Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
PROTECT-DIVERSITY

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Ionising Radiation for combined review of clinical trial of an investigational medicinal product

( ) Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device

( ) Clinical investigation or other study of a medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

(●) Other study

2a. Will the study involve the use of any medical device without a UKCA/CE UKNI/CE Mark, or a UKCA/CE UKNI/CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No

b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No

c) Will you be using existing human tissue samples (or other human biological samples)? ◯ Yes ◉ No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- ☑ England
- ☑ Scotland
- ☐ Wales
- ☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ◉ England
- ◯ Scotland
- ◯ Wales
- ◯ Northern Ireland
- ◯ This study does not involve the NHS

4. Which applications do you require?

- ☑ IRAS Form
- ☐ Confidentiality Advisory Group (CAG)
- ☐ HM Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

◯ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ◯ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out the research, e.g. NHS support costs) for this study provided by an NIHR Biomedical Research Centre, NIHR Applied Research Collaboration, NIHR Patient Safety Research Collaboration, or an NIHR HealthTech Research Centre in all study sites?

Please see information button for further details.

◯ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Research Delivery Network (RDN) Support and inclusion in the NIHR RDN Portfolio?

Please see information button for further details.

◉ Yes ◯ No

The NIHR Research Delivery Network (RDN) enables the health and care system to attract, optimise and deliver research across England e.g. by supporting the successful delivery of high-quality research, as an active partner in the research system.

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR RDN.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Other research

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
PROTECT-DIVERSITY

Please complete these details after you have booked the REC application for review.

REC Name:
London - City & East Research Ethics Committee

REC Reference Number:
24/LO/0887

Submission date:
18/11/2024

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Diversity in perioperative research

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Tom	Abbott
Post	Clinical Senior Lecturer		
Qualifications	MA PhD MRCP FRCA FHEA		
ORCID ID	0000 0002 8664 3001		
Employer	Queen Mary University of London		
Work Address	Royal London Hospital Adult Critical Care Research office London		
Post Code	E1 1FR		
Work E-mail	t.abbott@qmul.ac.uk		
* Personal E-mail	t.abbott@qmul.ac.uk		
Work Telephone	02035940348		
* Personal Telephone/Mobile	02035940348		

Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Dr	Mays	Jawad
Address	Queen Mary University of London		
	Joint Research Management Office, Dept W		
	69-89 Mile End Road London		
Post Code	E1 4UJ		
E-mail	research.governance@qmul.ac.uk		
Telephone	+44 (0) 20 7882 7275/6574		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	
Sponsor's/protocol number:	1.0
Protocol Version:	1.0
Protocol Date:	
Funder's reference number (enter the reference number or state not applicable):	n/a
Project website:	www.protectresearch.org

Registry reference number(s):
The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):
ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

(●) Yes ( ) No

Please give brief details and reference numbers.
This appendix is part of the PROTECT platform trial under IRAS 1008776

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Data efficient platform trials offering an opportunity to increase access to research and remove barriers in participation, thereby improving the diversity of patient participation. However, we don't know whether firstly, patient information and consent forms in electronic format and in multiple languages, or secondly, protected characteristics (diversity) data collected using Hospital Episode Statistics or traditional methods like patient questionnaires or direct questioning are suitable for surgical patients speaking different languages.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Perioperative trials are poorly representative of society. It is not possible to test an intervention in the entire population. Instead, clinical trials sample a sub-set of the population and extrapolate findings to other patients. This paradigm relies on unbiased sampling according to specified inclusion/exclusion criteria. However, reporting of key diversity characteristics, like ethnicity and socioeconomic status, is limited and clinical trial results are unlikely to be generalisable to the full population. During the COVID-19 pandemic a systematic review found that only 2% of clinicals trials reported ethnicity. In perioperative medicine, one third of trials reported ethnicity and over 96% reported sex. However, less than half analysed the results according to sex and only 4% considered ethnicity. Patients say that barriers include burdensome follow-up and consent processes, which are often only written in English.

The lack diversity in clinical trials is an important issue, which limits external validity. Trial samples are commonly biased by protected characteristics, including age, sex, ethnicity and socioeconomic status. Ethnic minorities are poorly represented in trials, despite comprising 12.5% of the UK population. In perioperative trials, ethnicity is reported in only 33% of cases. While 98% of clinical trials report sex, only one third report the primary outcome by sex, limiting the relevance of trial results to both sexes.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☑ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☐ Questionnaire, interview or observation study

- [x] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

(a) Compare the impact of using electronic multi-lingual consent forms compared to paper consent forms in English on the ethnic diversity of patients included in the study.

