



# Huber Social Human Research Ethics Committee **Standard Operating Procedures**

Version 2

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# 1. Objectives, Function and Scope

## 1.1 Objectives

The objectives of the Huber Social Human Research Ethics Committee (Huber Social HREC or HREC) are to:

- a. Assess the conduct of proposed human research, in particular that of social impact measurement research, against the ethical principles as outlined in the National Health and Medical Research Council (NHMRC)'s National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) (the "National Statement")<sup>1</sup>, the Australian Code for the Responsible Conduct of Research 2018 (the "Code"),<sup>2</sup> and the Huber Social Principles for Ethical Research (the "Principles"),
- b. Ensure the 'do no harm' principle is upheld in all human research projects reviewed, and that the protection of research participants' welfare and rights is of the utmost priority, and
- c. Facilitate human research, particularly social impact measurement research, that is or will be of benefit to the wider community.

## 1.2 Functions

The functions of the Huber Social HREC are to:

- a. Review each 'high-risk' human research project submitted as an independent body,
- b. Identify any potential conflicts of interest prior to review,
- c. Assess each project for compliance with the principles of ethical human research as set out in the National Statement, the Code, and Principles, including project methodologies and tools,
- d. Consider the ethical risks and benefits posed to participants of each aspect of the project, with particular attention to projects involving participants from marginalised social groups, including but not limited to:
  - i. Young people under the age of 18
  - ii. Aboriginal and/or Torres Strait Islander or other Indigenous Peoples
  - iii. People who are subject to cognitive impairment, intellectual disability or mental illness
  - iv. People who are victims of abuse or other physical or mental trauma
  - v. People who are subject to impaired capacity for communication
  - vi. People who are subject to monetary or in-kind inducements to participate in said research
- e. Promote open and free discussion of ethical assessments among the relevant Huber Social HREC members,

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<sup>1</sup> *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*. The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Available for download at [www.nhmrc.gov.au/guidelines/publications/e72](http://www.nhmrc.gov.au/guidelines/publications/e72)

<sup>2</sup> *Australian Code for the Responsible Conduct of Research 2018*. National Health and Medical Research Council, Australian Research Council and Universities Australia. Available for download at [www.nhmrc.gov.au/guidelines-publications/r41](http://www.nhmrc.gov.au/guidelines-publications/r41)



- f. Determine to approve, request more information, or withhold approval of research project, and whether to make recommendations or impose specific conditions attached to this decision,
- g. Communicate review decision in a timely and transparent method,
- h. Monitor ongoing research project measurement activities as necessary through reports, amendments, or other notifications,
- i. Receive and address any complaints or decisions appeals, and
- j. Provide routine updates to Huber Social HREC members on HREC activities, protocol updates, and other relevant information.

For human research projects considered to be 'low-risk,' an internal panel comprised of the Huber Social HREC Chair, Deputy Chair and Secretariat will be convened to carry out the above functions.

### 1.3 Scope

The responsibilities and functions of the Huber Social HREC apply to:

- a. Human research projects carried out by Huber Social staff,
- b. Human research projects carried out by Huber Social accredited consultants,
- c. Any client staff or other individuals who provide, conduct or support research activities of the aforementioned Huber Social human research projects, and
- d. Any external institutions seeking ethical approval of a human research project focussed specifically on undertaking social impact measurement (evaluation).

Huber Social HREC will accept another institution's HREC review and decision as sufficient ethical review, so long as the external institution is also an NHMRC registered HREC.



## 2. Membership

### 2.1 Composition

Huber Social HREC membership is established in accordance with the NHMRC National Statement. The committee will:

- a. Be comprised of at least eight members,
- b. Have an even mix of male and female members,
- c. Have no more than four internal (Huber Social) members,
- d. Meet the following membership requirements, as stated in the National Statement:
  - i. a chairperson with suitable experience,
  - ii. at least two lay people, one man and one woman, who have no affiliation with Huber Social and do not currently engage in medical, scientific, legal or academic work,
  - iii. at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people,
  - iv. at least one person who performs a pastoral care role in a community,
  - v. at least one lawyer, and
  - vi. at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.
- e. When necessary and deemed appropriate, the Huber Social HREC will be able to consult on ethical review of a project with a non-HREC member, provided they are considered to have the required expertise and have no conflict of interest with the project under review. These external experts will not have a vote in final approval decision.

### 2.2 Member appointment

#### 2.2.1 Recruitment requirements

- a. Members must be over the age of 18 years.
- b. Members must be able to demonstrate a deep understanding of:
  - i. Social and ethical issues in general,
  - ii. Social and ethical issues in specific areas of expertise,
  - iii. Social impact measurement approaches,
  - iv. Social and ethical issues and risks with respect to human research, and
  - v. Huber Social's vision and values
- c. Potential new members must apply to join the HREC using the HREC membership application form. Members will be asked to:
  - i. Detail their motivation for joining the HREC,
  - ii. Disclose any potential conflicts of interest, and



- iii. agree to fulfill member responsibilities.

### 2.2.2 Member selection

- a. Applications for new committee members must be reviewed by the Chair and Deputy Chair.
- b. They may use the new member criteria and evaluation matrix outline in the New Member Due Diligence form to assist in their assessment and decision making.

### 2.2.3 Member approval

- a. Appointment of each external Huber Social HREC Member must be approved by the Huber Social Board
- b. New members are advised via email by the Chair.
- c. Members are appointed for five-year terms and may serve no more than two terms with the committee.
- d. Extensions are permissible when necessary (i.e., while recruiting a new member to replace an outgoing member, or if said member has a unique expertise that is essential for the function of the HREC).

## 2.3 Member responsibilities

Upon acceptance of membership approval, HREC members are obliged to comply with the following responsibilities:

- a. New members must participate in a one-hour induction meeting with the Deputy Chair.
- b. Members must commit to a minimum level of participation in HREC activities:
  - i. Attendance at the Huber Social HREC annual meeting,
  - ii. Participation in at least three (3) review meetings per year, and
  - iii. Review and decision-making on at least three (3) human research projects per year.
- c. HREC members must maintain the currency of their knowledge with respect to the National Standards, the Code, and the Principles.
- d. HREC members are unpaid volunteers and may not receive financial compensation for their services.
- e. If a member is unable to fulfil these responsibilities, they may be eligible for dismissal from the HREC.

## 2.4 Leaving the HREC

- a. Members may leave the HREC at any time, either voluntarily or based on grounds for dismissal.
- b. The justifications for dismissal may include but are not limited to:
  - i. Failure to embody the values of Huber Social (integrity, communication, and adventure),
  - ii. Failure to meet the minimum requirements of participation in committee activities, or
  - iii. Failure to disclose a conflict of interest.
- c. Dismissal of an HREC member will be decided by the Huber Social Board in a simple majority vote.
- d. The HREC member in question will be notified of their dismissal via email and will have the opportunity to discuss this decision with the HREC Chair and Deputy Chair.

## 2.5 Liability Coverage for Members

- a. Huber Social accepts legal responsibility for all decisions and advice received from the Huber Social HREC members.



- b. As voluntary contributors to Huber Social research, Huber Social HREC Members are granted coverage under the Huber Social's Public Liability Insurance. Huber Social will provide legal protection in respect to any liabilities that may arise in the course of undertaking work as part of their Huber Social HREC Member duties, to the extent of this insurance.

## **2.6 Huber Social HREC Secretariat**

- a. To facilitate the function of the Huber Social HREC processes and governance, a Huber Social HREC Secretariat will also be established.
- b. Responsibilities will include administration of the review process, management of general correspondence, HREC review meeting scheduling, providing guidance in policies and procedures, and continued development of tools and templates.
- c. The secretariat will be comprised of one to two internal Huber Social staff, as needed and available.





## 3. HREC Meetings

### 3.1 Huber Social HREC Review Panels

- a. Due to the frequency of projects requiring review, a panel of members will be assembled to review each human research project.
- b. Panels consist of no less than five HREC members, including the Chair (or Deputy Chair), Secretariat, and at least three external Huber Social HREC members.
- c. Panel members are selected by the HREC Secretariat based on frequency of panels already served and topic of the project being reviewed.
- d. Depending on the subject matter of a project up for review, the Secretariat may ask specific HREC members with expertise in that topic to join the review panel that week, acceptance is not mandatory.

### 3.2 Frequency of meetings

- a. Huber Social HREC review panels are convened every two weeks, and last approximately one hour.
- b. HREC meeting panel assignments will be scheduled on a quarterly basis by the HREC Secretariat and meeting dates will be emailed to all HREC members no later than two weeks prior to the start of the next quarter.
- c. HREC members are responsible for notifying the HREC Secretariat of any scheduling conflicts well in advance of their appointed meetings.
- d. When a member is unable to participate in their scheduled project review, the HREC Secretariat will reschedule another member to maintain the necessary number of reviewers.
- e. If there are no projects to review at the time of a meeting, then the meeting may be cancelled.

### 3.3 Meeting attendance

- a. Attendance at the HREC review panel meeting is not mandatory, however it is encouraged.
- a. Members are required to confirm their ability to review and, if possible, attend the review panel meeting upon receiving the meeting agenda and project application materials.
- b. If a panel member is unable to attend a review meeting or believes that there may be a potential conflict of interest with the project being reviewed, they must communicate this conflict as soon as possible to the Secretariat so that a replacement panel member may be identified.
- c. If appropriate, the HREC review panel may invite other experts and or Project Leads to be present for the discussion of the proposed research. These external observers are not allowed a vote in the final decision.

### 3.4 Meeting agenda

- a. The agenda and application materials will be prepared and distributed by the HREC Secretariat.
- b. HREC project review meeting agenda and project application materials will be sent to panel members via email at least one week prior to the meeting.



- c. Each agenda will include, at minimum:
  - i. Date, time and location of meeting
  - ii. Names of panel member attendees
  - iii. Record of any disclosed conflicts of interests
  - iv. Reference number, name, and summary of project(s) up for review
  - v. Project application materials included in distribution

### 3.5 Meeting minutes

- a. The HREC Secretariat is also responsible for recording the minutes at each HREC review panel meeting, if they are unable to attend, then the Chair is responsible.
- b. Each meeting minutes will include, at minimum:
  - i. Date, time and location of meeting
  - ii. Names of panel member attendees
  - iii. Names of panel members absent
  - iv. Record of any disclosed conflicts of interests
  - v. Confirmation of quorum
  - vi. Reference number, name, and summary of project(s) up for review
  - vii. Discussion of ethical risks identified by panel members and potential strategies for mitigation
  - viii. Discussion of project benefits
  - ix. Motion for vote
  - x. Vote decision, including any specific conditions set as part of proposal
  - xi. Any other business
  - xii. Time of meeting close
- c. Minutes will be distributed to all panel members, including those who were not present due to scheduling conflict, for review and approval.
- d. All meeting minutes are kept confidential.

### 3.6 Meeting procedures

- a. Panel members should review the project application and supporting documents and submit a completed project assessment form (including decision recommendation) prior to the scheduled meeting.
- b. HREC project review meetings will take place online, with the objective of discussing any ethical concerns identified by panel members during their individual assessments of the project application and reaching a final decision on the ethical considerations of the project in question.
- c. If a panel member cannot attend the review meeting their views and recommendation will be presented by the Chair, based on the project assessment form completed by the member
- d. HREC decisions aim to be made unanimously, however, if necessary, a simple majority vote will determine the final decision. In the event of a tie, the Chair will make the final decision.
- e. Panel members may abstain from voting.
- f. The final decision will be recorded in the Decision Register and communicated to Project Lead via email by the HREC Deputy Chair within 48 hours of final decision being made.



- g. Where multiple projects are part of a larger program, the HREC may make separate decisions for each project and for the program as a whole.

### 3.7 Expedited meetings

- a. Expedited panel meetings may be convened by the Secretariat if a project review request meets one of the following criteria:
  - i. Delay of ethical review decision would have a severe negative impact on the remaining project timeline (i.e., make it no longer possible to collect baseline data from survey sample due to intervention commencement)
- b. An expedited review request must be made in the project assessment application by the Project Lead, along with justification for the expedited review.

### 3.8 Huber Social HREC Annual Meeting

- a. Once per year, the entire Huber Social HREC will be convened for a full committee meeting.
- b. During this meeting, members will have an opportunity to review existing policies and procedures, propose amendments or updates, and discuss any other relevant agenda items.
- c. Attendance at the Huber Social HREC Annual Meeting is mandatory for all members.

### 3.9 Conflicts of interest

- a. Upon joining to the Huber Social HREC, all members are responsible for declaring any existing potential conflicts of interest, financial or otherwise.
- b. It is the responsibility of the HREC member for updating the HREC Secretariat of any changes to their conflicts of interests, so that these can be recorded in their member file.
- c. A HREC member shall, as soon as practicable before the HREC panel review meeting, inform the HREC Secretariat if they have a potential conflict of interest in a project or other related matter(s) being considered in the meeting.
- d. The HREC Chair will determine if this results in a conflict of interest for the member and if so, the member will either:
  - i. Be removed from the review panel and replaced with another member who has no conflicts, in the event that there is only one project for review at that meeting, or
  - ii. Be asked to remove themselves from the meeting during the time for discussion and decision on the project or matters for which the member has reported the conflict. They will be allowed to return after the vote has been taken and will not be asked to assess any additional reviews related to said project.
- e. All declarations of conflict of interest will be noted in the HREC panel review meeting minutes.



## 4. HREC Project Application Review

### 4.1 Receiving new applications

- a. New applications for ethical review of any social impact measurement project (internal to Huber Social or external) must be submitted online through the Huber Social HREC Application Form.
- b. Applications must be submitted at least one week prior to the upcoming HREC panel review meeting to allow for sufficient time for project materials to be distributed to members and for them to complete their individual assessments before the meeting.
- c. For an application to be considered complete, the application must include the following:
  - i. Huber Social HREC Application Form completed to a sufficient standard such that the HREC review panel has enough information to make an informed decision.
  - ii. A project measurement plan:
    - A. For Huber Social measurement projects, the project's Measurement Plan in the standard Huber Social format and which has been approved by the project client.
    - B. For other measurement projects, clear documentation of the proposed need, objectives, methods, measurement activities, and limitations.
  - iii. The measurement tools that will be used:
    - A. For Huber Social measurement projects, a copy of the project's wellbeing survey.
    - B. For other measurement projects, a copy of the measurement tools that will be used, including surveys, focus group and interview guides, etc.
- d. Applicants are welcome to reach out to the HREC Secretariat for guidance on completing the application form.
- e. At the moment, applications for HREC review are free of charge but may be subject to a small fee in the future.

### 4.2 Multiple project applications

- a. Applicants may submit multiple projects for review, each should be submitted using a separate application form.
- b. Where multiple projects are part of a larger program, the review must consider the ethical issues and risks of each individual project and of the program as a whole.
- c. If any of the individual projects within a program is considered high-risk then the program must be considered high risk and subject to review by an HREC review panel (who must also review any low-risk projects included in the program).



### 4.3 Initial assessment

- a. The HREC Secretariat will make an initial assessment to determine project application's completeness, if any materials are missing or if the application is incomplete, the HREC Secretariat will communicate these findings to the Project Lead and advise on resubmission.
- b. Once complete, the HREC Secretariat will send the project application and materials to the HREC Deputy Chair for initial review to determine level of risk (low or high).
- c. If deemed low risk, the application will stay with the HREC Deputy Chair for further assessment and decision.
- d. If deemed high risk, the application and materials will be sent to the scheduled HREC review panel members for full assessment.
- e. Criteria for determining the risk level of project are contained in Table 3.1.

### 4.4 High risk application review

- a. High risk applications will be reviewed by all HREC review panel members individually before the scheduled HREC review panel meeting.
- b. Individual assessments will be submitted online using the Huber Social HREC Project Assessment Form, which requires members to
  - i. Assess whether there is sufficient information provided in the application form and materials to make an informed decision
  - ii. Assess the ethical risks and benefits of the project against the National Statement and Principles
  - iii. Make a recommendation with regard to approval of the project
- c. In the HREC review panel meeting, the Chair will present each project up for review by stating the name and providing a brief summary.
- d. The Chair will facilitate the review discussion such that all members are able to share their opinions on project risks and benefits.
- e. After full consideration of each project, the Chair will make a motion for a vote to be taken on one of four possible decisions:
  - i. **Grant approval to proceed**
    - A. The project is ethically acceptable, without any required modifications or additions.
  - ii. **Grant approval to proceed with specific conditions**
    - A. The project has successfully explained how it plans to mitigate potential ethical risks identified in the project plan, however, approval to proceed is contingent on specific conditions being met, as defined by the HREC review panel.
  - iii. **Withhold approval to proceed until further information is provided**
    - A. The HREC review panel may request additional information be submitted to further demonstrate successful mitigation of potential ethical risks or the extent of the benefits.
    - B. The project may not proceed until requested information has been submitted to the HREC Chair and Secretariat, and if necessary, the HREC review panel has reviewed and arrived at a new decision.
  - iv. **Deny approval to proceed –**
    - A. The HREC review panel will withhold approval when it believes the project has fundamental flaws that cannot be easily remedied and therefore requires rethinking the project approach from an ethical standpoint.



- B. The project may submit a new application if it can demonstrate that it has addressed these flaws, otherwise the project cannot proceed.
- f. If more information is requested, the Project Lead can share the additional information or materials directly to the HREC Chair. The HREC Chair will either circulate these materials to the HREC review panel members for ad hoc approval, or will make a decision on project approval if possible (i.e., if the requested additional information is minimal and satisfies the previous concerns identified by the HREC review panel members).
- g. If a project is denied, the Project Lead is invited to speak with the HREC Chair directly to further discuss the ethical risks identified and potential modifications that could be made to the project design such that the ethical risks are sufficiently minimised and are outweighed by the project's benefits.
- h. Exceptionally, a project decision may be delayed until more information is provided, at which point the HREC review panel will be assembled again to discuss the project.

#### 4.5 Low risk application review

- a. Low risk applications will be reviewed by the HREC Chair, Deputy Chair, and Secretariat.
- b. Low risk applications will be assessed in accordance with the standards set in the National Statement and the Principles.
- c. A review discussion will be held either in person or online, with a decision being agreed by consensus.

#### 4.6 Application decision communication

- a. Project review decisions are communicated to the Project Lead by the HREC Chair via email within 48 hours of a decision being made.
- b. If required, specific conditions will be set out in the decision notification with clear explanation for how these conditions should be met, documented and communicated to the HREC Chair.
- c. If additional information is requested, the decision notification will state what information is required and how it should be communicated to the HREC Chair or Secretariat.

#### 4.7 Project extensions, amendments or close out

- a. **Project extension** - As any project approval is for a set time period, if a project's measurement activities will not be finished within the period of the project's ethical approval, then the Project Lead must submit the Huber Social Project Extension form to continue with data collection. The HREC Chair will assess whether the proposed extension of time has any ethical implications beyond those already considered in the original approval and may then either grant approval or refer it the HREC for approval.
- b. **Amendments** - Any changes to measurement activities - including distribution timeline, measurement groups, or research tools - should be reported in writing to the HREC Deputy Chair and Secretariat. The HREC Deputy Chair will assess whether the proposed changes have any ethical implications beyond those already considered in the original approval then either grant approval or refer it the HREC for approval.
- c. **Close out** - Once a project's measurement activities have concluded, the Project Lead should submit the Huber Social Project Close Out form to record the termination of the HREC's ethical oversight.

#### 4.8 Reporting and handling of adverse events

- a. The HREC shall require that as a condition of approval of each project the Project Lead should report any significant ethical issues to the HREC in accordance with the guidelines in force with NHMRC.
- b. Adverse events should be notified to the HREC Secretariat for triage and management with the HREC Deputy Chair.



- c. Courses of action for handling adverse events will be dependent on the level of ethical risk associated with it.
- d. All adverse events reported and HREC responses will be recorded in the project's electronic record file.

#### 4.9 Monitoring research projects

- a. The HREC will monitor approved projects to ensure compliance with its ethical approval and any specific conditions set with that approval.
- b. The type of project monitoring is risk-based and can include:
  - i. Exception-based reporting
  - ii. Document audits
  - iii. Physical audits
- c. For projects whose measurement activity approval duration is longer than one year, the HREC will require annual progress report submissions from the Project Lead. These reports should include, at minimum:
  - i. Progress to date of the measurement activities,
  - ii. Evidence of compliance with specific conditions established in project approval, and
  - iii. Record of any adverse events or significant variations from the measurement plan.

#### 4.10 Withdrawal of ethical approval

- a. Where the HREC believes that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the original approval, the HREC may withdraw approval.
- b. In such circumstances, the HREC shall inform the principal investigator and the institution of such withdrawal of approval in writing (email) and recommend to the Project Lead that the project be discontinued, suspended, or that other necessary steps be taken.



**Table 1. Ethical Risk Categories**

RISK CATEGORY	KEY CRITERIA	REVIEW BODY
Low-Risk	<p>The only foreseeable risks are inconvenience or discomfort</p> <p>Measurement is non-invasive and based on:</p> <ul style="list-style-type: none"><li>• Surveys or questionnaires</li><li>• Interviews or focus groups</li><li>• Observation</li></ul> <p>Similar measurement approaches and tools have been used before, for example:</p> <ul style="list-style-type: none"><li>• Repeat measurements with the same client over time</li><li>• Measurement in a new location for an existing client</li><li>• Measurement for a new client in an existing sector (similar social impact models and question sets)</li></ul>	Reviewed internally by Huber Social HREC Chair, Deputy Chair and Secretariat
High-Risk	<p>Involves participants who are:</p> <ul style="list-style-type: none"><li>• Under the age of 18</li><li>• Indigenous</li><li>• Subject to cognitive impairment, intellectual disability or mental illness</li><li>• Victims of abuse or other physical or mental trauma</li><li>• Subject to impaired capacity for communication</li><li>• Subject to monetary or in-kind inducements to participate</li></ul> <p>Involves measurement in conditions that are:</p> <ul style="list-style-type: none"><li>• Remote or difficult to access</li><li>• Dangerous or unstable</li><li>• Difficult to monitor and verify</li></ul> <p>Involves measurement of programs or interventions that address sensitive or contentious issues such as:</p> <ul style="list-style-type: none"><li>• Suicide</li><li>• Drug addiction</li><li>• Eating disorders, body image</li><li>• Abuse, trauma or violence</li><li>• Discrimination</li></ul> <p>Requires significant development or testing of the measurement tools such as:</p> <ul style="list-style-type: none"><li>• An entirely new type of social impact model</li><li>• Translation into a new language or dialect</li><li>• Application in a new culture or novel measurement context</li></ul>	Review by set Huber Social HREC review panel





## 5. Reporting and Record Keeping

### 5.1 Reporting

- a. The Huber Social HREC will report annually to the NHMRC, through the Australian Health Ethics Committee (AHEC) per HREC registration requirements.
- b. In addition, the Huber Social HREC reports its activity to HREC members on a quarterly basis, and to Huber Social CEO and Board on a yearly basis.

### 5.2 Record keeping

- a. All review application materials are submitted online through the secure Huber Social HREC survey platform. Once applications and materials have been downloaded, the materials are stored in a secure electronic record system.
- b. All decisions are recorded in the Huber Social HREC Decision Register, and includes:
  - i. Project reference number
  - ii. Project title
  - iii. Project Lead name and institution
  - iv. Client name (if applicable)
  - v. Date of approval request
  - vi. HREC review outcome
  - vii. Project approval time period
  - viii. Specific conditions, if any
  - ix. Any amendments, extensions, or close out approvals
  - x. Any adverse events
  - xi. Any other comments or notes
- c. All project application materials, correspondence, and any other relevant documents are stored in the project's individual electronic record.
- d. All project assessments and correspondence between HREC Secretariat and members are stored in the project's individual electronic record.



## 6. Accountability

### 6.1 Accountability

- a. Huber Social HREC is only accountable for ethical review of the social impact measurement project being proposed, not the intervention or service that is being evaluated. However, Huber Social must be confident that the intervention or service being measured is an ethical undertaking and is being conducted by an ethical and reputable organisation.
- b. Huber Social HREC is accountable to the Project Leads/Primary Researchers of those human research projects submitted for ethical review:
  - i. To offer guidance and support on ethical approval application, including accessibility to all necessary resources,
  - ii. To provide a timely and transparent response when a decision has been made on the project status,
  - iii. To advise on concerns raised and strategies for mitigation, as appropriate, and
  - iv. To receive and address any complaints or requests made by the Project Lead/Primary Researcher with respect to an ethical approval decision.
- c. Huber Social HREC is accountable to the Huber Social CEO and Board:
  - i. To provide regular updates on HREC activities,
  - ii. To notify of any change in HREC membership, and
  - iii. To report any relevant issues or conflicts in a timely manner.
- d. Huber Social HREC is accountable to the HREC members:
  - i. To provide regular updates on HREC activities,
  - ii. To offer opportunities for continued learning and engagement with new ethical review processes, and
  - iii. To receive and address any complaints or requests made by HREC members.

### 6.2 Assurance

- a. On-going monitoring by the HREC may be built into the project approach or imposed by the HREC as a condition of approval.
- b. In addition, all projects must immediately notify the HREC Deputy Chair of any material changes to the approach, conditions or assumptions under which approval was granted.
- c. Any breach of the conditions of approval, no matter how small, must be immediately reported to the HREC Deputy Chair.
- d. Projects may also be subject to audit or review by at any time and without warning. The Huber Social HREC and its processes are also subject to audit.



### 6.3 Data privacy

- a. All records of the HREC, including applications, membership, training and compliance records, minutes and correspondence, will be kept as confidential files in accordance with the requirements of the Health Records and Information Privacy Act 2002 (HRIPA) and the State Records Act 1998.
- b. To ensure confidentiality, all documents provided to HREC members, which are no longer required, are to be disposed of in a secure manner.
- c. All project review applications, materials and data is stored locally in Australia.
- d. Any data pertaining to measurement projects shall be held for sufficient time to allow for future reference. The minimum period for retention for non-clinical research is at least 5 years after the date of publication or completion of the measurement activities or end of the study.



## 7. Complaints

### 7.1 Receiving and handling complaints about the conduct of research

- a. All complaints regarding the conduct of research will be sent to the HREC Secretariat at [ethics@hubersocial.com.au](mailto:ethics@hubersocial.com.au), this contact information must be presented on all research materials and tools used throughout the project.
- b. Complaints received will be acknowledged and reviewed by the HREC Deputy Chair.
- c. The Deputy Chair will initiate an investigation of the complaint and its validity and decide the appropriate course of action.
- d. If the complaint is substantiated, responding actions may include:
  - i. The requirement for amendments to the project, including increased monitoring by the HREC,
  - ii. Suspension of the project approval,
  - iii. Termination of the project approval, or
  - iv. Other action to resolve the complaint.
- e. The outcomes of the investigation will be communicated to the complainant.
- f. If the complainant is not satisfied with the outcome of the issue investigation, then the issue will be elevated to the Huber Social CEO for management and response.

### 7.2 Receiving and handling complaints about the HREC review process

- a. All complaints regarding the HREC review process will be sent to the HREC Secretariat at [ethics@hubersocial.com.au](mailto:ethics@hubersocial.com.au), this contact information is presented on all review application materials.
- b. Complaints received will be acknowledged and reviewed by the HREC Deputy Chair.
- c. The Deputy Chair will initiate an investigation of the complaint and its validity and decide the appropriate course of action, if the complaint is against the Deputy Chair, the Huber Social CEO will lead the investigation.
- d. The outcomes of the investigation will be communicated to the complainant.
- e. If the complainant is not satisfied with the outcome of the issue investigation, then the issue will be elevated to the Huber Social CEO for management and response.

### 7.3 Receiving and handling complaints about the HREC's decision to withhold approval

- a. All complaints regarding the conduct of research will be sent to the HREC Secretariat at [ethics@hubersocial.com.au](mailto:ethics@hubersocial.com.au), this contact information must be presented on all research materials and tools used throughout the project.
- b. Complaints received will be acknowledged and reviewed by the HREC Deputy Chair.
- c. The Deputy Chair will initiate an investigation of the complaint and its validity and decide the appropriate course of action.



- d. If the complaint is substantiated, responding actions taken by the HREC Deputy Chair may include:
  - i. Review of the project application, materials, and related documents,
  - ii. Reconvening of the HREC panel to review the risks and benefits identified and the justification for the final decision made,
  - iii. Convening of a secondary HREC review panel to assess the project application and materials and make a separate independent decision, and/or
  - iv. Revision of the previous decision made (if so, justification and the new decision will be recorded along with original decision made).
- e. The outcomes of the investigation will be communicated to the complainant.
- f. If the complainant is not satisfied with the outcome of the issue investigation, then the issue will be elevated to the Huber Social CEO for management and response.

