



Information about ACTIVE and the General Data Protection Regulations

Sponsor: Hull and East Yorkshire Hospitals NHS Trust **IRAS ID:** 224065

Title: ACTIVE trial about external frame versus internal locking plate for articular pilon fracture fixation

What is the purpose of the General Data Protection Regulations?

The General Data Protection Regulations (GDPR) were introduced on 25 May 2018. Under the GDPR, there is a legal basis for processing personal data we collect about you during research as this is being done in the public interest (schedule 6) and for scientific research purposes (schedule 9). The person whose personal data is being collected, held or processed is called the “data subject”. In the ACTIVE study there are the following data subjects:

- Patients who take part in the trial and who may or may not be interviewed
- Patients who do not take part in the trial but agree to an interview
- Hospital staff who agree to take part in an interview

In ACTIVE there is also a person for which there is a legal basis that he/she can decide whether a patient without capacity to consent should take part in the study. This is in effect until the patient has capacity to decide for themselves or the patient does not gain capacity and is withdrawn from the study. The only data collected on a person who agrees to a patient to take part in the study on their behalf, is their name and relationship to the patient, and will not be referred to further.

Under the GDPR, there is also a “data controller” who determines the purposes and the means of processing your personal data. Then the “processor” who processes your data on behalf of the controller. This is explained further in the following sections. Your data and privacy is very important to us and we want to be transparent about how your data shall be processed. The following expands on what is explained in your study information leaflet about who controls and processes your data if you agree to take part.

Who is responsible for looking after your information?

Hull and East Yorkshire Hospitals NHS Trust is the sponsor for this study and is based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this research and the sponsor will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. On behalf of Hull and East Yorkshire Hospitals NHS Trust, other collaborating institutions will be processing your data and keep identifiable information about you. If you agree to take part in the trial, the University of York Trials Unit who is undertaking the study on behalf of the sponsor will keep paper records on you for a minimum of five years after the study is complete and a minimum of 20 years in electronic format. If you agree to take part in an interview, this will be undertaken by members of the team at Newcastle University where data on you will be kept for a minimum of five years. Both University of York Trials Unit and Newcastle University will keep identifiable data about you (e.g. name and address) for a minimum of five years from the end of the study. A decision will then be made with the sponsor to delete this identifiable data if there is no further clinical need to know who you are and no further research is planned. Participating hospitals will also keep information on you for the purposes of the study for up to five years after the study is complete. All data will be disposed of securely.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. You can withdraw from the study at any time, but we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. To maintain confidentiality we will use a participant ID number to identify you. No identifiable data about you will be presented publically, it will all be anonymised.

Who will look after your information and have access to it?

If you agree to take part in the trial, the University of York will keep your name, contact details and date of birth confidential and will not pass this information to Hull and East Yorkshire Hospitals NHS Trust. The University of York will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Hull and East Yorkshire Hospitals NHS Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Hull and East Yorkshire Hospitals NHS Trust will only receive information without any identifying information. The people who analyse your information will not be able to identify you and will not be able to find out your name or contact details. For anyone who takes part in an interview, it will be Newcastle University who will look after your information and access it as already explained in this leaflet and the other study materials that have been shared with you. Finally participating hospitals at which you are recruited and receive your treatment will also access and look after your information.

How will your data be used for future research?

When you agree to take part in a research study, you will be asked whether the data collected on you 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.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

The information about you will be anonymised before being shared. Where information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

What to do if there is a problem?

If you wish to raise a complaint about how your data has been handled, you can contact the Trial Manager (Dr Stephen Brealey, telephone: +44(0)1904 321357 email: stephen.brealey@york.ac.uk) who will investigate the matter with the Sponsor and our Data Protection Officer. If you are not satisfied with our response or believe we are processing your data in a way that is not lawful you can complain to the Information Commissioner's Office.