(b) Compare the accuracy and completeness of protected characteristics data collection (age, sex, ethnicity, partner status, disability, pregnancy status, religion, sexual orientation and gender reassignment) using different methods (HES, electronic questionnaires, direct questioning).

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

N/a

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

The lack diversity in clinical trials is an important issue, which limits external validity. Trial samples are commonly biased by protected characteristics, including age, sex, ethnicity and socioeconomic status. Ethnic minorities are poorly represented in trials, despite comprising 12.5% of the UK population. In perioperative trials, ethnicity is reported in only 33% of cases. While 98% of clinical trials report sex, only one third report the primary outcome by sex, limiting the relevance of trial results to both sexes.

Data efficient platform trials offering an opportunity to increase access to research and remove barriers in participation, thereby improving the diversity of patient participation. However, we don't know whether firstly, patient information and consent forms in electronic format and in multiple languages, or secondly, protected characteristics (diversity) data collected using HES or traditional methods like patient questionnaires or direct questioning are suitable for surgical patients speaking different languages.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

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 .

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Evidence suggests that clinical trials are poorly representative of society and that the results of clinical trials may not be widely applicable to all patients. Our patient panel highlighted this as a particular cause for concern and were highly supportive of research to understand and improve diversity within clinical trials. Our patient representatives welcomed the use of routinely collected NHS data and patient questionnaires administered via text message or email to collected follow-up data and reduce the burden of patient visits for clinical trials.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [x] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

• Patients aged 18 years and over undergoing elective surgery

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

- Inability to provide informed consent
- Co-enrolment in PROTECT CTIMP comparisons
- Previous enrolment to the PROTECT-DIVERSITY comparison

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
ELigibility	1	0	10	Delegated member of the research team
Randomisation	1	0	10	Delegated member of the research team
Informed consent	1	0	10	Delegated member of the research team
Demographics	2	1	10	Delegated member of the research team
Review of medical notes	2	2	10	Delegated member of the research team
Follow up	1	0	10	Delegated member of the research team

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
n/a				

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

○ Yes ◉ No

A21. How long do you expect each participant to be in the study in total?

The trial will end for the patient after their surgery is complete.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

This is a very low-risk study. There will be no change to clinical care. The intervention under investigation is the mode of consent for research.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

A24. What is the potential for benefit to research participants?

There are no direct benefit in taking part in this research study but patients will help design future research which is representative of the needs of our patient population.

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? *May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.*

There will be no continued provision of intervention after the research has finished.

A26. What are the potential risks for the researchers themselves? *(if any)*

There are no risks to the researcher.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Potentially eligible participants will be screened by the direct care team for entry into the study in accordance with the PROTECT master protocol. Research delivery staff embedded within NHS trusts should be regarded as part of the direct care team. Research is a routine part of effective healthcare and will be subject to the same information governance requirements in this respect. Research delivery staff will therefore be able to screen operating theatre lists, electronic patient records, etc for eligible patients.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:
Only delegated members considered to be part of the direct care team will have access to patient information.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Potential participants will be approached by a delegated member of the research team.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

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.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Where possible all participants will be given a minimum of 24 hours between the time they are approached about the trial and the time when consent is given.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

◉ Yes
○ No
○ Not Known

If Yes, please give details and justify their inclusion. If Not Known, what steps will you take to find out?

In accordance with the eligibility criteria for the trial.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

If a participant is unable to read or sign the informed consent form but has capacity to give consent, this can be provided on the participant's behalf by a witness. A statement will be included in the consent form explaining that the participant understood the information and informed consent was given freely.

If translation of consent materials is required this will be done via the recruiting site's interpreting service, which may be an in-person interpreter, or a video/telephone interpreter service (e.g. Language Line). The details of the interpreter should be recorded on the consent form and in the participant's medical record, in addition to the standard record of the consent process. The use of friends or family members for translation of consent materials is prohibited. We will develop non-English ICF and PIS as we learn more about those most in demand for the PROTECT eligible patient population

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

A participant will be required to reconsent if there is new information available that is relevant to the study.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ◉ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☑ NHS computers

- ☐ Social Care Service computers
- ☐ Home or other personal computers
- ☑ University computers
- ☐ Private company computers
- ☐ Laptop computers

Further details:

A37. Please describe the physical security arrangements for storage of personal data during the study?

