Parent/Guardian Information Statement

[Insert site name]

HREC Project Number:	68948
Short Name of Project:	SCIENCE
Full Name of Project:	Surgery or Cast for Injuries of the EpicoNdyle in Children's Elbows
Protocol Number:	Version 4.2 dated 19/04/2021
Project Sponsor:	University of Oxford, United Kingdom
Chief Investigator	Professor Daniel Perry, University of Oxford
Local Principal Investigator(s)	*[Associate Investigator(s)]*
Local Site Phone and E-mail	*[Phone & E-mail]*

Thank you for taking the time to read this **Parent / Guardian Information Statement**. We would like to invite your child to take part in a research project that is explained in this form.

What is an Information Statement?

An Information statement tells you about the research project. It explains exactly what the research project will involve. This information is to help you decide whether or not you would like your child to take part in the research. Please read it carefully. This form is 6 pages long. Please make sure you have all the pages.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Taking part in the research project is up to you

It is your choice whether or not your child takes part in the research project. You do not have to agree if you do not want to. If you decide you do not want your child to take part, it will not affect the treatment and care your child will receive.

Signing the consent form

If you want your child to take part in the research, please sign the electronic consent form. By signing the form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to your child taking part in the project.

We will give you a copy of this form to keep.

1) WHAT IS THE SCIENCE STUDY?

The SCIENCE Study is trying to improve the treatment of children who have a broken bone in the elbow called an 'epicondyle fracture'. In Australia, and around the world, doctors treat these injuries in different ways. Half of doctors advise to rest the elbow in a cast or splint and allow it to heal by itself, whilst the other half advise surgery to fix the bone. Despite the number of these injuries, doctors are not sure whether one way of treating them is better than the other because existing research is of poor quality.

This study, which is led by the University of Oxford in the United Kingdom, will compare the two commonly used treatments in a group of 334 children:

1. Resting the arm in plaster cast for up to 4 weeks, to allow it to heal by itself.

2. Surgery to fix the bone, usually with a screw and resting the arm in a splint or cast for up to 4 weeks.

All patients will then be followed up in hospital, and get rehabilitation according to the usual practice of the treating hospital, which will include advice about moving the arm, and may include physiotherapy.

The only way to compare the treatments fairly is to create two groups of children who are the same, by a process called randomisation. You can't choose the treatment, and neither can the doctors, otherwise the groups would not be the same. When we have groups of patients who are as identical as possible, we can then compare them fairly in terms of outcomes.

2) WHY IS MY CHILD BEING ASKED TO TAKE PART AND WILL THERE BE EXTRA TESTS?

Your child is being asked to take part because they are aged between seven and 15 years and they have an x-ray showing a broken bone in the elbow, called a medial epicondyle fracture.

No, there are no additional tests. The study compares two treatments commonly used.

3) WHAT ARE THE POSSIBLE BENEFITS, RISKS, SIDE-EFFECTS, DISCOMFORTS AND/OR INCONVENIENCES?

This project may not directly benefit your child. However, we hope that the project may benefit other children with this type of broken bone in the future. It could do this by helping doctors decide how to treat the broken bone, with surgery, or simply with a cast.

Each of these routinely used treatments has potential advantages and disadvantages.

(1) Resting the arm in a plaster cast for up to 4 weeks, to allow it to heal by itself. The benefit is avoiding surgery. However, the main risk of this is that healing may be less reliable, which can lead to an unstable elbow causing pain, stiffness and/or clunking and may require more complex surgery later on.

(2) Surgery to fix the bone, usually with a screw and a splint or cast for up to 4 weeks. The benefit is more reliable healing. There are however risks of surgery, which include those associated with an anaesthetic (low risk), wound healing problems, pain or stiffness, injury to nerves supplying the fingers and breakage of the bone or metal. There is commonly the need for a second surgery to remove the screw once the bone has healed. These risks will be discussed further with your surgeon during a separate consent process.

There is also a possibility of unexpected or incidental findings as a result of the scans being done as part of your child's normal routine care. Any new or abnormal findings will be discussed with participants and relevant clinical follow-up offered as necessary.

X-rays taken as part of your child's normal routine care will be sent to The University Oxford for central review. Your child's name and other identifiable information will be removed before sending. If your child requires CT or MRI as part of their regular care, these images may also be sent in a similar fashion.

4) WHAT DOES THE STUDY INVOLVE?

If you decide you would like your child to take part, a member of the team will ask you to complete:

1. A contact information form so we can contact you about your child's recovery.
2. A questionnaire about the injury, pain, activities and feelings. This should take about 5-10 minutes.

We will then allocate your child fairly to one of the two treatment groups in the study. The doctors and nurses will then begin treatment.

During your child's recovery, we will have brief contact with you and/or your child by text message and/or email on four occasions (after six weeks, three months, six months and one year). We will ask questions about pain, activities, feelings, hospital attendances and school attendance. It is important that you try and complete the questionnaires with your child as soon as possible after they are received.

If you haven't completed the questionnaire after our first message, we will give you a reminder after a few days (by phone, text or e-mail based on your preference). If it is not completed after 1 week, or if we have any queries about the information you have already provided, we may call you to ask the questions over the telephone. We will ask you to provide contact details of up to two alternative friends or family members. This will help us contact you, if we are unable to get through. In the event that we are unable to contact you or your alternative contacts, we may contact your GP to collect information about your child's recovery.

We will collect details of your child's health information including relevant medical history and medications, your child's dominant arm, details of their injury and how it occurred, clinic notes, radiographs, pathology reports, questionnaire responses and details of complications related to the injury or treatment.

We are able to offer a $30 voucher after the completion of the final questionnaire to compensate you for costs (i.e. mobile phone data) incurred completing the questionnaires.

