# CELLOS Study: Delphi Survey Information Sheet for Healthcare Professionals and Researchers

**Contact: CELLOS.study@ndorms.ox.ac.uk**

**What is the purpose of the study?**

There are issues with the research evidence that underpins surgical decisions for children's elective lower limb orthopaedic surgeries. Many studies only focus on structural or functional outcomes, use unverified measurement tools, and lack consistency in what they measure. This makes it hard to synthesise study results for stronger evidence, particularly important for less common conditions.

To address this, the CELLOS study is developing a core list of important outcomes and measurement tools for these surgeries, to improve consistency between studies. A long list of outcomes has been developed from the literature and interviews with stakeholders. Through this Delphi survey and two subsequent consensus workshops, healthcare professionals, researchers, patients and their parents will decide on the core outcomes and measurement tools for research involving these patients.

**Why have I been invited?**

Approximately 150 people will take part in the Delphi Survey. Approximately 25 people will take part in each consensus workshop. We have invited you because:

Healthcare Professionals:
You are a Paediatric Orthopaedic Surgeon, Paediatric Orthopaedic Nurse, Orthotist, Prosthetist, Occupational Therapist, Physiotherapist or Podiatrist. You have at least two years of clinical practice. Your current role includes working with children post-CELLOS at any stage of rehabilitation.

Researchers:
You are a healthcare scientist, researcher, triallist or systematic reviewer. You have published research in paediatric orthopaedics in the past five years.

**Do I have to take part?**

No, it is up to you. If you change your mind later, you can choose to withdraw without giving a reason and without affecting your employment or legal rights.

You can take part in the Delphi survey without joining the consensus workshops. You can choose if you would like to be invited to the consensus workshops when completing the consent form.

**What will happen if I decide to take part?**

After reading this information sheet, you will complete a consent form if you wish to participate.

You will then complete the first round of the Delphi survey. This will include sharing demographic data, voting on the outcome domains, and suggesting any further outcome domains and outcome measurement tools. The survey will take approximately 15 minutes to complete.

When the first round of the survey closes, the data will be analysed. Outcome domains will be removed which are voted as important, or voted as not important. New domains suggested by participants will be added.

You will be sent a second round, and vote on outcome domains which don't have agreement. This process will be repeated until there is agreement on all domains. There will be a maximum of four rounds. If you don't complete a round you will be sent two reminder emails.

After the Delphi survey, two consensus workshops will be held. One will discuss the outcome domains voted as 'important'. The second will discuss outcome measurement tools for the final core outcome domains. These workshops will include approximately 25 participants and will be held online using Microsoft Teams. They will be audio and video recorded using Microsoft Teams. You will be sent an optional evaluation form after each workshop. You will be invited to an optional debriefing meeting after each consensus workshop. These will not be recorded. If you choose to in the consent form, you may be invited to join one or both workshops.

**What are the advantages or disadvantages of taking part?**

There are no immediate benefits for participating. If you complete the maximum of four rounds of the Delphi survey, it will take approximately one hour. If you are invited to take part in a consensus workshop, these will each take approximately four hours. No further disadvantages are anticipated.

**Will my participation be kept confidential?**

Yes. Information that can identify you will only be held securely by the Doctoral Investigator for the purposes of the study. Responsible members of the University of Oxford and regulatory authorities may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

**What will happen to the results of this study?**

The findings will be written up as a thesis for a DPhil in Musculoskeletal Sciences at the University of Oxford. A copy will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available. Academic publications, conference presentations, an information pack, an animated video and lay reports will also be shared. If you are interested in the reading the results, a short report will be published and links to academic papers shared on our X (Twitter) page: @CELLOSstudy

We would like to use quotes from you in the results we share. The quote will be published under a pseudonym (fake name) and all identifiers removed. Every effort will be made to maintain your confidentiality.

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

If you chose to withdraw your contact details will be erased from the study. You can also request to have your responses to the survey erased. The deadline for this is seven days after the survey round

closes. After this your data will be analysed and it will no longer be possible to remove your data. As the workshops are a group exercise, if you participate, it will not be possible to remove your data but you can still withdraw.

**What if there is a problem?**

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

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 or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

**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 in order to undertake this study and will use 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 for a maximum of three months after the study has finished. This will include your contact details.

The Delphi survey will be conducted using a secure online survey platform. We will store the data online until the end of this study. Once the study is finished, we will download it to the University of Oxford network drive and erase it from the online survey platform. The data from the survey will be anonymised when it is downloaded.

The workshops will be audio and video recorded to allow analysis. This recording will be completed over Microsoft Teams. The video file will be saved on the secure University of Oxford network drive in a password protected file, where only the research team can access it. It will be kept for five years along with the research data. A backup recording will be made with an encrypted digital recorder. This will be kept only until the video recording is checked.

For the consensus workshops, a third-party online meeting facilitation company will be used. If any participants need a translator, a third-party supplier will be used. Before the workshop, all third-party suppliers will sign a contract to say that they will maintain participant confidentiality.

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 use your information by contacting CELLOS.study@ndorms.ox.ac.uk

**Who is organising and funding the study?**

The CELLOS study is sponsored by the University of Oxford. It is funded by the National Institute for Health and Care Research (NIHR) Doctoral Clinical Academic Fellowship.

**Who has reviewed the study?**

This study has been reviewed and given a favourable opinion by Harrow Research Ethics Committee (reference 24/PR/0719).