Any personal data will be stored in NHS or University computers that are password and user access limited.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

The CI will ensure that all participating partner organisations will maintain the confidentiality of all subject data and will not reproduce or disclose any information by which subjects could be identified, other than reporting of SAE, if applicable. Information regarding study participants will be kept confidential and managed in accordance with the Data Protection Act (2018), the UK Policy Framework for Health and Social Care and REC. All study data will be stored in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments and the Data Protection Act. Study data will be archived in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and all subsequent amendments, and as defined in the Sponsor SOP for archiving.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Delegated members of the research team who are considered to be part of the direct care team will have access to the patients personal data during the study. Direct access will also be granted to authorised representatives from the Sponsor, host institution, and the regulatory authorities to permit study-related monitoring, audits, and inspections.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Data will be generated at NHS sites and processed at Queen Mary University of London and Swansea University in accordance with the master protocol. This will be analysed by a delegated member of the research team such as statistician.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Tom	Abbott
Post	Clinical Senior Lecturer		
Qualifications	MA PhD MRCP FRCA FHEA		
Work Address	Royal London Hospital		
	Adult Critical Care Unit Research		
	London		
Post Code	E1 1FR		
Work Email	t.abbott@qmul.ac.uk		
Work Telephone	02035940348		
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ◉ Over 3 years

If longer than 12 months, please justify:
According to Sponsor's archiving policy, personal data will be stored for 5 years.

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

Sponsor's archiving policies will be followed.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

(●) Yes ( ) No

Please give details, or justify if not registering the research.
The study will be registered on ISRCTN.

Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [ ] Internal report
- [ ] Conference presentation
- [x] Publication on website
- [ ] Other publication
- [x] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [ ] Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

No identifiable information or data will be used to report the results of the study. Only pseudonymised data will be used to analyse the results of the study

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
The results will be published in publicly available registers (ISRCTN) and on the HRA website.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [x] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [ ] Review within the Chief Investigator's institution or host organisation
- [ ] Review within the research team
- [ ] Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The research was peer-reviewed by independent members as part of the grant application process.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

☐ Review by independent statistician commissioned by funder or sponsor
☐ Other review by independent statistician
☐ Review by company statistician
☑ Review by a statistician within the Chief Investigator's institution
☐ Review by a statistician within the research team or multi−centre group
☐ Review by educational supervisor
☐ Other review by individual with relevant statistical expertise
☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Kamran	Khan
Department	William Harvey Research Institute		
Institution	Queen Mary University of London		
Work Address	Critical Care and Perioperative Medicine Research Group		
	Adult Critical Care Research Unit 4th Floor		
	London		
Post Code	E1 1FR		
Telephone	020 3594 0348		
Fax			
Mobile			
E-mail	k.khan@qmul.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

Reciprocal diversity index for ethnicity on a scale of 0 to 100.

A58. What are the secondary outcome measures? *(if any)*

o Completeness of data collection for protected characteristics.
o Degree of agreement for protected characteristics data between data collection modalities.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	532
Total international sample size (including UK):	532
Total in European Economic Area:	0

Further details:

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

A total sample size of 250 participants will give 99% power to detect a difference in RDI of 1.0 from a population mean value of 5.14, and 94% power to detect a difference in proportion recruited from 0.2 to 0.4, assuming a type one error rate of 5%.

A61. Will participants be allocated to groups at random?

