UCT FHS CRC Protocol template for non-investigational medicinal product studies

# 

# UCTlogo No shadow

# Group/study logo

# Study name, acronym

# Study number

Protocol version no and date

[Add names of]

Author(s):

Sponsor(s):

Funder(s):

Study coordination centre:

**Study Management Group**

Principal Investigator:

Co-investigators:

Statistician:

**Study Coordination Centre**

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

Study Coordinator:

Address:      

Tel:       E-mail:

Fax:       Web:

**Clinical Queries**

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

**Sponsor**

UCT is the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Deputy Director at:

University of Cape Town, Clinical Research Centre

Old Main Building, L51

Groote Schuur Hospital

Observatory

0214066281

**Funder**

[Who is funding the study if different to Sponsor]

Every care was taken in drafting this protocol, but corrections or amendments may be necessary. These will be circulated to investigators and approved before implementation. 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 and other relevant regulatory requirements.

**Table of Contents**

[1. INTRODUCTION 6](#_Toc388512667)

[1.1 Background 6](#_Toc388512668)

[1.2 Rationale for current study 6](#_Toc388512669)

[2. STUDY OBJECTIVES 6](#_Toc388512670)

[3. STUDY DESIGN 6](#_Toc388512671)

[3.1 Study outcome measures 6](#_Toc388512672)

[4. PARTICIPANT ENTRY TO THE STUDY 6](#_Toc388512673)

[4.1 Pre-registration evaluations 6](#_Toc388512674)

[4.2 Inclusion criteria 6](#_Toc388512675)

[4.3 Exclusion criteria 6](#_Toc388512676)

[4.4 Withdrawal criteria 7](#_Toc388512677)

[5. ADVERSE EVENTS 7](#_Toc388512678)

[5.1 Definitions 7](#_Toc388512679)

[5.2 Reporting procedures 7](#_Toc388512680)

[6. ASSESSMENT AND FOLLOW-UP 8](#_Toc388512681)

[7. STATISTICS AND DATA ANALYSIS 8](#_Toc388512682)

[8. REGULATORY ISSUES 8](#_Toc388512683)

[8.1 Ethics approval 8](#_Toc388512684)

[8.2 Consent 8](#_Toc388512685)

[8.3 Confidentiality 8](#_Toc388512686)

[8.4 Indemnity 8](#_Toc388512687)

[8.5 Sponsor 8](#_Toc388512688)

[8.6 Funding 8](#_Toc388512689)

[8.7 Audits 9](#_Toc388512690)

[9. STUDY MANAGEMENT 9](#_Toc388512691)

[10. PUBLICATION POLICY 9](#_Toc388512692)

[11. REFERENCES 9](#_Toc388512693)

[EXAMPLE APPENDICES 10](#_Toc388512694)

**Glossary of Abbreviations**

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

**Keywords**

[Insert a list of keywords]

**Study Summary**

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

**Reference diagram (e.g. flow of assessments)**

[if appropriate]

# 1. INTRODUCTION

## 1.1 Background

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

## 1.2 Rationale for current study

[To include: research question and hypothesis]

# 2. STUDY OBJECTIVES

[List the primary, secondary and other study objectives]

# 3. STUDY DESIGN

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

[Interventions]

[Study population – number and type]

[Selection and Recruitment]

[Randomisation & allocation procedures]

[Duration]

[Methods for protecting against bias]

[Reliability]

[Data collection and management]

[Statistical methods]

## 3.1 Study outcome measures

[Are there endpoints to the study?]

# 4. PARTICIPANT ENTRY TO THE STUDY

## 4.1 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]

## 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 and justifications]

# 5. ADVERSE EVENTS

## 5.1 Definitions

**Adverse Event (AE):** any untoward medical occurrence in a patient or clinical study subject which does not necessarily have a causal relationship with an intervention.

**Serious Adverse Event** **(SAE):** any untoward and unexpected 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**

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.

## 5.2 Reporting procedures

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

**5.2.1 Non serious AEs**

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

**5.2.2 Serious AEs**

An SAE form should be completed and faxed to the Sponsor within 24 hours. However, [add protocol-specific conditions], and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

AEs and SAEs should be reported as required by Local Research Ethics Committee andr other regulatory authorities (if applicable).

**Please send SAE forms to:** **xxx**

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

# 6. ASSESSMENT AND FOLLOW-UP

[Will there be a follow up? When and what will their assessments consist of in terms of, for instance, efficacy and safety]

[Definition of end of study]

# 7. STATISTICS AND DATA ANALYSIS

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

# 8. REGULATORY ISSUES

## 8.1 Ethics approval

Approval will be obtained from the UCT Human Research Ethics Committee [and the following local ethics committees, as appropriate: ]. Data and all appropriate documentation will be stored for a minimum of 5 years after the completion of the study, including the follow-up period.

## 8.2 Consent

[If using anonymised tissue samples only, this section will not be 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.

## 8.3 Confidentiality

The Principal Investigator will preserve the confidentiality of participants taking part in the study in compliance with data protection legislation.

Anonymity will be ensured with the use of a master code which will be kept in a separate secure filing cabinet. All computers will be password protected.

## 8.4 Indemnity

UCT holds a non-negligent harm insurance policy which applies to this study.

## 8.5 Sponsor

UCT will act as the main Sponsor for this study. Delegated responsibilities assigned to the research team running this study will be documented.

## 8.6 Funding

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

## 8.7 Audits

The study may be subject to inspection and audit by UCT CRC under their remit as Sponsor and other regulatory bodies to ensure adherence to South African Good Clinical Practice if required.

# 9. STUDY MANAGEMENT

[Details of day-to-day management of the study]

# 10. PUBLICATION POLICY

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

# 11. 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)
* WHO / ECOG Performance status
* PIS, Consent form, GP letter (although may be more practical to have them separate)
* Expected adverse effects
* Schedule of events table

**Example 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 |  |  |  |  |  |  |  |  |  |