[Insert Study Title]

[The research methods/protocol document details the research methodology and the application form serves as a lay summary of the study.]

**Study Management Group**

Principal Investigator:

Co-investigators:

**Sponsor**

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Research Governance and Integrity.

This protocol describes the [insert study title] study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Principal Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research It will be conducted in compliance with the protocol, Data Protection Act 2018 and General Data Protection Regulations (Europe) and other regulatory requirements as appropriate.

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## **INTRODUCTION**

### 1.1 Background

*To include a review of previous studies.*

### **1.2 Study Rationale**

*To include: reason for doing study, research question and hypothesis.*

## STUDY OBJECTIVES

*What are you hoping the study achieves? List the primary, secondary and other study objectives.*

## STUDY DESIGN

*Detail how this study will be conducted from advertising to data processing. Include points below:*

* *Type of study: survey, interviews, focus groups, simulator study*
* *Recruitment methods: how you will recruit participants, use of participant information sheets and consent forms*
* *Duration of study from advertising and recruitment to end of data collection*
* *Number of participants*

## PARTICIPANT RECRUITMENT

### 4.1 Pre-recruitment evaluations

*Are there any requirements that a participant must fulfil? E.g., fitness test, allergy test.*

### 4.2 Inclusion Criteria

*Include justifications, if necessary.*

### 4.3 Exclusion Criteria

*Include justifications, if necessary.*

### 4.4 Withdrawal Criteria

*Describe procedures for stopping early, when can a participant withdraw from the study, how and who to contact. Include details of data usage once participant has withdrawn, will the data be used once it has been anonymised.*

## ADVERSE EVENTS

Delete section 5 for non-interventional studies e.g. studies using interviews, surveys, questionnaires.

### 5.1 Reporting Procedures

All adverse events (AEs) should be reported. Any questions concerning adverse event reporting should be directed to the Principal Investigator in the first instance.

##### 5.1.1 Non serious AEs

All such events, whether expected or not, should be recorded.

##### 5.1.2 Serious AEs

A Serious Adverse Event (SAE) form should be completed and emailed to the Principal Investigator within 24 hours.

All SAEs should be reported to the Ethics and Research Governance Coordinator when the Principal Investigator believes the event was:

* ‘related’, i.e. resulted from the administration of any of the research procedures; and
* ‘unexpected’, i.e. an event that is not listed in the protocol as an expected occurrence

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

## ASSESMENT AND FOLLOW UP

*Will there be a follow up? What will it consist of?*

## REGULATORY ISSUES

### 7.1 Ethics approval

The Principal Investigator has obtained approval from the Head of Department and [approval from the Research Governance and Integrity Team (RGIT)/ favourable opinion from Imperial College Research Ethics Committee (ICREC). (delete as appropriate)]. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

### 7.2 Consent

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered, and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time. (amend as appropriate).

### 7.3 Confidentiality

The Principal Investigator will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research. Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

### 7.4 Indemnity

Imperial College London holds negligent harm insurance policies which apply to this study.

### 7.5 Sponsor

Imperial College London will act as the main sponsor for this study.

### 7.6 Funding

[Insert name] are funding this study/ This study is not funded. *(delete as appropriate)*

*Any per participant payments and investigator payments should be detailed here.*

### 7.7 Audits

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor.

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## PUBLICATION POLICY

*The study publication policy should be described in full.*

## REFERENCES

*List of useful and relevant references for the study.*