(●) Yes ( ) No

If yes, please give details of the intended method of randomisation:
Randomisation will occur immediately prior to the approach for informed consent. Participants will be randomised 1:1 to electronic or paper consent using block randomisation with randomly permuted blocks of four participants.
The code creating the randomisation sequence will be prepared by the statistician for this comparison. The allocation sequence will be concealed using sealed envelopes, which will be prepared for each participating site by the statistician for this comparison.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The primary analysis will use a two-tailed t-test for difference in mean RDI and confidence interval, presented using heat maps and/or bar charts. Secondary outcome data will be presented as n (%) stratified by data collection modality. Completeness of data collection will be tested using Chi-squared. Agreement between data collection modalities will use intra-class correlation coefficient (ICC) with a two-way random effects model measuring absolute agreement between modalities for each protected characteristic, presented as ICC with a 95% confidence interval. A full statistical analysis plan will be developed prior to final analysis of this comparison.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Prof	Rupert	Pearse
Post	Professor & Consultant in Intensive Care Medicine		
Qualifications			
Employer	Queen Mary University of London		
Work Address	Royal London Hospital		
	Critical Care and Perioperative Medicine Research Group		
	London		
Post Code	E1 1FR		
Telephone	02035940348		
Fax			
Mobile			
Work Email	r.pearse@qmul.ac.uk		

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	Queen Mary University of London
Given name	Mays
Family name	Jawad
Address	Joint Research Management Office, Dept W, 69-89 Mile End Road
Town/city	London
Post code	E1 4UJ
Country	United Kingdom
Telephone	020 7882 7275
Fax	
E-mail	Research.governance@qmul.ac.uk

Legal representative for clinical investigation of medical device (studies involving Northern Ireland only)
Clinical Investigations of Medical Devices that take place in Northern Ireland must have a legal representative of the sponsor that is based in Northern Ireland or the EU

Contact person

Name of organisation	
Given name	
Family name	
Address	
Town/city	
Post code	
Country	
Telephone	
Fax	
E-mail	

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] No application for external funding will be made

What type of research project is this?

- ( ) Standalone project
- ( ) Project that is part of a programme grant
- ( ) Project that is part of a Centre grant
- ( ) Project that is part of a fellowship/ personal award/ research training award
- (•) Other

Other – please state:
This trial is part of the PROTECT platform trial IRAS 1008776

Please give details of funding applications.

Organisation	Academy of Medical Science
Address	41 Portland Place London
Post Code	W1B 1QH
Telephone	
Fax	
Mobile	
Email	

Funding Application Status: (•) Secured ( ) In progress

Amount: £29,625

Duration
Years: 2
Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

Organisation	British Journal of Anaesthesia
Address	3rd Floor 56 Wellington Street, Leeds West Yorkshire,

Post Code LS1 2EE
Telephone
Fax
Mobile
Email

Funding Application Status: (•) Secured ( ) In progress

Amount: £299.853

Duration
Years: 2
Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (•) No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (•) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Dr	Mays	Jawad

Organisation: Joint Research Management Office (JRMO)
Address: Dept W 68-89 Mile End Road

Post Code: e1 4UJ
Work Email: Research.governance@qmul.ac.uk
Telephone: 02078827275
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select the Regional Research Delivery Network for the NHS Organisation identified in A68-1:

North Thames

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 02/09/2024
Planned end date: 01/02/2027
Total duration:
Years: 2 Months: 4 Days: 0

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☑ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 10

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	8
☐ NHS organisations in Wales	
☑ NHS organisations in Scotland	2
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	

☐ Educational establishments

☐ Independent research units

☐ Other (give details)

Total UK sites in study: 10

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The Sponsor or delegate retains the right to audit any study, study site or central facility. In addition, any part of the study may be audited by the funders where applicable

A75-1. What arrangements will be made to review interim safety and efficacy data from the trial? Will a formal data monitoring committee or equivalent body be convened?

Not applicable, this is a feasibility trial to compare modes of consent and compare the accuracy of protected characteristics data collection using different methods.

If a formal DMC is to be convened, please forward details of the membership and standard operating procedures to the Research Ethics Committee when available. The REC should also be notified of DMC recommendations and receive summary reports of interim analyses.

A75-2. What are the criteria for electively stopping the trial or other research prematurely?

The comparison steering committee will decide if the trial should be stopped early.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Sponsor's indemnity will apply

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Sponsor's indemnity will apply

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

◉ Yes ○ No

If Yes, please give details of the compensation policy:
Queen Mary University of London insurance does offer "no-fault" compensation where, on the balance of probability, the harm was likely caused by the trial procedures.

