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** |  |