



## CRAFFT – Children’s Radius Acute Fracture Fixation Trial. Older Child Information Sheet

### A study about children with arm injuries

We would like to ask you and your family if you would take part in a study called CRAFFT.



#### WHAT IS CRAFFT?

The CRAFFT Study is finding out the best way to treat a broken wrist where the bones have moved out of place - just like yours.

Doctors can treat this injury in two ways but they don’t know which is best.

#### WHY ARE YOU ASKING ME?

Research is done to find out more about something. The CRAFFT Study is a research study. We are asking lots of children in the country who have the same injury as you if they want to take part.

One treatment is to put the arm in a plaster cast for four to six weeks, with the bones resting in their current position. This lets the broken bones grow back into the right position naturally. With this treatment the wrist might not look fully straight for a few months.

The other treatment is to put the bones back in the right position. This means you will take some medicine to make you sleep so you can have an operation or procedure. While you are asleep, a plaster cast, and sometimes also metal plates or wires, will be used to hold the bones in place. After the procedure the arm is put in a plaster cast for four to six weeks.

#### WHAT TREATMENT WILL I GET?

You will get either of the two treatments. Both have the same chance of being chosen. A computer will fairly decide which treatment you are given.

We are doing this study because this is the best way to find out which treatment works best to help children with this injury in future.

## DO I HAVE TO SAY “YES”?

No you don't. If you decide to say no, nobody will mind and you will get the normal care that is done at the hospital that you are in. If you say yes, you can still change your mind.

## WHAT HAPPENS IF I CHANGE MY MIND?

You can change your mind at any time and we will stop contacting you. If you do change your mind, please ask your parents to let your doctor or one of the research team members know.

## WHAT WILL HAPPEN IF I SAY YES?

One of your doctors or nurses will ask you to sign a form called an “Assent Form”. This is just to say that you understand the study and what will happen. Your parent or guardian will be sent a copy of the form to keep.

Your parent or guardian will need to sign a consent form to agree to you taking part as well.

We will ask you to answer some questions about pain and how much you can use your arm. We'll send these four times in the first year and then yearly for another two years to the mobile phone or e-mail address that your family tell us to.

## WHO WILL KNOW I'M IN THIS STUDY?

You will be given a special identification number and any information that you give us will be linked only to this number. This means that only the people who are treating you, or who need to contact you, will know who you really are.

## WHAT DO I DO NOW?

Talk with your family about what you are being asked to do. The doctors and nurses would also be happy to answer questions if you would like them to.

Further details of the study can be on our website [www.CRAFFTstudy.org](http://www.CRAFFTstudy.org)

Thank you for reading this leaflet