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN1	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Shaun May shaun.may@nhs.net
	Organisation name	BARTS HEALTH NHS TRUST	Qualification (MD...)	MD
	Address	THE ROYAL LONDON HOSPITAL 80 NEWARK STREET LONDON	Country	United Kingdom
	Post Code	E1 2ES		
	Country	ENGLAND		
IN3	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Gary Minto gary.minto@nhs.net
	Organisation name	UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST	Qualification (MD...)	MD
	Address	DERRIFORD HOSPITAL DERRIFORD ROAD DERRIFORD PLYMOUTH	Country	United Kingdom
	Post Code	PL6 8DH		
	Country	ENGLAND		
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Jennifer Edwards jennifer.edwards4@gjnh.scot.nhs.uk
	Organisation name	NHS National Waiting Times Centre Board	Qualification (MD...)	MD
	Address	Agamemnon Street		

		CLYDEBANK DUNBARTONSHIRE	Country	United Kingdom
	Post Code	G81 4DY		
	Country	SCOTLAND		

IN4

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Joyce
		Middle name	
		Family name	Yeung
		Email	j.yeung.4@warwick.ac.uk
Organisation name	UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST	Qualification (MD...)	MD
Address	QUEEN ELIZABETH HOSPITAL MINDELSOHN WAY EDGBASTON BIRMINGHAM WEST MIDLANDS	Country	United Kingdom
Post Code	B15 2GW		
Country	ENGLAND		

IN5

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Ashok
		Middle name	
		Family name	Sundar
		Email	sundar.ashok@nhs.net
Organisation name	CROYDON HEALTH SERVICES NHS TRUST	Qualification (MD...)	MD
Address	CROYDON UNIVERSITY HOSPITAL 530 LONDON ROAD THORNTON HEATH	Country	United Kingdom
Post Code	CR7 7YE		
Country	ENGLAND		

IN6

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

		Forename	Mandeep
		Middle name	
		Family name	Phull
		Email	mandeep.phull@nhs.net
Organisation name	BARKING, HAVERING AND REDBRIDGE UNIVERSITY HOSPITALS NHS TRUST	Qualification (MD...)	MD
Address	QUEENS HOSPITAL	Country	United Kingdom

	ROM VALLEY WAY
	ROMFORD
Post Code	RM7 0AG
Country	ENGLAND

IN7

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename	Caroline
Middle name	
Family name	Thomas
Email	caroline.thomas27@nhs.net
Qualification (MD...)	MD
Country	United Kingdom

Organisation name	LEEDS TEACHING HOSPITALS NHS TRUST
Address	ST. JAMES'S UNIVERSITY HOSPITAL
	BECKETT STREET
	LEEDS
Post Code	LS9 7TF
Country	ENGLAND

IN8

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename	Ronelle
Middle name	
Family name	Moulton
Email	ronelle.mouton@nbt.nhs.uk
Qualification (MD...)	MD
Country	United Kingdom

Organisation name	NORTH BRISTOL NHS TRUST
Address	SOUTHMEAD HOSPITAL
	SOUTHMEAD ROAD
	WESTBURY-ON-TRYM BRISTOL
Post Code	BS10 5NB
Country	ENGLAND

IN9

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename	Patrice
Middle name	
Family name	Forget
Email	forgetpatrice@yahoo.fr
Qualification (MD...)	MD
Country	United Kingdom

Organisation name	GRAMPIAN
Address	SUMMERFIELD HOUSE
	2 EDAY ROAD
	ABERDEEN
Post Code	AB15 6RE

	Country	SCOTLAND

IN10

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

		Forename	Sham
		Middle name	
		Family name	Jhanji
		Email	shaman.jhanji@rmh.nhs.uk
Organisation name	THE ROYAL MARSDEN NHS FOUNDATION TRUST	Qualification (MD...)	MD
Address	FULHAM ROAD	Country	United Kingdom
	LONDON GREATER LONDON		
Post Code	SW3 6JJ		
Country	ENGLAND		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.

10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.

12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- (●) Chief Investigator
- ( ) Sponsor
- ( ) Study co-ordinator
- ( ) Student
- ( ) Other – please give details
- ( ) None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Thomas Abbott on 18/11/2024 11:02.

Job Title/Post:	Clinical Senior Lecturer
Organisation:	QMUL
Email:	t.abbott@qmul.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Dr Mays Jawad on 18/11/2024 11:08.

Job Title/Post:	Research Governance Operations Manager
Organisation:	Queen Mary University of London
Email:	research.governance@qmul.ac.uk