5) CAN MY CHILD STOP TAKING PART IN THE STUDY?

Your child can stop taking part in the study at any time. You just need to tell us so. You do not need to tell us the reason why. Leaving the study will not change the level of care they will receive. You can change your mind at any time and can contact the research team using the electronic forms that you receive. If your child leaves the project any 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 personally-identifiable information possible.

6) WHO HAS FUNDED THE STUDY?

The study has been funded by the UK National Institute for Health Research - Health Technology Assessment (reference number 17/18/02).

7) WHO IS INVOLVED WITH THE STUDY?

The University of Oxford in the UK is the sponsor for the study, and the day to day running of the study is being completed by Oxford Trauma, a research group of the Nuffield Department of Rheumatology, Orthopaedics and Musculoskeletal Sciences (NDORMS) at the same University.

The study is running at hospitals in Australia, New Zealand, as well as hospitals throughout the UK.

The Royal Children's Hospital (RCH) in Melbourne led the setup for hospitals in Australia.

8) WHAT WILL BE DONE TO MAKE SURE MY CHILD'S INFORMATION IS CONFIDENTIAL?

The University of Oxford is the data controller for this study. This means that they, as well as study investigators at your treating hospital, are responsible for looking after this information and using it properly.

Your child will be given a unique study identification number which will be used for all of the information we collect from you about your child. Identifiable data is information with personal identifiers attached to it, including name, date of birth, UR number and email address. De-identified data is where we remove all personal identifiers from your child's information, including name, date of birth and email address and replace your child's name with a code.

Your child's identifiable and de-identified data will be entered directly into the study database, including a copy of your signed consent form. Data will be entered into this database by study investigators and yourself, including the questionnaires. This information will be transferred to and stored at The University of Oxford, using a confidential, secure, encrypted web-based system. This means that it is protected as it moves between your computer and the secure data cloud at The University of Oxford.

Data from the questionnaires will also be sent to the study team at your child's treating hospital so their doctor will have full oversight of the data in relation to your child's study participation. Your child's personal data will only be used as explained in this information sheet.

We will use your name and contact details to contact you and/or child about the research study, to make sure that relevant information about the study is recorded for your child's care and to oversee the quality of the study.

Individuals from the University of Oxford, an approved auditor appointed by the RCH Human Research Ethics Committee and regulatory organisations may look at your child's records to check the accuracy of the research study. The only people in the University of Oxford who will have access to identifiable information will be the people required 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.

The University of Oxford and your child's treating hospital will be using information from you, your child and their medical records in order to undertake this study and will use the minimum personally-identifiable information possible (the University of Oxford will not be able to access your child's medical records). We will keep identifiable information, such as your contact details, for 12 months after the study has finished.

De-identified research data and your consent forms containing personal information, will be stored securely at the University of Oxford and your child's treating hospital until the youngest participant in the study reaches 25 years of age. After this time, the consent forms will be securely destroyed.

To advance science, medicine and public health, we may also need to share your child's de-identified data with other ethically approved research projects, biobanks, or medical journals. If we need to do this, we will remove identifying details and give the data a special code number. Only the research team on this project will be able to match your child's name to their code number.

We will put security measures in place to protect your child's data if and when we give it to other people, as mentioned above.

Despite our best efforts, there is a small chance that your child could be re-identified by someone outside of this research project. In the unlikely event that this happens, someone from the research team will contact you. If, at any point, you think that your child may have been re-identified, please let us know.

[FOR RCH SITE ONLY] The RCH and Murdoch Children's Research Institute are research partners. This means that the two organisations will always share research information with each other.

At the end of the research project, we may present the results at conferences. We may also publish the results in medical journals. We will do this in a way that protects your child's privacy.

9) FUTURE RESEARCH USING YOUR INFORMATION

When you agree to take part in a research study, the information about your child's health and care may be provided to researchers running other research studies at the University of Oxford and in other organisations. These organisations may be universities, healthcare organisations or companies involved in health and care research in this country or abroad. Your child's 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. **Your child's data will not be protected by Australian Regulations.**

This information will not identify your child and will not be combined with other information in a way that could identify them. The information will only be used for the purpose of health and care research, and cannot be used to contact them or affect their care. It will not be used to make decisions about future services available to your child, such as insurance.

10) RIGHTS TO ACCESS YOUR INFORMATION

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

You have the right to access and correct the information we collect and store about your child. This is in line with relevant Australian and/or Victorian privacy and other relevant laws. Please contact us if you would like to access this information.

Further information about your rights with respect to your child's personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

You can find out more about how we use your information at www.ScienceStudy.org.

11) WHO HAS APPROVED THE STUDY

In the UK, this study has been reviewed and approved by an independent group of people, called a Research Ethics Committee. The study was approved on 25th March 2019 under reference number 19/NW/0158.

In addition, we have full approval from the Human Research Ethics Committee at The Royal Children's Hospital Melbourne, Australia to conduct this study (HREC 68948). We will provide regular reports to update them on how the study is going.

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

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

13) WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you would like more information about the project, please contact:

SCIENCE Study Study Local Principal Investigator	**UK SCIENCE Study Chief Investigator**
[Local Investigator name]	Professor Daniel Perry
[Site & Location]	Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences University of Oxford, Kadoorie Centre, John Radcliffe Hospital Oxford, UK, OX39DU
[PI Email]	Daniel.Perry@ndorms.ox.ac.uk
[PI Phone Number]	UK Phone 01865 228929

You can contact the Director of Research Ethics & Governance at The Royal Children's Hospital, Melbourne if you:

- have any concerns or complaints about the project
- are worried about your child's rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on 03 9345 6924