

A study about children with arm injuries
PATIENT INFORMATION SHEET AND ASSENT FORM
(For patients 7-11 years old)

Study title:	SCIENCE		
Sponsor:	University of Oxford, UK (Starship Child Health in NZ)		
Locality:	Southland Hospital	Ethics committee ref.:	21/NTB/161
NZ Chief investigator:	Dr Nichola Wilson	Contact phone number:	0211441162
Site Principal Investigator:	Dr Pierre Navarre	Contact phone number:	021379764



- **Invitation for children with arm injuries like yours**

We would like you to ask you to help us with our research study.

Please read the information carefully and talk to your mum, dad or carer about the study. Ask us if there is anything that is not clear or if you want to know more. Take time to decide if you want to take part. It is up to you if you want to do this.

- **Why are we doing his study?**

The SCIENCE Study is finding out the best way to treat an elbow injury like yours.



Doctors can treat this injury in two ways but they do not know which is going to be best.

One way is to put your elbow in a plaster cast or splint, and it will heal by itself.

The other way is to fix your elbow in the right position, which means using a screw or a wire to hold you elbow in place. You will be asleep during a small operation when this happens. We will give you medicine to make you sleepy.

- **Do you have to be in this study?**

You don't have to take part if you don't want to. You and your mum and dad or your carer, and whānau should talk about it. If together you decide not to take part, that's OK.

- **Will taking part help you?**

Yes, your injured arm will be repaired or put in plaster to help it heal. We would do this if you were not in the study as part of our usual care of your injury. Being in the study will help us with the care of other children in the future.

- **Will anyone know if you take part in this study?**

Your family and your doctor will know you are taking part. Some people from the study team will also know you are taking part. But no-one else.

You can talk to anyone you want about the study. You can ask any questions you have. But we won't tell anyone else you are taking part.

- **Who will answer your questions about the study?**

If you want to know more ask Mum or Dad or carer as they have some papers with more information about it. Or you can ask the doctor lots of questions.

- **What if there is a problem or something goes wrong?**

Tell us if there is a problem and we will try and sort it out straight away. You and your mum, dad or carer can contact the nurse or doctor looking after you.

Thank you



Assent Form

7 to 11 years olds

Study title (lay): **SCIENCE**

Locality: Southland Hospital

Ethics committee ref.: 21/NTB/161

Lead investigator: Dr Pierre Navarre

Contact phone number: 021379764

Does the child wish to complete an assent form? **YES** **NO**

PLEASE select your answer to the questions below (Yes or No) or have your parent select for you.

- | | YES | NO |
|---|--------------------------|--------------------------|
| • Have you read (or been read to) about the study? | <input type="checkbox"/> | <input type="checkbox"/> |
| • Has somebody else explained the study to you? | <input type="checkbox"/> | <input type="checkbox"/> |
| • Do you understand what this study is about? | <input type="checkbox"/> | <input type="checkbox"/> |
| • Have you asked all the questions you want? | <input type="checkbox"/> | <input type="checkbox"/> |
| • Have you had your questions answered in a way you understand? | <input type="checkbox"/> | <input type="checkbox"/> |
| • Are you happy to take part (you can say no)? | <input type="checkbox"/> | <input type="checkbox"/> |
| • Do you understand it's OK to stop taking part at any time? | <input type="checkbox"/> | <input type="checkbox"/> |

If you **do** want to take part in this study, please write your name and today's date below. If you don't like writing, please ask someone to help you or you could add an X where you need to sign. Someone else can write your name and the date for you.

Your Name _____

Your signature _____

Today's Date _____

Statement of person conducting assent discussion:

- I have explained all aspects of the study to the participant to the best of his or her ability to understand.
- I have answered all the questions from the participant relating to this research.
- The participant agrees to be in the research.
- To the best of my knowledge, the participant's decision to enrol is voluntary.

The study doctor and study staff agree to respect the participant's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Printed name of the person obtaining assent

Signature of the person obtaining assent

Date