**Management and Outcomes of Perioperative Care among European Diabetic Patients: (MOPED): A prospective observational, international cohort study**

***Dear Patient,***

We invite you to participate in a study of the care of patients with diabetes who undergo surgery. We are asking permission to collect some information about your operation and about your diabetes care before, during and after surgery. We will not make any changes to your care as part of this study.

Before deciding whether to take part, please read the following information leaflet carefully. A member of the local research team will talk about the study with you and answer your questions. Participation in the study is voluntary. If you choose not to take part or withdraw your consent later on, this will have no impact on the care that you receive.

## Why is this study being carried out?

At present, healthcare professionals across Europe, including the UK, have varying approaches to how they look after patients who have diabetes around the time of surgery. This study aims to look at the care of diabetes in patients having surgical operations and how patients with diabetes recover after surgery. The study looks at care before, during, and for the first 30 days after surgery. The results will help to identify the best ways to look after patients with diabetes who are undergoing surgery in the future. We hope to include at least 5,000 patients from all over Europe.

## How is the study carried out?

If you decide to take part in the study, your participation will last from the time of surgery until 30 days after the surgery. Your study participation will involve:

* Reading this information sheet and signing a consent form
* The research team at your hospital will collect information from your medical records on your age, sex, medical conditions, diabetes, your operation, and glucose control.
* The research team at your hospital may ask you to complete to a short questionnaire about your overall well-being called the Quality of Recovery (QoR-15) scale. Only patients still in hospital the day after their surgery will be asked to do this.
* A member of the local research team will telephone you 30 days after your surgery if you have been discharged from hospital. They will ask you how you have been and how many days you have been at home since your surgery. This short interview will take less than five minutes

The research team at your hospital will collect information from your medical records for up to 30 days after your operation if you remain in hospital. This will include information on your diabetes care and whether you experienced any complications of surgery during or after your hospital stay.

## What are the possible benefits of taking part?

Participation in the study will not necessarily benefit you during your hospital stay. The information we get from this study will improve our understanding of how patients with diabetes are looked after during anaesthesia and surgery and how they get on for the first 30 days afterwards. This might lead to improvements in care in the future. A link to the main publication from the study will be made available on the European Society of Anaesthesiology and Intensive Care website at: www.esaic.org/research/clinical-trial-network/completed-trials/

## What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks. However, as explained above, we will call you via telephone 30 days after your surgery if you have been discharged from hospital, for a standardised interview which takes less than five minutes.

## What is expected from me?

The information which we hope to get from the short telephone interview 30 days after surgery is an important part of the study. If your contact details change before we have got in touch with you, please inform us using the details below.

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical study as a result of negligence on the part of a member of the study team this liability cover would apply.

## Is it possible to withdraw from the study during its course?

You are under no obligation to take part and declining to be involved will not affect the care you receive. If you agree to participate but then change your mind, you are still free to withdraw at any point and this will not affect the care you receive. If you decide to withdraw from the study, no further data will be collected. However, data that has been collected and encoded (identified by a number) up to this point will remain encoded and be used in subsequent analyses. Please talk to your local investigator if you decide to opt out.

***Who is organising and funding the study?***

This is an international study that is being conducted with the support of the European Society of Anaesthesiology and Intensive Care (ESAIC). The Chief Investigator of the study is Professor Donal Buggy of University College Dublin and the study team has members from European Countries including the UK. The UK Lead Investigator is Dr Simon Howell of the University of Leeds. The ESAIC is providing infrastructure support for the study including administrative support, providing the study database, and supporting study meetings. The British Journal of Anaesthesia, Royal College of Anaesthetists and College of Anaesthetists of Ireland had awarded a grant to support the study in the UK and Ireland. The University of Leeds is acting as the UK sponsor for the study.

The study protocol has been reviewed by the European Society of Anaesthesiology and Intensive Care prior to adoption as an ESAIC study, by the UK National Institute of Anaesthesia and the College of Anaesthetists of Ireland as part of the grant awarding process, and by the NHS Research Ethics Committee.

## Information about data protection

The benefit of this study will be to develop scientifically founded recommendations for anaesthesiologists caring for diabetic patients having surgery. The data collected include your chronic health conditions, your current health status, your treatment, the results of examinations required by the study protocol, and your ethnicity. We expect that the results of the study will benefit future patient and lead to wider public health benefits.

Records of personal data collected by the local research team for this study will not be sent outside of the local hospital. This includes your name address, date of birth, telephone number and NHS or hospital number. People will use this information to do the research or to check your records to make sure that the research is being done properly. ‘Everything you say/report is confidential unless you tell us something that indicates you or someone else is at risk of harm. We would discuss this with you before telling anyone else.’

No personal data will be sent outside the hospital where you have your operation. The medical data collected for the study will be entered into an electronic database using a code number, so that members of the study team outside of the hospital will not know your identity. The study database will be run and maintained by ESAIC. The database will not contain any personal details that would allow you to be identified. The data will be shared with, Regulatory Authorities, and to third parties acting on their behalf if required.

The University of Leeds and the ESAIC are acting as joint Data Controllers for this study, therefore they are responsible for looking after your data and using it properly by respecting your rights. Contact details for the University of Leeds and ESAIC Data Protection Officers and to the University of Leeds information governance webpages are given below. You can also speak to the with the research team at your hospital who can direct your questions to the University of Leeds or the ESAIC. You should be aware that contacting any external body carries the risk of you losing your anonymity.

The MOPED local study data will be kept for at least ten years. The data will be stored securely, and your personal data will remain at your local hospital and be stored separately from the medical data collected for the study. All the coded data relating to the study in the ESAIC Central database will be stored electronically for at least 10 years. At the end of this period, the data will be destroyed.

At the end of the study your data might be shared with research teams in other organisations for further research, subject to appropriate approvals. These organisations may be within the UK, the European Economic Area (EEA) or outside the EEA. In this case no personal identifiable data will be shared. If your data is transferred outside of the EU, ESAIC is responsible for protecting your personal data and will ensure that adequate safeguards are in place.

What are your choices about how your information is used?

* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.
* If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

You can find out more about how we use your information as follows:

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
* <https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/02/Research-Privacy-Notice.pdf>.
* by asking one of the research team
* by contacting the University of Leeds data protection officer on dpo@leeds.ac.uk
* by contacting the ESAIC data protection officer on privacy@esaic.org- more information can be found here: https://www.esaic.org/uploads/2023/04/information-about-data-protection-uk-1.pdf

***Complaints***

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should contact the Local Trust Research Team or the Patient Advice and Liaison Service (PALS) at the Trust. Contact details are given at the end of this letter. The United Kingdom local sponsor of MOPED is the University of Leeds. The sponsor representative can be contacted on governance-ethics@leeds.ac.uk to raise concerns outside the Trust.

Any questions concerning the study should be addressed to:

Hospital Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Telephone:\_\_\_\_\_\_\_\_

Research Team Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Telephone:\_\_\_\_\_\_\_\_

If you have any questions related to your rights as a study participant, you can contact the local R&D office at:

The Local Trust Patient Advice and Liaison Service (PALS) Office can be contacted at:

Dr Simon Howell
Associate Professor of Anaesthesia, University of Leeds
UK Lead Investigator for the MOPED Study
On behalf of the MOPED Study Steering Committee and UK Local Investigators