Leaflet to be sent to sites for all subjects consented prior to new versions of GDPR PIS’ being released

TOXYC Trial

The General Data Protection Regulation (GDPR), came into force on 25th May 2018, As you are a patient in a trial consented prior to study documentation being amended to reflect this change, we have put together a leaflet to inform you of issues you need to be aware of in light of this new regulation.

This leaflet contains information on how we will use your data, who will have access to your data, and for how long we will store your information. For further information on the specific data we collect and use, please refer to the trial specific text on the following page. You can also visit www.ucl.ac.uk/situ and select the GDPR tab or contact situ.trials@ucl.ac.uk.

UCL is the sponsor for the study based in the United Kingdom. We will be using information from you and your medical records in order to undertake the study, UCL will act as the data controller for this study. This means that UCL is responsible for looking after your information and using it properly. UCL will keep identifiable information about you for a number of years after the study has finished. For more information about this, please refer to the SITU site or GDPR tab.

UCL will collect information about you for research purposes from the trial centre (study site) you are part of. This information may include personal information including; your name, NHS number, contact details, other identifiers that may be specific for the trial you are part of, and health information, which is regarded as a special category of information. We will use this information in accordance with our instructions for the trial.

The trial centre (study site) 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 UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The trial centre (study site) will pass these details to UCL along with the other personal information collected. The only people in UCL who will have access to information that identifies you will be people who need to contact you 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 contact details or any other personally identifiable information.
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 amount of personally-identifiable information possible.

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.

If you have any concerns or queries, you can find out more about how we use your information at www.ucl.ac.uk/situ and select the GDPR tab or contact situ.trials@ucl.ac.uk.

**Study Specifics**

**TOXYC:** A randomised controlled trial of targeted oxygen therapy in mechanically ventilated critically ill patients - a feasibility study

The TOXYC Trial holds your data for 5 years after study completion.