ongoing risk to you is very small.

We've already explained that the amount of radiation for these x-rays is very small, though ionising radiation may cause cancer many years or decades after exposure. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only an extremely small chance of this happening to you. There are no direct benefits, however, your participation would help us improve treatment for future patients with similar injuries. The study will also provide information on the best use of resources within the NHS.

5) WHO HAS FUNDED THE STUDY?

The study is funded by the National Institute for Health and Care Research (NIHR) Health technology Assessment (HTA) Programme (Reference NIHR132675).

6) WHO IS INVOLVED WITH THE STUDY?

Alder Hey Children's NHS Foundation Trust is the sponsor for the study, which means they will provide oversight and insurance for it. The quality of the study will be overseen by Oxford Clinical Trials Research Unit, with the day-to-day running being completed by Oxford Trauma and Emergency Care at the University of Oxford. Researchers from the University of Oxford and Bangor will help with the analysis of the information gathered but will not be able to identify you or find out your name/contact details.

The research team has a lot of experience in caring for children and young people with injuries and is active in health research. Parents and children have been involved in the development of this study and are also involved in its management.

7) WHO HAS APPROVED THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and been given a favourable opinion by East Midlands - Nottingham 1 Research Ethics Committee.

8) HOW WILL THE INFORMATION COLLECTED BE HANDLED?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. The Universities of Oxford, and Bangor, together with Alder Hey Children's NHS Foundation Trust, are the main data controllers and are responsible for looking after your information and using it properly.

A copy of your consent form will be stored at the University of Oxford for up to 5 years after the end of the study, or 12 months after the youngest participant in the study reaches the age of 16 years, whichever is longest.

We will be using information from you and your medical records in order to undertake this study, and will use the minimum personally identifiable information possible.

This information will include:

- Your name
- Your NHS/CHI/H&C number
- Your contact details

Your treating hospital will collect this information in accordance with our instructions. Copies of the completed questionnaires will be sent to the research team at your treating hospital. The collected data will be stored securely in a de-identified (pseudonymised) form – this means it will be very hard to identify you from it.

Your personally identifiable information and contact details will be stored separately to the data collected for the study.

Should you choose to be contacted via SMS/text message, your phone number will be shared with our text message provider (SMS Works) for the purposes of sending the message. This information will be retained for a maximum of 3 months by SMS Works before being deleted from their records.

The University of Oxford and your treating hospital will use your name, health record number (e.g. NHS/CHI/H&C number) and contact details to contact you about the research study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Oxford, Alder Hey Children's NHS Foundation Trust, and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your treating hospital will pass these details to the University of Oxford along with the information collected from you and/or your medical records.

The only people who will have access to information that identifies you will be people who need to contact you, to enable your follow-up in this study, or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, health record number or contact details.

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 hold about you.

Currently, there is little information available on the long-term effects of having an ankle fracture as a child. We would like to collect information related to your injury in the future. If you agree to

continue to take part in this study, you will have the option to take part in future research using the data saved from this study. Collection of any additional information than what is described in this information leaflet is subject to further funding and ethical approval. Once such approval is in place, we will contact you and ask if you are willing to consent to long-term follow up related to the ODD SOCKS study. In order for us to facilitate contacting you in the future, if you agree, we will store your contact details and NHS/CHI/H&C number for 5 years after the study has finished or 12 months after the youngest participant turns 16, whichever is longest.

If you do not agree to be contacted for future research, we will store your contact details and NHS/CHI/H&C number for 12 months after the completion of the study.

9) CAN I STOP TAKING PART IN THE STUDY?

You can change your mind at any time and can contact the research team by email at ODDSocks@ndorms.ox.ac.uk. Leaving the ODD SOCKS study will not change the level of care you will receive.

If you withdraw from the study, your study participation will end, and the study team will stop collecting information from you. Information collected up until your withdrawal from the study will continue to be used and included in the study. To safeguard your rights, we will use the minimum personal identifiable information possible.

10) WHERE CAN I FIND OUT MORE ABOUT HOW MY INFORMATION IS USED?

You can find out more about how we use your information:

- From the ODD SOCKS website: www.ODDSocks.org
- By contacting the ODD SOCKS study team at Oxford: ODDSocks@ndorms.ox.ac.uk
- At www.hra.nhs.uk/information-about-patients
- By asking one of the research team at your treating hospital
- In the Health Research Authority leaflet available from www.hra.nhs.uk/patientdataandresearch
- By contacting the University of Oxford Data Protection Officer on data.protection@admin.ox.ac.uk
- By contacting the Alder Hey hospital Data Protection Officer on dpo@alderhey.nhs.uk
- By contacting Bangor University Data Protection Officer on l.d.williams@bangor.ac.uk
- In Bangor University's Data Protection Policy available from: http://www.bangor.ac.uk/governance-and-compliance/dataprotection/index.php.en

If you are not happy with the way your information is being handled, or with the response received from us, you have the right to lodge a complaint with the Information Commissioner's Office at Wycliffe House, Water Lane, Wilmslow, SK9 5AF (https://ico.org.uk).

11) RIGHTS TO ACCESS YOUR INFORMATION

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at https://compliance.admin.ox.ac.uk/individual-rights

12) INFORMATION SHARING FOR OTHER RESEARCH

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. This 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, or for related teaching purposes.

The information that will be shared will not identify you and will not be combined with other information in a way that could identify you. It will only be used for the stated research and teaching purposes and will not allow you to be contacted nor will it be used to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

13) WILL WE BE INFORMED OF THE RESULTS OF THE STUDY?

The study is registered on the clinical trial registry, ISRCTN16320803, which can be accessed at this website: https://www.isrctn.com/ISRCTN16320803

The study results will be available to you at the end of the study at www.ODDSocks.org. All results will be de-identified, meaning that no one can identify you from the results directly.

14) WHAT IF THERE IS A PROBLEM?

If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Mr Nicholas Peterson who is the overall study lead on 0151 228 4811, or email ODDSocks@ndorms.ox.ac.uk. You may also contact the Sponsor at Alder Hey Children's NHS Foundation Trust on 0151 252 5570 or email research@alderhey.nhs.uk.

Every care will be taken over the course of this study. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the NHS Trust where you are being treated but you may have to pay legal costs. The normal NHS complaints procedures should be available to you.

For independent advice, please contact NHS Complaints. Ask your treating hospital for the contact details or visit https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/.This is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. However, they cannot provide information about this research study.