Parent/Guardian Information Sheet

Study title:	**SCIENCE**		
Sponsor:	University of Oxford, UK (Starship Child Health in NZ)		
Locality:	Auckland District Health Board Starship Child Health	Ethics committee ref.:	21/NTB/161
NZ Chief investigator:	Dr Nichola Wilson	Contact phone number:	0211441162

You are invited to take part in a study on the treatment of children who have a broken bone in the elbow called an 'epicondyle fracture'. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign a Consent Form electronically. You will be given a copy of both the Participant Information (online and/or on paper) and the Consent Form to keep.

This document is 9 pages long. Please make sure you have read and understood all the pages.

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 New Zealand, 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 it has never been researched.

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.

Your child has got this type of broken bone, and the doctors in your hospital would like to invite your child to take part in the study. You are free to decide whether or not you wish for your child to take part. Your decision will not affect the level of care your child will receive and the team treating you will decide on the best way to treat you child's broken bone. The research team is happy to answer any questions that you may have.

2) WILL THERE BE EXTRA TESTS?

No, there are no additional tests. The study compares two treatments commonly used in New Zealand, Australia and the United Kingdom.

3) ARE THERE ANY RISKS IN TAKING PART?

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 is less reliable, which may lead to an unstable elbow causing pain, stiffness and/or clunking and may rarely need 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.

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 consent form. Older children/adolescents will also be asked to complete an assent form. This shows that they also give their permission.
2. A contact information form so we can contact you about your child's recovery.
3. 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 by text message and/or email on four further 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. We will use a small image in any e-mails that we send to you to let us know when you have opened the e-mail. We will use this information so that we can improve the timing of sending you and other participants information about your participation in this study.

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 contact you to ask the questions over the telephone or by email/text. We are able to offer a $50 voucher at the end of the first year to compensate you for costs (i.e. mobile phone data) incurred completing the questionnaires.

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

You may withdraw your consent for the collection of your information at any time, by informing your doctor or the research team. Leaving the study will not change the level of care they will receive.

If you withdraw your consent, 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. This is to protect the quality of the study. To safeguard your rights, we will use the minimum personally-identifiable information possible.

6) WHO HAS FUNDED THE STUDY?

In the United Kingdom, the study has been funded by the National Institute for Health Research Health Technology Assessment (reference number 17/18/02). New Zealand's involvement in the study is funded by the Starship Foundation.

7) WHO IS INVOLVED WITH THE STUDY?

The University of Oxford in the United Kingdom 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 New Zealand research team is working with Oxford Trauma in the United Kingdom.

The research team is qualified to do this study because they have all the specialties and skills needed. The 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 offer relevant advice, from a lay perspective, on study management.

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

The StarShip Hospital in Auckland led the set up for hospitals in New Zealand. Dr Nichola Wilson is the New Zealand representative on the management group of the SCIENCE study.

8) WHAT WILL HAPPEN TO MY INFORMATION?

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 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. Your identifiable and de-identified information 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, such as the questionnaires sent 6 weeks, 3, 6 and 12

months after injury. 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.

Your data from the questionnaires will also be sent to your study team at the site where you will have consented for the study, in this way your doctor will have full oversight of the data in relation to your study participation. Your personal data will only be used as explained in this information sheet.

All storage will comply with local and/or international data security guidelines. The study will comply with the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 (UK), of which articles 6 & 9 govern the lawful basis for the processing of your personal data. and the New Zealand Privacy Act 2020.

We will use your name, NHI number and contact details to contact you about the research study, and to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

Individuals from the University of Oxford, an approved auditor appointed by the New Zealand Health and Disability Ethics Committee and regulatory organisations may look at your child's 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, your child and/or their medical records. The only people in the University of Oxford who will have access to information that identifies either of 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, NHI number or contact details.

During the study your child's information will be sent from the hospital in New Zealand to The University of Oxford (UK), and from The University of Oxford (UK) to the treating hospital in New Zealand.

