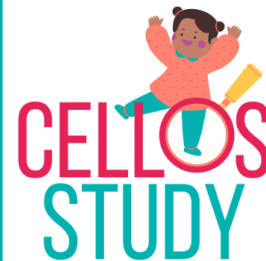


# THE CELLOS STUDY: INFORMATION SHEET FOR PARENTS AND GUARDIANS



## WHAT IS THE CELLOS STUDY?

The CELLOS Study is researching children's planned surgery to the bones and muscles of their legs. This includes surgery from their hips to their feet. The study is trying to find out what researchers should measure before and after surgery, to see if they got better. Things we can measure are called 'outcomes'. Examples might be how much pain your child has, or how often they go to school.

We want to speak to you to understand what outcomes parents think are important. We may also want to speak to your child, if you are happy for them to take part.

## WHY HAVE I (AND POSSIBLY MY CHILD) BEEN INVITED TO TAKE PART?

You have been invited to take part because: 1) You live in England, Wales or Northern Ireland. 2) You are the parent or carer of a child or young person between 0 and 25 years old 3) Your child had (or will have) planned surgery to the bone or muscles of their legs when they were under 18 years old.

We may have also invited your child who had (or will have) this surgery to take part if they: 1) Also live in England, Wales or Northern Ireland. 2) Are currently between 8 and 25 years old.

## WHAT HAPPENS IF WE DECIDE TO TAKE PART?

You will have a conversation with a researcher. This will be audio recorded. You can decide when and where this will take place. We can meet you online using Microsoft Teams. We can also meet you in person. This can be at your home or somewhere close, like a community hall.

This conversation will take about 45 minutes if you take part alone. It will take about one hour with your child. If your child is over 16 years old, you can choose to take part together or separately.

## DO WE HAVE TO TAKE PART?

No, it is your choice to take part. If you choose not to, it will not detriment your legal rights or child's hospital treatment.

If you decide to take part and change your mind during the project, you can withdraw. You don't have to give a reason.

## WHAT ARE THE ADVANTAGES AND DISADVANTAGES?

There is a small risk that you or your child might find the questions we ask upsetting.

There are no immediate benefits if you take part. However, we hope this research will improve evidence for children's leg surgery.

You will be offered £20 gift voucher for taking part. Reasonable travel expenses can be reimbursed.

YOU CAN FIND MORE DETAILED INFORMATION ABOUT THE CELLOS STUDY BY READING THE REST OF THIS INFORMATION SHEET

## The CELLOS Study: What is important to measure after children have planned operations for orthopaedic conditions affecting the leg from hips to toes?

### INFORMATION SHEET FOR PARENTS AND CARERS

*If you need an audio or translated copy of this sheet,  
please let the research team know at [CELLOS.study@ndorms.ox.ac.uk](mailto:CELLOS.study@ndorms.ox.ac.uk)*

#### 1. Introduction

You, and maybe also your child, are being invited to take part in a research project called the CELLOS Study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

#### 2. Why is this research being conducted?

Surgeons use research findings to decide which surgery is most appropriate for children who need planned surgery to their legs, from their hips to their feet. However, there are some problems with the research that surgeons rely on. Some studies only measure how the child's leg moves before and after surgery. This does not consider other important outcomes from the surgery, like if the child can play more sport after surgery. Some studies also measure these outcomes in ways that are designed for adults rather than children. This makes it hard to use research findings to guide surgeons.

To address this, the CELLOS study is creating a list of the most important outcomes for children who need non-emergency surgery to their legs. It will also look into how to measure these outcomes.

We want to speak to children and young people, parents/carers and healthcare professionals. We want to know what everyone thinks researchers should measure before and after surgery. This will help us understand what outcomes are important, and why they are important. We will use this information to write a survey where people can vote on how important each outcome is.

#### 3. Why have I been invited to take part?

We have invited you to take part because:

- You are the parent or carer of a child or young person. They are between 0-25 years old.
- Your child had planned orthopaedic leg surgery (surgery to the bones or muscles of their leg). This surgery happened while they were under 18 years old. If they have not had this surgery yet they will have it soon, while they are still under 18 years old.
- You are living in the England, Wales or Northern Ireland.

We may have also invited your child if they:

- Had planned orthopaedic leg surgery (surgery to the bones or muscles of their leg). This surgery happened while they were under 18 years old. If they have not had this surgery yet they will have it soon, while they are still under 18 years old.
- Are between 8-25 years old.
- Are currently living England, Wales or Northern Ireland.

#### **4. Do I have to take part?**

No. It is up to you to decide whether to take part. You can withdraw from the study by telling us. You do not have to give a reason. This will not affect your legal or medical rights. If you chose to withdraw your contact details will be erased. You will no longer be contacted about the study.

You can also ask to have the recording or transcript of the conversation erased. The deadline for this is 14 days after your conversation with the researcher. After this time your data will be analysed with others. This means it will no longer be possible to remove your data, but you can still withdraw.

#### **5. What will happen to me if I take part in the research?**

We would like to speak to you, and your child if they meet the above criteria. We would like to understand what researchers should measure before and after surgery. We are planning to speak to about ten children and parents.

If your child is also taking part and they are under the age of 16 years old, we will speak to you both at the same time. If they are over 16 years old you both can chose to speak to us together or separately.

We will ask you to complete a 'consent to be contacted' form. This tells us you are interested in taking part and will collect some information about you. We would like to speak to different types of people, to make sure we understand a wide perspective. We will use the information you share to decide who we should speak to.

If you are selected, the conversation will be arranged at a time convenient to you. You can choose how to meet us. We can either meet online (using Microsoft Teams) or in person. If you choose to meet in person, this can be at your home, or somewhere nearby such as a local hospital or community centre. This will depend on what we can book in your area. If your child is also taking part, we may be able to book a room in a local attraction. This might be a zoo or science centre.

