**[FULL STUDY TITLE]**

## [Short Title or Acronym]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Phone | Email | Institution | Study Role (e.g. Principal Investigator) |
| XXX | 04 XXX | xxx@mater.org.au | Mater  |  |
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|  |  |  |  |  |
|  |  |  |  |  |

**LAY DESCRIPTION OF THE PROJECT** [2-3 LINES ONLY]

This study will be conducted in such a way that it complies with:

* [Your respective professional Code/s of Conduct, e.g. Australian Medical Association Code of Conduct for Medical Practitioners. If you are a specialist, you may have more than one professional Code of Conduct];
* [Any requirements as defined by your Board/s of professional registration e.g. Australian Health Practitioner Regulation Agency];
* Catholic Health Australia (2001). Code of Ethical Standards for Catholic Health and Aged Care Services in Australia;
* Current best practices in [the field or discipline of your study, including offering best current clinical practices and treatments in all arms of your study];
* Current best practice in ethics including abiding by the *National Statement* and all other relevant NHMRC standards;
* Relevant State and Commonwealth Acts and legislations; and
* Relevant Institutional policies and procedures (available on Mater Document Center).

**CONTENTS PAGE**

***[Delete headings that are not applicable to your study]***

## INTRODUCTION [~250 words] [*page number]*

## BACKGROUND [2x A4 pages maximum]

## AIM(S) OF STUDY

### Primary Aim(s)

### Secondary Aim(s)

## OBJECTIVE(S)

### Primary Objective(s)

### Secondary Objective(s)

## HYPOTHESI(E)S

### Primary Hypothesi(e)s

### Secondary Hypothesi(e)s

## STUDY DESIGN

## STUDY SETTING/LOCATION(S)

## STUDY DURATION

## STUDY POPULATION

### Recruitment Process

### Inclusion criteria

### Exclusion criteria

### Potential for Risk, burdens and benefits

## STUDY OUTCOMES

### Primary Outcome

### Secondary Outcome(s)

## STUDY PROCEDURES

### Recruitment and consent of participants

### Withdrawal of participants from a study

#### Participant withdrawal from study procedures

#### Participant withdrawal from a study

### Randomisation

### Measurement tools used

### Study involvement by participants

### Data management

### Safety considerations/Patient safety

### Data monitoring

## SAMPLE SIZE AND DATA ANALYSIS

### Sample size and statistical power

### Data analysis plan

## ETHICAL CONSIDERATIONS

## DISSEMINATION OF RESULTS AND PUBLICATIONS

## OUTCOMES AND SIGNIFICANCE

## BUDGET

## GLOSSARY OF ABBREVIATIONS

## REFERENCES

## APPENDICES

## INTRODUCTION [~250 words]

## BACKGROUND [2x A4 pages maximum]

## AIM(S) OF STUDY

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### Primary Hypothesi(e)s

### Secondary Hypothesi(e)s

## STUDY DESIGN

## STUDY SETTING/LOCATION(S)

## STUDY DURATION

|  |  |  |  |
| --- | --- | --- | --- |
| Milestone | e.g. 2020 | 2021 | 2022 |
| [Year Quarter or months in this row ->] | I | II | III | IV | I | II | III | IV | I | II | III | IV |
| Ethics application |  |  |  |  |  |  |  |  |  |  |  |  |
| Governance (Site Specific Application or SSA) and contract Agreements |  |  |  |  |  |  |  |  |  |  |  |  |
| Study Planning |  |  |  |  |  |  |  |  |  |  |  |  |
| Participant recruitment |  |  |  |  |  |  |  |  |  |  |  |  |
| Data analysis |  |  |  |  |  |  |  |  |  |  |  |  |
| Write up of results |  |  |  |  |  |  |  |  |  |  |  |  |
| Progress report to Ethics and Governance |  |  |  |  |  |  |  |  |  |  |  |  |
| Final report to Ethics and Governance |  |  |  |  |  |  |  |  |  |  |  |  |
| Presentation and/or Publication of findings |  |  |  |  |  |  |  |  |  |  |  |  |

## STUDY POPULATION

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## BUDGET [delete items not applicable]

|  |  |  |  |
| --- | --- | --- | --- |
| Item/s | BUDGET for Site | In-Kind | Cash |
| FUNDING |
| Grant |  |  |  |
| Sponsor [Individual / organisation or group taking in responsibility to initiate, manage or finance the study] |  |  |  |
| EXPENSES |
| Personnel |  |  |  |
| Principal Investigator |  | [unless funding support is provided, this is often recorded as in-kind support as a proportion of FTE or number of hours/week donated to the study] |  |
| Associate Investigator/s |  | [unless funding support is provided, this is often recorded as in-kind support as a proportion of FTE or number of hours/week donated to the study] |  |
| Research Assistant |  | [unless funding support is provided, this is often recorded as in-kind support as a proportion of FTE or number of hours/week donated to the study] |  |
| Interpreter |  |  |  |
| Clinical or Teaching relief or backfill |  | [unless funding support is provided, this is often recorded as in-kind support as a proportion of FTE or number of hours/week donated to the study] |  |
| Research equipment |  |  |  |
| Itemised property purchased specifically for the study (e.g. digital camera) |  |  |  |
| Research Consumables/Material |  |  |  |
| Participant honorarium/payment |  |  |  |
| Test tubes for blood samples; tissues; gloves etc. (itemise) |  |  |  |
| If Biomedical research, animal costs or lab consumables and/or maintenance costs (itemise) |  |  |  |
| Associated Research Costs |  |  |  |
| Pathology |  |  |  |
| Pharmacy |  |  |  |
| Diagnostic – other (e.g. radiology) |  |  |  |
| Publication |  |  | [e.g. article publication fees] |
| Travel |  |  |  |
| Conference registration fee |  |  |  |
| Airfare/travel cost |  |  |  |
| Accommodation |  |  |  |
| Miscellaneous |  |  |  |
| HREC application fee | NB. Mater does not charge HREC application fees where there is a Mater or Mater Research employee on the study team. Please see the Mater Research Ethics and Governance Fees on our website for guidance |  |  |
| Site Specific Application (SSA)/ Governance fee | NB. Please see the Mater Research Ethics and Governance Fees on our website for guidance |  |  |
| Site rental fee/s for office, meeting room or lab use |  |  | [These may also be provided in-kind] |
| TOTAL Expenses |  |  |  |

## GLOSSARY OF ABBREVIATIONS

## REFERENCES

## APPENDICES

(e.g. Training log; Data collection form)