TO BE PRINTED ON LOCAL TRUST HEADED PAPER

GDPR Addendum to the Participant Information Sheet

Version 1.0, 03-Dec-2018

Study Title: Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease; The STOP-ACEi Trial.

Study IRAS Number: 138827

Introduction

This Addendum to the STOP-ACEi Participant Information Sheet, which you have already received, provides new information following the introduction of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 on 25 May 2018. The new information is as follows.

Additional information

Hull and East Yorkshire Hospitals NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and 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. As a NHS organisation 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.

Hull and East Yorkshire Hospitals NHS Trust will keep identifiable information about you for up to 25 years after the study has finished.

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.

You can find out more about how we use your information at https://www.hey.nhs.uk/privacy/data-protection/.

<Insert Trust name> will collect information from you and/or your medical records for this research study in accordance with our instructions.

<Insert Trust name> will use your name, NHS number and contact details 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. Individuals from Hull & East Yorkshire Hospitals NHS Trust, the University of Birmingham and regulatory organisations may look at your medical and research records to check the accuracy of the research study. <Insert Trust name> will pass these details to Hull & East Yorkshire Hospitals NHS Trust and the University of Birmingham along with the information collected

from you and your medical records. The only people in Hull & East Yorkshire Hospitals NHS Trust or the University of Birmingham who will have access to information that identifies you will be people who are involved in this research project or audit the data collection process.

<Insert Trust name> will keep identifiable information about you from this study for up to 25 years after the study has finished.

The information that will be provided to the Sponsor and other organisations involved in this research is specified in the Participant Information Sheet. All other aspects of the Participant Information Sheet, which you have already consented to, will remain in effect.

Hull & East Yorkshire Hospitals NHS Trust will collect information about you for this research study from your NHS medical records. This information will include your name and health information. When you joined the study, you may have also chosen to provide your NHS number. These details are regarded as a special category of information. We will use this information to check the research is being done correctly and, if you have provided additional optional details, to use your centrally held electronic NHS records in further research after this research project has ended.

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.

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.

Where this 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.

Where can I get further information?

For queries about the study or for further information, please contact:

<Insert local PI name>, Tel: <insert local PI contact details>, STOP-ACEi Principal Local Investigator

Professor Sunil Bhandari, Tel: 01482 674566, STOP-ACEi Chief Investigator

The STOP-ACEi trial co-ordinating centre is located at the Birmingham Clinical Trials Unit, Institute of Applied Health Research, Public Health Building, University of Birmingham, Edgbaston, Birmingham B15 2TT. Tel: 0121 415 9130, Fax: 0121 415 9135, Web address: www.birmingham.ac.uk/stopacei. Email: stopacei@trials.bham.ac.uk.

Please keep a copy of this addendum with the Participant Information Sheet and the signed consent form for the study.

Original to be kept in the Investigator Site File, 1 copy in the hospital notes, 1 copy to the patient.