If you are meeting in person, we will bring a consent form to the meeting for you (and a consent/assent form for your child) to sign. If you are meeting online, we will send you an online consent form (and a consent/assent form for your child) to complete before the meeting. Completing a consent form (or assent form for children under 16 years old) tells us you are happy to take part.

The conversation will take about 45 minutes if you take part on your own. It will take about 60 minutes if your child also takes part. We will only need to speak to you once. If you or your child need to take a break, you can let the researcher know. They will be more than happy to help.

We will ask you questions about:

- Your child's surgery.
- What you were hoping would change after surgery.
- What you have found did change after surgery.

- Why these changes were important to you or your child.
- You may be told about some example patients. You will be asked what you think researchers should measure for these patients.

If your child is also taking part, we may use cards with cartoons with them or ask them to draw some pictures. This might help them talk about the changes before and after surgery. We will bring any pens, pencils and paper they will need.

This conversation will be audio recorded. If your child draws some pictures, we will take pictures of these on a camera or may keep the drawings.

## **6. What are the possible advantages and disadvantages or risks in taking part?**

There are no immediate benefits for taking part. However, we hope that this study will improve the research evidence for children's planned leg surgery.

There is a small risk that you (or your child) will find the questions we are asking upsetting. This is more likely if you have had a bad experience with surgery. If any questions are too upsetting, you can let the researcher know and they can move on. You can stop at any time if you want to.

## **7. Expenses and payments**

After the meeting, you will be offered a £20 gift voucher. This is a thank you for participating.

If you choose to meet in-person outside of your home, you will also be offered reimbursement for reasonable travel expenses or a mileage allowance. The University of Oxford policy regarding expenses can be found at: <https://finance.admin.ox.ac.uk/claimants-expenses-guidance>

To claim expenses, we will ask you to complete a University of Oxford form which will ask contact information and payment details.

## **8. What information will be collected and why is the collection of this information relevant for achieving the research objectives?**

Your conversation with the researcher will be recorded. It will be audio recorded, so only your voices are included. It will be recorded using two encrypted digital recorders, one as a backup. The recording will be saved on a computer, then erased from the digital recorders.

This recording will then be turned into a written transcript. Once it has been checked the recording on the computer will also be erased. We will then analyse the transcripts to see what outcomes people said were important. We also want to understand why these outcomes are important.

## **9. Will the research be published? Could I be identified from any publications or other research outputs?**

The results will be written as a thesis for a DPhil at the University of Oxford. A copy of the thesis will be deposited both in print and online in the Oxford University Research Archive. It will be publicly available to use in future research.

In addition, several academic publications, conference presentations, an information pack for researchers, an animated video and reports in charity magazines will be developed. We would like your permission to use quotes from you in any research outputs. We may also use quotes or

drawings from your child, if they take part. The quotes or drawings will be published under a pseudonym (fake name) and all identifiers removed. Every effort will be made to maintain your confidentiality.

If you want to read about the results, a summary will be published on the study X (Twitter) page: @CELLOSstudy

#### **10. Will my and my child's participation be kept confidential?**

Yes. All study records and data will be identified only by a code. We will only use your name, email address or telephone number when we need them to contact you. Information that can identify you will be held securely by Doctoral Investigator (Eileen Morrow) for the purposes of the study. Confidentiality will be maintained as far as it is possible. Unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies. We would discuss it with you first. We will ask for your child's General Practitioner (GP) contact details on your consent form to facilitate any safeguarding referrals, in the unlikely event this is required. We will not use these details for any other reason.

Responsible members of the University of Oxford, regulatory authorities and the relevant NHS Trusts may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

#### **11. What will happen to my data?**

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 University of Oxford is the sponsor for this study. It is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you only in order to undertake this study and will ask you the minimum personally identifiable information possible. We will store any research documents with personal information, such as consent forms, securely at the University of Oxford for five years after the end of the study, as part of the research record. We will keep any other identifiable information about you for, such as contact details, for less than three months after the study has finished.

A third-party transcription service will be used to turn your conversation recording into a written manuscript. If you require a translator for your conversation a third-party translating service will be used. Before taking part, all third-party suppliers will sign a contract to say they will keep participant confidentiality.

If you ask for travel expenses, your bank details will be stored by the finance team for seven years. This is in accordance with University of Oxford financial policy.

If you have been recruited to this study through Oxford University Hospitals NHS Foundation Trust (OUH), the OUH will use your child's name and NHS number to oversee the quality of the study.

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>

You can find out more about how we will use your information by contacting the study team at [CELLOS.study@ndorms.ox.ac.uk](mailto:CELLOS.study@ndorms.ox.ac.uk)

### **12. Who is funding the research?**

This study has been funded by the National Institute for Health and Care Research (NIHR) Doctoral Clinical Academic Fellowship.

### **13. Who has reviewed this research?**

This research has received sponsorship from the University of Oxford (reference: 17847). This research has also received a favourable opinion from the Harrow Research Ethics Committee. (reference: 24/PR/0719).

### **14. Who do I contact if I have a concern about the research or I wish to complain?**

If you have a concern about any aspect of this study, please speak with the research team. They will do their best to answer your questions. They can be contacted at [CELLOS.study@ndorms.ox.ac.uk](mailto:CELLOS.study@ndorms.ox.ac.uk)

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Eileen Morrow at [Eileen.Morrow@ndorms.ox.ac.uk](mailto:Eileen.Morrow@ndorms.ox.ac.uk) or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at [rgea.complaints@admin.ox.ac.uk](mailto:rgea.complaints@admin.ox.ac.uk) or on 01865 616480.

*Thank you for considering taking part.*