**CLINICAL TRIAL PROTOCOL SYNOPSIS / RESEARCH PROPOSAL OUTLINE**

We welcome and encourage the submission of new research proposals for consideration by Melanoma and Skin Cancer Trials (MASC Trials).

Please complete this template with information about your research proposal. Your proposal will be reviewed by the appropriate Discipline Specific Advisory (or Advisories) and take into consideration the strategic objectives of MASC Trials. We will provide feedback after review, advise if the proposal will progress to the Scientific Advisory Committee, and outline how we can work with you to develop your idea to attain endorsement by the Board of Directors.

For grant writing and application submission services, please provide a completed proposal draft, including budget, at least 8 weeks before the agency submission deadline.

Note that MASC Trials will seek input from the Cancer Australia Quality of Life Office and CREST Health Economics Group on protocols in development. All studies require consumer review, which will be arranged by MASC Trials.

**Relevant MASC Trials Discipline-specific Advisory for review of your proposal**

(More than one Advisory can be selected)

|  |  |
| --- | --- |
| Medical Oncology Advisory | Dermatology Advisory |
| Radiation Oncology Advisory | Surgical Oncology Advisory |
| Nursing, Allied Health, Public Health and Primary care Advisory | Australasian Merkel Cell Carcinoma Interest Group (AMIGOs) |
| Australasian Ocular Melanoma Alliance (AOMA) | Non-Melanoma Skin Cancer Advisory |

**Lead Investigators and/or groups and their affiliations:**

Investigator name/University Affiliation: [Insert investigator name/university affiliation]

Monash University Affiliation  Yes  No

**Project Title**

[Insert project title]

**Clinical Trial** [indicate which phase] **or**  **Clinical Study** (includes pilot studies)

**Brief Background and Rationale** (with references)

[Insert background and rationale]

**Aim**

[Insert aim]

**Objectives**

*In addition to other objectives, consider potential impacts of disease and intervention on patient-reported outcomes (e.g. symptoms, functioning and quality of life)*.

[Insert objectives]

**Hypothesis**

[Insert hypothesis]

**Population and Setting**

[Insert population and setting]

**Interventions (if applicable)**

[Insert interventions]

**Primary Outcome**

[Insert primary outcome]

**Secondary Outcome**

[Insert secondary outcome]

**Quality of Life Outcome**[If relevant, discuss how quality of life or other patient-reported outcomes will be assessed]

**Study Design and Procedure – Outline Only**

[Insert study design]

**Statistical Considerations / Sample Size / Data Collection**

[Insert statistical considerations]

**Timeline**

[Insert timeline]

**Proposed Funding Sources**

[Insert proposed funding]

**Outline of Feasibility / Recruitment**

[Insert feasibility/recruitment]

**MASC Trials resourcing required**

|  |  |
| --- | --- |
| Biostatistical support | Project sponsorship |
| Project management | Data management |
| Grant writing and application submission | Other (*please outline below*) |

[Insert other resourcing as required]

**HEALTH ECONOMIC CHECKLIST for CLINICAL TRIALS**

Have you incorporated a health economic analysis/study to your trial?

Yes, *please follow* ***Pathway A***

No, *please follow* ***Pathway B***

*Please refer to this* [*website*](https://www.uts.edu.au/sites/default/files/2019-04/crest-factsheet-why-economic-%20evaluation.pdf%20if) *if you want to know more about conducting a health economic analysis.*

|  |
| --- |
| **Pathway A:** A health economic analysis is either being considered or some rationale has been proposed that supports its consideration. |

1. **What type of clinical trial is this trial?**

Interventional

Observational (non-interventional)

1. **What is the aim of your study (*choose all that apply*)?**

Descriptive (i.e. systematic review of the literature)

Change current practice *(e.g Phase III)*

Construct a registry

Instrument validation

Feasibility study *(e.g. Phase II, randomised Phase II)*

Safety *(e.g Phase I, Phase Ib)*

Other

[Please specify] *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

1. **Is the intervention expected to impact the quality of life (QoL) of patients or carers?**

Yes *(please describe how it is expected to change QoL relative to current practice)*

[Description] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No *(go to question 5)*

1. **If differences in terms of QoL are expected, do you plan to use any generic or disease specific instrument to measure quality of life?**

Yes

[Which one/s] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

1. **Have you identified any potential differences in terms of resource use between the intervention and comparator/current practice (which may result in differences in costs)?**

Yes *(go to question 6)*

No *(go to question 9)*

1. **What do you think is contributing to the difference in resource use (*choose all that apply*)?**

The intervention itself.

Differences in the incidence of AEs which lead to differences in management, hence costs.

Differences in the management of the disease other than the intervention.

The intervention is expected to prolong life; hence patients are expected to incur more healthcare costs.

Differences in concomitant medications.

Differences in required procedures.

Differences in numbers of cases detected (for diagnostic interventions).

1. **Do you think patients incur costs beyond health- related costs (i.e. time, carers, productivity, etc.)?**

Yes

No

1. **Are you considering asking patients for consent to access their Medicare data (MBS & PBS) and/or hospital record data to identify resource use?**

Yes

No

1. **In the context of this research, are you interested in knowing the preferences of patients or carers for the treatment options being compared in the trial?**

**Recommendation**:

*If you answered* ***yes*** *to questions 3, 5 and/or 9, please contact MASC to request a health economics audit for this study.*

Yes

No

|  |
| --- |
| **Pathway B:** A health economic analysis is not currently being considered, but it would be helpful to assess whether it might be relevant |

1. **What type of clinical trial is this trial?**

Interventional

Observational - non-interventional (*go to question 5)*

1. **What is the aim of your study (*choose all that apply*)?**

Descriptive (i.e. systematic review of the literature)

Change current practice (e.g Phase III)

Construct a registry

Instrument validation

Feasibility study (e.g Phase II, randomised Phase II)

Safety (e.g Phase I, Phase Ib)

Other

[Please specify] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Is the intervention expected to impact the quality of life (QoL) of patients or carers?**

Yes (please describe how it is expected to change QoL relative to current practice)

[Description] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

1. **Have you identified any potential differences in terms of resource use between the intervention and comparator/current practice (which may result in differences in costs)?**

Yes (please provide description below)

[Description] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No *(go to question 5)*

1. **Have you planned to collect data regarding resource use related to the intervention?**

Yes

No

1. In the context of this research, are you interested in knowing about the preferences of patients or carers for the alternative treatment options in the trial?

Yes

No

**Recommendation:***If you answered* ***yes*** *to questions 3, 4, and/or 6, please contact MASC to request a health economics audit for this study.*

**Documents attached (e.g. draft protocol, publications)** (provide filenames or description)

[Insert filenames or descriptions]

We value your privacy. By completing this form you consent to the collection, use and storage of your personal information in accordance with our Privacy Policy available from www.masc.org.au/privacy-policy/.

**Please email this completed form and any attachments to** [**grants@masc.org.au**](grants@masc.org.au)**.**