General Data Protection Regulation (GDPR) Participant Information

POst Stroke Intervention Trial In Fatigue. The POSITIF Trial

The EU General Data Protection Regulation (GDPR), along with the new UK Data Protection Act, will govern the processing (holding or use) of personal data in the UK.

You are receiving this as you have indicated that you would like to participate in the POSITIF trial. The information below details what data is held about you and who holds or stores this data.

The University of Edinburgh and NHS Lothian are the co-sponsors for this study based in [the United Kingdom. We will use information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The co-sponsors will keep identifiable information about you.

As a University we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. 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. If you withdraw from the study, 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.

Providing personal data directly e.g. verbally, in a questionnaire or from your care provider

The Edinburgh Clinical Trials Unit (ECTU) will keep your name, Community Health Index (CHI) number and contact details confidential and will not pass this information to the co-sponsors. ECTU 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 the co-sponsor organisation and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The Co-sponsor organisation will only receive information without any identifying information. The statisticians or people who analyse the information will not be able to identify you and will not be able to find out your name, CHI number or contact details.

For the purpose of monitoring the quality of the advice you were given during the study, for research purposes, ECTU will allow independent clinicians access to the recordings of some of the telephone calls conducted between participants and the research nurses. During the research study the independent clinicians may access personal data or other identifiable personal data or clinical information held in the ECTU database. Agreements will be entered in into with the independent clinicians to ensure compliance with data protection legislation and to ensure that your personal data remains confidential.

ECTU will keep identifiable information about you from this study for 10 years after the study has finished.

Use of data for future research

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.

Contact for further information

You can find out more about how we use your information and our legal basis for doing so in our Privacy Notice at www.accord.scot.

For further information on the use of personal data by NHS sites, please link to the Health Research Authority (HRA) website; https://www.hra.nhs.uk/information-about-patients/.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/.

Data Protection Officer contact information:

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