**Template Protocol for non-CTIMPs**

<Study Acronym>

<Full study title>

<Version number and date>

MAIN SPONSOR: Imperial College London/Imperial College Healthcare NHS Trust (delete as applicable)

FUNDERS: xxx

STUDY COORDINATION CENTRE: xxx

IRAS Project ID: xxx

REC reference: xxx

**Protocol authorised by:**

|  |  |  |
| --- | --- | --- |
| **Name & Role** | **Date** | **Signature** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Study Management Group**

Chief Investigator:

Co-investigators:

Statistician:

Study Management:

**Study Coordination Centre** *(may not be applicable)*

For general queries, supply of study documentation, and collection of data, please contact:

Study Coordinator:

Address:       **Registration:**

Tel:       E-mail:

Fax:       Web address:

**Clinical Queries**

Clinical queries should be directed to xxx who will direct the query to the appropriate person

**Sponsor**

Imperial College London/Imperial College Healthcare NHS Trust (delete as applicable) is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Research Governance and Integrity Team

Imperial College London and Imperial College Healthcare NHS Trust

Room 215, Level 2, Medical School Building

Norfolk Place

London, W2 1PG

**Tel**: **0207 594 9480**

[Imperial College - Research Governance and Integrity Team (RGIT) Website](https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/)

**Funder**

[Who is funding the study]

This protocol describes the xxx 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 Chief 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, the Data Protection Act and other regulatory requirements as appropriate.

**Table of Contents Page No**

[1. INTRODUCTION 7](#_Toc33098103)

[1.1. BACKGROUND 7](#_Toc33098104)

[1.2. RATIONALE FOR CURRENT STUDY 7](#_Toc33098105)

[2. STUDY OBJECTIVES 7](#_Toc33098106)

[3. STUDY DESIGN 7](#_Toc33098107)

[3.1. STUDY OUTCOME MEASURES 7](#_Toc33098108)

[4. PARTICIPANT ENTRY 7](#_Toc33098109)

[4.1. PRE-REGISTRATION EVALUATIONS 7](#_Toc33098110)

[4.2. INCLUSION CRITERIA 7](#_Toc33098111)

[4.3. EXCLUSION CRITERIA 8](#_Toc33098112)

[4.4. WITHDRAWAL CRITERIA 8](#_Toc33098113)

[5. ADVERSE EVENTS 8](#_Toc33098114)

[5.1. DEFINITIONS 8](#_Toc33098115)

[5.2. REPORTING PROCEDURES 8](#_Toc33098116)

[6. ASSESSMENT AND FOLLOW-UP 9](#_Toc33098117)

[7. STATISTICS AND DATA ANALYSIS 9](#_Toc33098118)

[8. REGULATORY ISSUES 9](#_Toc33098119)

[8.1. ETHICS APPROVAL 9](#_Toc33098120)

[8.2. CONSENT 10](#_Toc33098121)

[8.3. CONFIDENTIALITY 10](#_Toc33098122)

[8.4. INDEMNITY 10](#_Toc33098123)

[8.5. SPONSOR 10](#_Toc33098124)

[8.6. FUNDING 10](#_Toc33098125)

[8.7. AUDITS 10](#_Toc33098126)

[9. STUDY MANAGEMENT 11](#_Toc33098127)

[10. PUBLICATION POLICY 11](#_Toc33098128)

[11. REFERENCES 11](#_Toc33098129)

**Glossary of Abbreviations**

|  |  |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Keywords**

[Insert a list of keywords]

**Study Summary**

|  |  |
| --- | --- |
| **TITLE** |  |
| **DESIGN** |  |
| **AIMS** |  |
| **OUTCOME MEASURES** |  |
| **POPULATION** |  |
| **ELIGIBILITY** |  |
| **duration** |  |

**Reference diagram**

[if appropriate]

# INTRODUCTION

* 1. BACKGROUND

[To include: review of previous studies, disease particulars, incidence, current treatment options, risks and benefits]

* 1. RATIONALE FOR CURRENT STUDY

[To include: research question and hypothesis]

# STUDY OBJECTIVES

[List the primary, secondary and other study objectives]

# STUDY DESIGN

[Type of study: eg tissue collection, physiological, epidemiological etc]

[Duration]

[Number and type of subjects]

* 1. STUDY OUTCOME MEASURES

[Are there endpoints to the study?] List the primary and secondary outcomes measures.

