Peer Review Proforma

The purpose of the review is to identify areas for improvement which will ensure the project is scientifically valid. Refer to the [Peer Review Process](https://www.thermh.org.au/file/3521) document for information on research requiring peer review.

**Person responsible for completing sections of the form noted below:**

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| --- | --- |
| Section A | To be completed by Principal Investigator only if applicable |
| Section B | To be completed by Principal Investigator |
| Sections C – F | To be completed by Peer Reviewer |
| Section G | To be completed by Principal Investigator in response to the peer review |

# Section A (complete only if your research does not require peer review)

Evidence of peer review has not been provided with this application (insert reason below). If you are unsure please contact the Office for Research on 03 9342 8530.

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# Section B

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| **Project Title** |  |
| **Version number & date of Protocol under review** |  |

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| **Name: Principal Investigator** |  |
| **Position Title** |  |
| **Department / Group** |  |
| **Institution** |  |

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| **Name: Peer Reviewer** |  |
| **Position Title** |  |
| **Department / Group** |  |
| **Institution** |  |
| **Experience relevant to this research application** |  |

# Section C: Peer Reviewer Declaration

(Tick one option only)

I declare and agree to the following:

* I agree to maintain confidentiality of all matters and documents regarding this project; and
* I am independent of this project; and
* I agree that I have no potential conflicts of interest in reviewing this research protocol

**OR**

I declare I have the following potential conflicts of interest:

Provide details of the actual or potential conflict of interest in the space provided below, including any:

1. Personal involvement or participation in the research. \*
2. Financial or other interest or affiliation, or
3. Involvement in competing research

\* Peer Reviewer cannot, under any circumstances, be an investigator on this study.

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# Section D

Please provide a general overview/discussion of the project with specific reference to:

* Research question(s) and experimental design
* Whether the research is worthwhile
* Are there concerns about the investigational product? (if applicable)
* Safety issues
* Oversight/monitoring of the study
* Informed consent
* The Participant Information and Consent Form (PICF)
* Risks v Benefits
* Qualification/competence/experience of the research

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* *Using the drop-down function in the right column indicate per each criterion if, in your opinion, the criterion has been addressed – Yes / No / NA*
* *Provide an explanation for any ‘No’ response*
* *Record any comments regarding required changes or suggestions which could improve the project in the* [*Section E*](#SectionE)*.*

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| **CRITERIA** | | **YES / NO / NA** |
| **Project details:** Has all appropriate information been included?  (Investigator details and project title, protocol version number and date) | |  |
| **Research question:** Is there a clearly and precisely defined, answerable question?  Is there a clear aim or objective? | |  |
| **Background:** Is the research question an important one? Does the background information provided give a good rationale for why the project is being done? Is the study useful to clinical practice? Is there a real problem/ knowledge gap that needs filling? | |  |
| **Plan of Investigation:** | | |
| 1 | **Design:** is the design appropriate to the aim? Will the study address the question being asked and is it likely to produce an answer? |  |
| 2 | **Bias and confounding**: Has the study been designed to minimise the risk of bias? Have the investigators adequately accounted for the influence of potential confounders? |  |
| 3 | **Randomisation and Blinding:** Where applicable, is enough detail provided on exactly how randomisation and blinding will be achieved, including who is responsible? |  |
| 4 | **Sampling issues:** Will the proposed study group be large enough to provide sufficient statistical precision or power, where appropriate? Is there a reasonable justification for the proposed sample size? Will the sample collected be reasonably representative of the population in question? |  |
| 5 | **Feasibility:** Is there sufficient evidence to indicate that it will be possible to obtain the numbers required for the study? Is the study feasible in terms of funds, time and other resources? |  |
| 6 | **Participants:** Are the criteria for eligibility clear and justified? Have the methods used to identify, approach, recruit and consent participants been clearly and completely described? |  |
| 7 | **Intervention or exposure:** Is the intervention or exposure factor clearly described in adequate detail, where appropriate? If the intervention is a drug, are details of dose, delivery, preparation, handling and compliance provided? |  |
| 8 | **Procedure plan:** Has an appropriate plan of the study been detailed? Is the estimated duration of the project stated and appropriate? Is it clear how a participant will progress through treatments, procedures, assessments and visits, where applicable? |  |
| 9 | **Outcome measures:** Are these appropriate and achievable? Are definitions sufficiently detailed? Is the relevant data being collected on the proposed outcomes? |  |
| 10 | **Adverse Events:** Is there an appropriate plan for detecting, managing, recording and reporting defined adverse events, where applicable? |  |
| 11 | **Data collection:** Are the proposed data collection tools and data management systems appropriate for the project? |  |
| 12 | **Analysis:** Is there an adequate indication of what analysis will be done on outcome measures to answer the research question? Are the proposed analyses appropriate? |  |
| 13 | If the project reviewed is a clinical trial protocol - does the protocol meet the recommendations for a minimum set of scientific, ethical, and administrative elements that should be addressed in a clinical trial protocol identified in the [SPIRIT 2013 Statement](http://www.spirit-statement.org/spirit-statement/)? |  |
| **Project management:** Have adequate arrangements been specified for conduct and oversight? | |  |
| **Expertise:** Does the research team include (or have access to) all the necessary expertise for the project? | |  |
| **Ethical issues:** Have any potential ethical issues been addressed? Are risks to participants minimised? | |  |

# Section E

Each question, comment, suggestion or requirement should be separately bulleted. Where applicable reference the section and page number.

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| **General Comments** (Remarks that the investigator does not need to respond to) |
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| **Required Changes** (Points that the investigator must address by either making the required change, or producing a cogent argument against the change) |
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| **Suggested Changes** (Points that the reviewer thinks may improve the project. They are not of such importance that they would render the project scientifically invalid/unethical if the investigator did not address the issues) |
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# Section F

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| **Peer review outcome:** (reviewer to circle) | |
| **A** | **No changes required:** take the study forward to submission. |
| **B** | **Changes suggested:** at the discretion of the investigator; take the study forward to submission. |
| **C** | **Changes required:** decision about acceptability of subsequent changes at the discretion of the HREC reviewer. A peer reviewer does not need to review the amended protocol prior to submission. |
| **D** | **Changes and further peer-review required:** decision about acceptability of the subsequent changes at the discretion of the reviewer following a peer review of the amended protocol. An additional review & proforma should be completed to document the review of the amended protocol. |

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| **Peer Reviewer Signature** |  | **Date** |  |

# Section G: To be completed by the Principal Investigator

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| **Principal Investigator declaration:** | |
| I confirm that I have read the Peer Review **and** (select appropriate response and if desired, add further comments) | |
|  | **I accept the Peer Reviewers comments and have addressed changes** (where applicable). I have included a description of the amendments and amended documents in the below comments section. |
|  | **I disagree with the Peer Review:** provide supporting comments/justification and state if any changes to the protocol or other documents have been made. |
| **Principal Investigator response to Peer Review:** | |

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| **Principal Investigator Signature** |  | **Date** |  |