Data Protection Information Sheet

Feasibility and design of a trial to determine the optimal mode of delivery in women presenting in preterm labour or with planned preterm delivery: CASSAVA

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

You are receiving this as you are considering being a participant on this clinical research study. The information below details what data will be held about you and who will hold or store this.

The University of Edinburgh and NHS Lothian are the co-sponsors for this study based in the United Kingdom. We will use information provided by you 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 for 3 years after the study has finished

As a University and 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. 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

We do ask you for information which may directly identifying you (e.g. name, address, phone number, email address) and some demographic data which can indirectly identified you (e.g. ethnicity, gender, occupation, workplace and department). This information is recorded, only if you provide on the survey(s) or forms provided to you by the researchers.

We will use your name, contact details postcode, email address and telephone number provided to contact you about the research study, and make sure that relevant information about the study is recorded for your responses, and to oversee the quality of the study.

Individuals from co-sponsors and regulatory organisations may look at your research records to check the accuracy of the research study. The Research team will pass these details to co-sponsors along with the information collected from you. The only people in co-sponsors who will have access to information that identifies you will be people who need to contact you to regarding your participation 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, or contact details.

The research team will keep identifiable information about you from this study for 3 years after the study has finished.

Use of data for future research

When you agree to take part in a research study, the information provided may be shared with other 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.

Information which is shared will be anonymised (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.

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 healthcare 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 and/ or the sponsor.

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 and on the University of Edinburgh Website https://www.ed.ac.uk/records-management/privacy-notice-research

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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