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Improving diversity in clinical research for patients undergoing surgery (PROTECT-DIVERSITY)

Submission date 26/11/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/12/2025	**Overall study status** Ongoing	
Last Edited 05/08/2026	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
The lack of diversity in clinical trials is an important issue, which limits external validity. 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 data collection using different methods such as in your medical records, as part of questionnaires and by asking participants questions.

Who can participate?
Adults aged 18 years and over undergoing elective surgery.

What does the study involve?
Patients will be asked to consent to be 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, gender and gender identity will be collected as part of the PROTECT trial, and patients can refuse to answer any questions they do not want to.

What are the possible benefits and risks of participating?
The information collected may improve how we collect diversity information for patients taking part in clinical trials in the future. There are no disadvantages to taking part in this study.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
The study is starting in December 2025 and will run for 2 years.

Who is funding the study?
The British Journal of Anaesthesia and the Academy of Medical Sciences

Who is the main contact?
Dr Tom Abbott, protect-admin@qmul.ac.uk

Contact information

Type(s)
Scientific, Public, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
350756

Central Portfolio Management System (CPMS)
65329

Grant Code
WKR0-2023-0016

Study information

Scientific Title
Diversity in perioperative research

Acronym
PROTECT-DIVERSITY

Study objectives
1. Compare the impact of using multi-lingual consent forms with consent forms in English on the ethnic diversity of patients included in the study.
2. Compare the accuracy and completeness of protected characteristics data collection using different methods.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 10/02/2025, London – South East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8222; londonsoutheast.rec@hra.nhs.uk), ref: 24/LO/0887

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Single

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Adult patients undergoing elective surgery

Interventions
Current interventions, as of 05/08/2026:

The master protocol is registered at https://www.isrctn.com/ISRCTN14639555

The method of informed consent will use either an electronic or paper method, which is consistent with the master protocol. For this comparison, the language of the consent form materials will be determined at random before approaching the patient, which includes consent for entry into the platform. Since the intervention in question is the process of consent, it will not be possible to obtain consent before the 'intervention' i.e. the consent process. In this case, there will be a waiver of consent to randomise to intervention or usual care (multi-lingual consent materials vs. english consent materials). After randomisation, the patient will complete the consent process using either multi-lingual consent documents or consent documents in English, according to group allocation. This process supersedes the procedure for timing of informed consent detailed in the master protocol section nine, which will apply to consent for inclusion in the platform (master protocol) and this comparison. Electronic consent materials will be translated into Polish, Romania, Panjabi, Urdu, Portuguese and Bengali. Translations will be undertaken by an approved/certified provider

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Previous interventions:

The master protocol is registered at https://www.isrctn.com/ISRCTN14639555

The method of informed consent will use either an electronic or paper method, which is consistent with the master protocol. For this comparison, the mode of consent (electronic or paper) will be determined at random before approaching the patient, which includes consent for entry into the platform. Since the intervention in question is the process of consent, it will not be possible to obtain consent before the 'intervention' i.e. the consent process. In this case, there will be a waiver of consent to randomise to intervention or usual care (electronic consent or paper consent). After randomisation, the patient will complete the consent process using either electronic multi-lingual consent documents or paper consent documents in English, according to group allocation. This process supersedes the procedure for timing of informed consent detailed in the master protocol section nine, which will apply to consent for inclusion in the platform (master protocol) and this comparison. Electronic consent materials will be translated into Polish, Romania, Panjabi, Urdu and Portuguese, which are the five most common languages for people where English/Welsh is not their first language. Translations will be undertaken by an approved/certified provider

Intervention Type
Other

Primary outcome(s)
Reciprocal diversity index for ethnicity on a scale of 0 to 100 at end of trial

Key secondary outcome(s)
1. Completeness of data collection for protected characteristics at trial end
2. Degree of agreement for protected characteristics data between data collection modalities at trial end

Completion date
01/08/2028

Eligibility

Key inclusion criteria
1. Patients aged 18 years and over undergoing elective surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Inability to provide informed consent
2. Co-enrolment in PROTECT CTIMP comparisons
3. Previous enrolment to the PROTECT-DIVERSITY comparison

Date of first enrolment
06/03/2026

Date of final enrolment
01/08/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type

Government

Funder Name
British Journal of Anaesthesia

Alternative Name(s)
British Journal of Anaesthesia Ltd, BJA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Consent form	19/06/2025	01/12/2025	No	No

Other files	Protocol appendix version 4.0	18/06/2026	05/08/2026	No	No
Participant information sheet	version 3.0	18/06/2026	05/08/2026	No	Yes
Protocol file	version 3.0	19/06/2025	01/12/2025	No	No