# PARTICIPANT ENTRY

* 1. PRE-REGISTRATION EVALUATIONS

[What tests need to be included before a participant can enter the study? Eg, FBC, LFT, biopsy, CT scan. All screening procedures should be included]

* 1. INCLUSION CRITERIA

[Include justifications, if necessary]

* 1. EXCLUSION CRITERIA

[Include justifications, if necessary]

* 1. WITHDRAWAL CRITERIA

[Describe procedures for stopping early]

# ADVERSE EVENTS

* 1. DEFINITIONS

**Adverse Event (AE):** any untoward medical occurrence in a patient or clinical study subject.

**Serious Adverse Event** **(SAE):** any untoward medical occurrence or effect that:

* **Results in death**
* **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
* **Requires hospitalisation, or prolongation of existing inpatients’ hospitalisation**
* **Results in persistent or significant disability or incapacity**
* **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

* 1. REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

**5.3.1 Non serious AEs**

All such events, whether expected or not, should be recorded- it should be specified if only some non-serious AEs will be recorded, any reporting should be consistent with the purpose of the trial end points.

**5.3.2 Serious AEs**

An SAE form should be completed and emailed to the Chief Investigator within 24 hours. However, relapse and death due to <condition>, and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the <name of REC> where in the opinion of the Chief Investigator, the event was:

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

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all related and unexpected SAEs.

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

**Contact details for reporting SAEs**

[**RGIT@imperial.ac.uk**](mailto:jrco@imperial.ac.uk)

**CI email (and contact details below)**

**Please send SAE forms to: xxx**

**Tel: xxx (Mon to Fri 09.00 – 17.00)**

# ASSESSMENT AND FOLLOW-UP

[Will there be a follow up? When and what will their assessments consist of? Efficacy assesments, if applicable, should be included] Describe how incidental findings will be identified, reviewed and reported, and to which individuals they will be reported to (i.e. GP, clinical care team).

[Definition of end of study]

# STATISTICS AND DATA ANALYSIS

[Statistical plan, eg sample size calculation and data analysis.]

Data and all appropriate documentation will be stored for a minimum of 10 years *(5 years if ICHT sponsored study)* after the completion of the study, including the follow-up period.

# REGULATORY ISSUES

* 1. ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the xxx Research Ethics Committee (REC) and Health Research Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. 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.

* 1. CONSENT

(If study does not involve consent, this section is not relevant)

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. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant’s best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

* 1. CONFIDENTIALITY

Pseudonymised data is data that can be linked back to a person (e.g. coded data). It is considered both personal and identifiable data. Anonymised data is data that has no code and cannot be linked back to a person (e.g. aggregated data for publication, data without a code that cannot be linked back to a person)

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

Data will be anonymised/pseudonymised (delete as applicable)

Data will be transferred to (insert third party name as appropriate or delete)

* 1. INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study/ Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Resolution for NHS Trusts in England, which apply to this study (delete as applicable)

* 1. SPONSOR

Imperial College London/Imperial College Healthcare NHS Trust (delete as applicable) will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

* 1. FUNDING

xxx are funding this study. [Any per participant payments, investigator payments should be detailed here]

* 1. AUDITS

The study may be subject to audit by Imperial College London/ Imperial College Healthcare NHS Trust under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

# STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through xxx.

*(delete once inserted) CI to include study specific reporting requirements/notification responsibilities for the study*

# PUBLICATION POLICY

[The study's publication policy should be described in full]

# REFERENCES

[List of useful and relevant references for the study]

**EXAMPLE APPENDICES**

Appendices should be additional information to the protocol and can consist of:

* Common Terminology Criteria for Adverse Events (NCI CTC)
* RECIST criteria
* WHO / ECOG Performance status
* PIS, Consent form, GP letter (although may be more practical to have them separate)
* Expected side effects
* Schedule of events table

**Appendix 1. Summary of investigations, treatment and assessments**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Exam** | | **Week of Treatment** | | | | | | | | |
|  | Pre-treatment | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| MRI | X |  |  | X |  |  | X |  |  |  |
| Chest x-ray | X |  |  |  |  |  |  |  |  |  |
| History, physical exam | X |  |  |  |  |  |  |  |  |  |
| ECG | X |  |  |  |  | X |  |  |  |  |
| WHO performance status | X |  |  |  |  |  |  |  |  |  |
| FBC, U&E, LFT | X | X | X | X | X | X | X | X | X | X |
| Informed consent | X |  |  |  |  |  |  |  |  |  |