Diversity in Perioperative Research Study (PROTECT-DIVERSITY)

PARTICIPANT INFORMATION SHEET

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Principal Investigator: [insert PI name]

IRAS: 350756

As part of the PROTECT programme, you are being invited to take part in the PROTECT-DIVERSITY research study, intended to improve the care of patients having an operation. Before you decide whether to take part, it is important to understand why this research is being done and what it involves. Please take time to read the following information. Talk to your friends and family about the study if you wish and ask us if anything is unclear.

Why are we doing this research?

We are doing this study to check whether consent forms in several different languages can improve access to research for patients having surgery. We will also compare the accuracy and completeness of diversity (protected characteristics) data collection using different methods such as in your medical records, as part of questionnaires and by asking you questions.

Why have I been invited?

You have been invited because you are going to have surgery and are taking part in a study where your demographic information will be collected. You may be invited to take part in other PROTECT platform studies if you are eligible.

Do I have to take part?

No. It is up to you to decide whether or not you would like to take part in the study. If you decide to take part, you will be asked to sign a consent form. 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. If you decide not to take part, or later to withdraw, this will not affect any part of the care you receive.

What would taking part involve?

We will ask you to consent to be a part of the PROTECT Trial. The consent materials will either be in a traditional paper format or an electronic format, and presented at random in multiple languages. Information such as sex, ethnicity, partnership status, disability,

pregnancy status, religion, sexual orientation and gender and gender identity will be collected from you as part of the PROTECT trial, and you can refuse to answer any questions if you do not want to. We will use this information to see what method of data collection accurately captures diversity data in clinical trials.

What will happen if I don't want to carry on with the study?

If you decide not to take part, or later to withdraw, this will not affect any aspects of the care you receive. You are free to stop taking part at any time without giving a reason. If you decide to withdraw from the PROTECT-DIVERSITY study, you will remain part of the PROTECT platform, unless you tell us otherwise. Please refer to the PROTECT platform Participant Information Sheet under section 'What will happen if I don't want to carry on with the study?'.

What are the possible benefits of taking part?

The information we collect may improve how we collect diversity information for patients taking part in clinical trials.

What are the possible disadvantages or risks of taking part?

There are no disadvantages in taking part in this study, only information available to us will be collected.

How will my information be used?

You can find out how we will use your information by referring to the relevant sections in the PROTECT Participant information sheet which will be provided to you alongside this document.

Who is funding the research?

The study is funded by the British Journal of Anaesthesia and the Academy of Medical Sciences.

What will happen to the results of this study?

Once the study is complete, we will prepare and publish a scientific report. The results will be available to the hospitals that took part in the study. We may share information relating to the study in scientific meetings and it may be published in scientific journals. The results including a plain English summary of the findings will be published on the PROTECT website and you will be able to request a copy by contacting the study team via email: protect-admin@qmul.ac.uk

Further Information

Further information will also be available on the study website: https://www.qmul.ac.uk/protect/studies/diversity

Thank you for taking time to read this information sheet.

Your study doctor is:	
Name:	Contact phone number:
Your research/specialist nurse is:	
Name:	Contact phone number: