APPLICATION FOR ETHICS APPROVAL
SITCM HUMAN RESEARCH ETHICS COMMITTEE (HREC)

Office Use Only

Ethics application number:

Date of application submission:

Notes: This form should be completed in accordance with (1) National Statement on Ethical Conduct In Human Research, (2) SITCM Research Application Guide, and (3) SITCM Research Policy Framework.

1. Level of ethical review

Please indicate the type of HREC review for your application based on level of ethical review:

☐ Full HREC review

☐ Low risk HREC review

2. Information of applicant and study team

2.1 Applicant:

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Role in the study

Brief overview of qualifications and experience relevant to the research study (max 300 words):

2.2 Members in the study team (Please list all researchers other than the applicant)

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<th>Title and Name</th>
<th>Affiliation</th>
<th>Role in the study</th>
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3. Study details

Applicatio For for HREC Approval
### 3.1 Study title:

- [ ]

### 3.2 Study timeframe:

- **Proposed commence date of activities which require human ethics approval:**
- **Anticipated completion date:**

### 3.3 Aim and rational of the study (max 200 words)

- [ ]

### 3.4 Background to the study (including a brief literature review) (max 300 words)

- [ ]

### 3.5 Study methods (max 400 words)

- [ ]
4. Recruitment

4.1 Brief profile of target participants (if the study involves children, please describe how the study complies with "Chapter 4.2: Children and Young People in the National Statement") (max 300 words)

4.2 Target sample size and power calculation (max 200 words)

4.3 Participant recruitment strategy, including inclusion and exclusion criteria (max 300 words)

4.4 Brief description of recruitment materials (max 300 words)
5. General ethical considerations

5.1 The anticipated risks to participants when undertaking the study (max 200 words)

5.2 Brief protocol to minimise and manage the risks in Section 5.1 (max 300 words)

5.3 The likely benefits of study participation that will justify the anticipated risk (max 200 words)

5.4 Protocol for managing and reporting on adverse events during the study (max 200 words)

5.5 Brief description of reimbursement and financial or other rewards as a result of participation, if any (max 300 words)

6. Data collection, analysis, reporting and keeping
6.1 Type of data that will be collected in the study (max 100 words)

6.2 Compliance with the Guidelines under Section 95 and 95A of the Privacy Act 1988
If the study (1) relates to public health or public safety, or to the management, funding or monitoring of a health service, and/or (2) involve collection, use or disclosure of health information held by an organisation without consent from the individuals, please describe a proposal below as to why the public interest value of your study out-weighs the public interest in the protection of privacy (please address appropriate sections of the Guidelines under Section 95 and 95A of the Privacy Act 1988) (max 200 words).

6.3 Protocol to protect the privacy and confidentiality of study data throughout the study (your response should also include the data storage methods, the length of time that the data and materials will be retained) (max 300 words).

6.4 Plan of data analysis and access control (max 300 words)

6.5 Plan of making the study outcomes publicly accessible (including the format e.g. peer-reviewed articles, conference presentations, and media interview) (max 200 words)

7. Other ethical considerations
7.1 Funding sources of study, if applicable (max 150 words)

7.2 Anticipated potential conflict of interest during the study, and plan to address these issues (max 200 words)

7.3 Other ethical or relevant issues which are not previously declared (max 300 words)

8. Study team members' qualifications and experience

Please enclose/attach the CV of every member in the study team which should adequately reveal relevant research qualifications and experience.
9. Declaration by study team members

I have thoroughly read the following documents:
- National Statement on Ethical Conduct in Human Research (2007)
- Australian Code for the Responsible Conduct of Research
- SITCM Research Application Guide
- SITCM Research Policy Framework

I, the study team members, agree to:
- conduct the project in accordance with the responsibilities under the *National Statement on Ethical Conduct in Human Research (2007)* and the *Australian Code for the Responsible Conduct of Research*
- start this study only after obtaining final approval from the Human Research Ethics Committee at SITCM
- notify the HREC any adverse or unforeseen events from the study; requesting amendments for approval prior to commencement
- provide an annual progress report to the HREC for the duration of the research project
- provide the HREC with a final report, within one year after study completes
- will take responsibility for the confidential maintenance of the research materials as per relevant guidelines and policies.

All persons named in Section 2 are required to sign below:

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10. Procedures to submit this application

a. Prepare all support documents mentioned in this application, including members’ CVs
b. Print the completed form and collect all signatures
c. Scan the signed application and combine it with all attachments as one PDF file and email to: ethics@sitcm.edu.au
d. Applications must be received by the SITCM HREC Secretary a minimum of three weeks (15 working days) before the Committee is scheduled to meet for the application to be considered for review at that meeting.