Parent/Guardian Information Sheet

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'. About one thousand children sustain this injury in the UK each year. 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 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. 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 the NHS.

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 (Week 6, Month 3, Month 6, Year 1) and annually until your child is fully grown (16 years old). We will ask questions about pain, activities, feelings, hospital attendances, school attendance and costs that you may have incurred in relation to this injury (i.e. days absent from work etc). 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 the questionnaire is not completed, 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 £10 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 can change your mind at any time and can contact the research team using the electronic forms that you receive. 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. 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 National Institute for Health Research Health Technology Assessment (reference number 17/18/02).

7) WHO IS INVOLVED WITH THE STUDY?

The study is the work of children's bone specialists across the UK, with research support from the University of Oxford.

The University of Oxford 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).

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 are involved in the management.

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 and is responsible for looking after your information and using it properly.

We 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. We will keep identifiable information about you both, such as you and your child's contact details, for 12 months after the study has finished.

We will store the de-identified research data and research documents with personal information, such as consent and assent forms, securely at the University of Oxford until the youngest participant reaches 21 years old as per the University requirements for studies that include child participants.

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 an electronic database This information will be transferred to, and stored at the University of Oxford, using a confidential, secure, encrypted web-based system. All storage will comply with local data security guidelines.

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 we explain in this information sheet.

We will collect the NHS number (or CHI number in Scotland or H&C number in Northern Ireland) of your child, which we will store securely for 30 years. This will enable the opportunity to collect long-term information relating to the elbow which are recorded within routine hospital records (i.e. any elbow surgery). Whilst we will collect and store this information, the future use of this information will be subject to future ethical/regulatory approvals.To achieve this, with your consent, we may share your child's NHS/CHI/H&C number with NHS Digital and/or National Services Scotland (NSS) and/or NHS Wales Informatics Services and/or Health & Social Care (HSC) in Northern Ireland (these are official government bodies who will treat this information confidentially). The information we share will be used by NHS Digital/ NSS/ NHS Wales Informatics Services/HSC and other central UK NHS bodies in order to provide us with information about your child's health status.

Your treating hospital will collect information from you, your child and/or your child's medical records for this research study in accordance with our instructions. Your treating hospital will keep identifiable information about you from this study for a minimum of 12 months after the study has finished.

The University of Oxford and your treating hospital will use your name, NHS/CHI 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. Individuals from the University of Oxford 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, NHS number (or CHI number in Scotland/H&C number in Northern Ireland) or contact details.

The lawful basis for the processing of your personal data is governed by the General Data Protection Regulation (GDPR) & Data Protection Act (DPA) 2018 Articles 6 & 9. The University of Oxford will not transfer your personal data to any third countries or international organisations.

If you are concerned about how your personal data is being used, please contact the Chief Investigator/study team at: daniel.perry@ndorms.ox.ac.uk

If you are still not satisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at:

ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/

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.

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.

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?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by Greater Manchester Central Research Ethics Committee.

12) WILL WE BE INFORMED OF 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 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 wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Daniel Perry who is the overall study lead on 01865 223114 or at daniel.perry@ndorms.ox.ac.uk, or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG, email ctrg@admin.ox.ac.uk.

The University of Oxford is the Sponsor for this study and has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial. NHS indemnity covers any other clinical treatment with which you are provided.

For independent advice, please contact NHS Complaints. Ask your treating hospital for the contact details or visit https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/. This is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. However, they cannot provide information about this research study.