



The PIC Bone Information Study

Interview Information Summary for Parents

1) What is the PIC Bone Information Study?

We are inviting you to take part in an interview as part of the PIC Bone study.

This will involve talking with a researcher about the care your child received when s/he recently attended hospital with a painful limb. This is so we can improve the experience of hospital care for families in the future when a child has a painful limb.

Before you decide whether or not to take part in an interview, please take time to read this sheet and discuss it with others if you wish.

2) Do I have to take part?

The interviews are voluntary and if you don't want to take part, that's ok. Your child's care will not be affected and you don't need to give a reason.

3) What do I need to know about the Information Study interviews?

If you agree to take part, a researcher will contact you to arrange a convenient time to talk with you. With your permission the conversation will be audio recorded. If your child is old enough we will ask you if we can talk with your child about their experience of attending hospital too. Parents and children can take part in the discussion together or separately, whichever they prefer.

The Information study will be conducted by the University of Liverpool. The interviews can take place by video call, telephone, or in-person (usually in your home) depending on your preference. Interviews will last about an hour. If there are any questions you don't want to answer, just tell the researcher and they will move to the next question. You can also stop the interview at any point.

4) What will happen to all the information about me?

All information collected during this study will be kept confidential. This means that apart from the PIC Bone Information Study research team, no one, including your child's doctors and nurses, will know what you have said. If anything arises during the conversation that is of concern (e.g. regarding a child's safety), we will discuss this with you and may be obliged to contact the relevant child safeguarding team. All other information will be kept confidential.

The audio recordings will be typed out by an agency, but all names will be removed before analysing the transcripts. The audio recordings will then be destroyed. The transcripts will be securely stored at The University of Oxford and The University of Liverpool for 5 years. Your contact details will be destroyed at the end of the Information Study.



We may use quotes from some transcripts when we publish the findings but we will always make sure no one can be identified from the quotes.

You can withdraw from the Information Study without giving a reason. You can also ask for your data to be destroyed, but if you withdraw after the analysis has begun it will not be possible to remove your data from the study.

The study results will be made available on the study website when the study is finished. [Insert study website URL]. A link to the website will also be provided via email or text message. You can also view an animated study explainer video on this website.

5) How to contact us?

Please contact the <Information Study researcher name and email> if you would like more information.

What will happen if I don't want to carry on with the study?

If you do not agree for your child to be part of this study, this will not change the care they will receive. You can change your mind at any time and can contact the research team using the contact details on the last page of this sheet.

Consent

We will ask you to sign a consent form, indicating you agree to your child taking part in the study. To do this, we will send you a link via email and you can agree to participation electronically. Alternatively, you may sign a paper consent form or a remote consent form. We don't mind which way you chose!



What if there is a problem?

If you have a concern about any aspects of the PIC Bone study, you should speak with your clinical/research team at your hospital. They will do their best to answer your questions

PI/RN number again

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you remain unhappy and wish to complain formally you can contact your local team (details above), or you may contact the University of Oxford Research Governance and Assurance Team office on 01865 616480, or the head of CTRG, email RGEA.Complaints@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) 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. PALS is unable to provide information about this research study.



This study does NOT involve any extra tests or visits to the hospital!



Will taking part in the study be kept confidential?

Yes, only the study team and members of your clinical care team will know about you taking part in the study. When you consent, your details will be passed to the study team in Oxford in case they would like to contact you in three months to see how your child is doing. This includes your name and telephone number. A study identification number will be given to each participant when consent is given. All personal information will be stored in a secure database at the University of Oxford.

Responsible members of the University of Oxford [and the relevant NHS Trust(s)] may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Who is involved with the study?

- A group of surgeons, doctors and scientists who have many years of experience with working with children and young people in the healthcare setting.
- They work with the Surgical Intervention Trials Unit (SITU) in Oxford who will help manage the project. The SITU team have experience with bone and joint research.
- Generation R (a network of Young People's Advisory Groups) are also supporting the design and delivery of this study.
- The study is funded by a grant from the National Institute for Health and Care Research, an organisation that supports research involving children and young people.
- The study is sponsored by the University of Oxford and has been reviewed by your local hospitals research department.
- The University of Oxford and The University of Liverpool will be using information from you and your child's medical records to undertake this study and will act as the joint data controllers for this study.
- **The study has also been reviewed by a research ethics committee, who have agreed it is being conducted in a correct and appropriate manner.**

PIC Bone Team
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**How will information about my child be used?**

UK 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 Liverpool are the data controllers for the information study and are responsible for looking after your information and using it properly.

Your data will only be shared among members of the research team, though audio recording of interviews may be transcribed by an approved University transcriber. It will not be shared with anyone else except with your consent or as required by law.

The forms with information about your interview responses will only identify you by a study number. Your personal information (for example, your name so that we can keep track of who has participated in the study) will be stored in a secure place, separate from your study file and will not be entered into the study database. The study data, with identifying information removed, will be securely stored in a locked office in the research office and on secure servers at the University of Oxford and the University of Liverpool. The Universities of Oxford and Liverpool have robust data security measures in place. This makes the risk of data breaches minimal. We will be using information from you and/or your child's medical records and will use the minimum personally-identifiable information possible. Any identifiable information will be retained for one year after the study has finished (5 years for anonymised information). The investigators agree not to attempt to connect your information back to you after the study is completed.

Interviews will be audio recorded, whereas in discussion groups the researcher will make notes only. We will not collect any data that can identify you (e.g. name, NHS number) during the interview. Audio recordings and handwritten notes will be transcribed, and any identifiers will be removed. We will not keep any codes or keys that link you to your anonymised data. Audio files and handwritten notes will be destroyed as soon as they have been transcribed. The transcripts will be stored with password protection. All data will be destroyed 5 years after the end of the research project. Audio files will be transcribed by a university approved transcription service. Our transcribers use a secure system for uploading audio files for transcription. They do not keep the audio recording.

When the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure.

UK 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.web.ox.ac.uk/individual-rights>.