The University of Oxford and your 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 about you both, such as your contact details, for 12 months after the study has finished.

De-identified research data and research documents with personal information, such as consent and assent forms, will be stored securely at the University of Oxford and your treating hospital until the youngest participant reaches 26 years old as per the as per New Zealand requirements for studies that include child participants. After this time, the data will be securely destroyed.

Within Aotearoa, Māori data is protected by the same legislation as everyone else's data and therefore falls within the Privacy Act 2020. Māori data is also considered a taonga and is therefore protected by Te Tiriti o Waitangi which is expressed through the data sovereignty principles.

This study has been fully reviewed by the Health & Disability Ethics Committee along with the study data management plan. The plan addresses the Māori data sovereignty principles of Whakapapa; Tika; Manaakitanga; and Mana as they apply to the way in which data is respectfully and with consent, obtained, stored and either destroyed or curated. As outlined we understand that participation in this type of study requires careful consideration. You may wish to discuss the study with your whānau or whakapapa before deciding to be involved. Should you have any concerns regarding appropriate practice/tikanga to address cultural issues arising from your participation in the study please let us know.

9) FUTURE RESEARCH USING YOUR INFORMATION

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. Your 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.

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

You will not get reports or other information about any research that is done using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

10) 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.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. This is in line with relevant New Zealand 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 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, in New Zealand this study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The [insert Committee name] has approved this study. We will provide regular reports to update them on how the study is going.

12) CAN I FIND OUT THE RESULTS OF THE STUDY?

The study is registered on the clinical trial registry, ISRCTN16619778, which can be accessed at this website: http://www.isrctn.com/ISRCTN16619778

The study results will be available to you online 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) WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

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

If you have any questions, concerns or complaints about the study at any stage, you can contact:

SCIENCE Study Local Principal Investigator	**UK SCIENCE Study Chief Investigator**
Nichola Wilson	Professor Daniel Perry
Paediatric Orthopaedic Department, Auckland District Health Board, 2 Park Rd, Grafton, Auckland	Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences University of Oxford, John Radcliffe Hospital Oxford, UK, OX3 9DU
n.wilson@auckland.ac.nz	Daniel.Perry@ndorms.ox.ac.uk
0211441162	UK Phone +441865 228929
	UK Sponsor
	University of Oxford Clinical Trials and Research Governance (CTRG)
	Joint Research Office, Boundary Brook House, Oxford, UK, OX3 7GB
	ctrg@admin.ox.ac.uk
	UK Phone +441865 616480

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Maori health support please contact:

Dr Helen Wihongi – Director of Maori Health Research

Phone: +64 9 486 8920 ext 43204

Email: helen.wihongi@waitematadhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC

Email: hdecs@health.govt.nz

Parent/Guardian Consent Form

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NZ Chief investigator:	Dr Nichola Wilson
Contact phone number:	0211441162

An interpreter is available on request

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
I have been given sufficient time to consider whether or not my child will participate in this study.
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
I understand that my child taking part in this study is voluntary (my choice) and that I may withdraw my child from the study at any time without this affecting your child's medical care.
I consent to the research staff collecting and processing my child's information, including information about their health.
If I decide to withdraw my child from the study, I agree that the information collected about my child up to the point when I withdraw them may continue to be processed.

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my child's relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
I understand that my child's participation in this study is confidential and that no material, which could identify your child personally, will be used in any reports on this study.
I understand the compensation provisions in case of injury during the study.
I know who to contact if I have any questions about the study in general.
I understand my child's responsibilities as a study participant.
I wish to receive a summary of the results from the study.

Declaration by <u>Parent/Guardian</u>

I hereby consent for my child to take part in this study.

Name of Child (please print) _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the parent/guardian of the participant, and have answered the parent/guardian's questions about it.

I believe that the participant's parent/guardian understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____