Study title

**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 be conducted in compliance with the protocol, Data Protection Act 2018 and General Data Protection Regulations (Europe) and other regulatory requirements as appropriate.

**TABLE OF CONTENTS**

[1. INTRODUCTION 3](#_Toc528676441)

[1.1 Background 3](#_Toc528676442)

[1.2 Study Rationale 3](#_Toc528676443)

[2. STUDY OBJECTIVES 3](#_Toc528676444)

[3. STUDY DESIGN 3](#_Toc528676445)

[4. SECONDARY DATA 3](#_Toc528676446)

[4.1 Database 3](#_Toc528676447)

[5. REGULATORY ISSUES 3](#_Toc528676448)

[5.1 Ethics approval 3](#_Toc528676449)

[5.2 Consent 4](#_Toc528676450)

[5.3 Confidentiality 4](#_Toc528676451)

[5.4 Funding 4](#_Toc528676452)

[5.5 Audits 4](#_Toc528676453)

[6. STUDY MANAGEMENT 4](#_Toc528676454)

[7. PUBLICATION POLICY 4](#_Toc528676455)

[8. REFERENCES 4](#_Toc528676456)

## **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 how you will obtain the secondary data*

*Type of study: what information does the data contain*

*consent forms*

## SECONDARY DATA

### 4.1 Database

Describe where you are obtaining the data from, how and any permissions you have to use/access the data.

## REGULATORY ISSUES

### 5.1 Ethics approval

The Principal Investigator has obtained approval from the Head of Department and [approval from the Research Governance Integrity Team (RGIT)/ favourable opinion from the Science, Engineering and Technology Research Ethics Committee (SETREC). (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.

### 5.2 Consent

*Do you have any evidence of participants consent for their data to be used in studies other than what it was originally collected*

### 5.3 Confidentiality

*Only applicable if non-anonymised data is being used*

The Principal Investigator will preserve the confidentiality of participants and fulfil transparency requirements under the General Data Protection Regulation. 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.

### 5.4 Funding

[Insert name] are funding this study.

*Any per participant payments, investigator payments should be detailed here*

### 5.5 Audits

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

## STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through [insert name].

## PUBLICATION POLICY

*The study publication policy should be described in full*

## REFERENCES

*List of useful and relevant references for the study*