



INCLUDOVATE
INNOVATE FOR INCLUSION

Includovate's Human Research Ethics Committee Terms of Reference



Business for good

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1. General Overview

Includovate is a research incubator dedicated to developing solutions for issues of inequality and exclusion. Its approach involves designing interventions and utilising research to transform the social, political, economic, and environmental systems that perpetuate injustice. By employing the methodology of "systems change," Includovate tackles complex challenges that disproportionately impact marginalised and vulnerable communities. It adopts an action-oriented approach to change mindsets and structural conditions that keep unequal systems in place. The result is bespoke and manageable innovations that lead to lasting gender equality and social inclusion.

As a social enterprise, Includovate invests some of its profits into independent research. It builds the capacity of local researchers to lead, publish and improve the quality of the research performed in low-income countries. Includovate employs global south researchers to lead solutions design and collaborates with international experts who contribute to methodological excellence and theoretical knowledge. Includovate shifts the power balance of knowledge creation to those with less power by helping more researchers of the Global South publish.

Much of Includovate's research includes human participants. Utmost care shall be taken to ensure that the rights and interests of human participants are not compromised and that all research is carried out in an ethical manner.

To assist with this, Includovate has established an Includovate Human Research Ethics Committee (also known as HREC), which serves as an independent body and includes internal and external members). The HREC's primary purpose is to improve the quality of the research carried out by Includovate, and partners to protect the rights and welfare of research participants by applying ethical standards to all research. These guidelines set out how the HREC will come into effect and carry out its work effectively.

This TOR is adopted from the National Statement from the Institutional Human Research Ethics Committee (HREC) of the Australian National Health (later will be referred as the National Statement), as revised in 2023, especially its values and principles of ethical research.

2. Definitions/Abbreviations:

In this document, the following terms and abbreviations shall have the following meanings ascribed to them:

- **Human Research Ethics Committee (HREC):** The ethical review board responsible for assessing research proposals involving human participants at Includovate.



- **TOR:** Terms of Reference.
- **Unaffiliated Researchers:** Researchers who are not affiliated with Includovate but seek the ethical review of their research proposals by the HREC.
- **Multicenter research studies:** Studies conducted in more than one research location within one country or in multiple different countries.

3. Scope of Responsibility:

- The Includovate Human Research Ethics Committee (HREC) is responsible for the ethical review and oversight of research projects involving human participants. This includes but is not limited to the evaluation of research design, methodology, participant recruitment, informed consent procedures, data collection, data privacy of participants, as submitted by researchers affiliated or not affiliated with Includovate. HREC is responsible solely for ethical, not scientific review of projects, which is conducted by the client prior to application for ethical review. Includovate HREC also reviews multicenter research, making sure to adhere to the highest possible ethical standards.

4. Membership:

4.1: Composition

- HREC is an independent committee established by Includovate. It stands alone and is headed by a Chair. Its primary purpose is to protect the rights and welfare of research participants by applying ethical standards to all research.
- HREC comprises a team of members who are of different cultural and gender diversity who meet the requirements as per National Statement on Ethical Conduct in Human Research:
- The minimum membership of the HREC is eight and includes the following categories:
 - a) a chairperson with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out their obligations under the National Statement;
 - b) two people who bring a broader community or consumer perspective and who have no paid affiliation with the Includovate;
 - c) person(s) with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional;
 - d) a person who performs a pastoral care role in a community including, but not limited to, An elder or community leader, a chaplain or a minister of religion or other religious leader;
 - e) a qualified lawyer; and



- f) two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.
- In addition to the minimum requirements, Includovate has established a pool of qualified members, who are to fill in on a rotating basis in case any core member is not available.
- Most members are volunteers, however, the chair position is held by an Includovate staff member. This member performs the chair role as part of their paid employment with Includovate.

4.2 Application for Membership

- Includovate actively recruits HREC members when membership gets low by advertising on the public website: www.includovate.com and by putting advertisements on social media platforms such as LinkedIn.
- Application to become a member of the HREC is open all year long. Any interested candidate may send their application via [Includovate HREC Members Pool Registration Form](#). The Chair will be responsible for reviewing and vetting individuals who express interest in joining the HREC.
- Members are required to undergo detailed ethics training and sign non-disclosure agreements prior to becoming a member. Each member undergoes induction training and subsequent training according to the needs.

5. Delegation of Authority:

- The HREC may delegate specific tasks and responsibilities to subcommittees or designated individuals in the HREC as deemed necessary for efficient operations, in particular Includovate Safeguarding Committee in case of projects involving vulnerable groups, e.g. children or persons with disabilities. The Safeguarding Committee can be consulted on specific questions or tasked with close monitoring of research after HREC approval in order to ensure proper safeguarding of their rights. Delegation shall be conducted in accordance with established procedures and guidelines, with the HREC retaining ultimate accountability.

6. Review of Multicentre Research

- The HREC has established procedures for the ethical review and approval of multicentre research projects, ensuring coordination with other Ethics Committees when necessary. These procedures shall uphold ethical standards across all participating institutions.

The procedures shall be as follows:



i.Pre-submission stage:

- a. **Initial Contact:** When a multicentre research project is being developed, the lead researcher or research team should initiate contact with the HREC to inform them of the upcoming submission.
- b. **Preliminary Assessment:** The HREC will conduct a preliminary assessment to determine if the research meets the criteria for multicentre review. Criteria may include the involvement of multiple institutions, shared data, and multi-site recruitment.

ii.Submission stage:

- a. **Centralised Submission:** The lead researcher should prepare a centralised submission package that includes the research proposal, informed consent forms, participant recruitment materials, and any other relevant documents. This package should be submitted to the HREC.
- b. **Review Coordination:** The HREC will coordinate the review process across participating institutions. This may involve liaising with other ethics committees and ensuring consistent review criteria and timelines.

iii.Review and Evaluation:

- a. **Initial review:** The HREC will conduct an initial review of the submission to assess its ethical considerations, including participant recruitment, informed consent procedures, data handling, and potential risks.
- b. **Consultation:** The HREC may consult with other ethics committees or experts as needed to address specific aspects of the research.
- c. **Feedback and clarifications:** The lead researcher may receive feedback and/or clarification requests from the HREC regarding the research proposal.

iv.Ethical Approval and Conditions:

- a. **Approval decision:** The HREC will make a decision regarding the ethical approval of the multicentre research project. Approval may be granted with or without conditions.
- b. **Conditions:** If conditions are imposed, the lead investigator must address them before the research can proceed. Conditions may relate to participant protection, informed consent, data security, or other ethical concerns.



v. Communication:

- a. **Notification:** The HREC will notify the lead researcher of the approval decision, including any conditions and required revisions.
- b. **Communication to other Institutions:** The HREC will communicate the approval decision and conditions (if any) to the ethics committees of all participating institutions to ensure consistent oversight.

vi. Monitoring and Reporting:

- a. **Ongoing oversight:** The HREC, in coordination with participating institutions, will provide ongoing oversight of the multicentre research project to ensure compliance with approved ethical standards. The monitoring may be delegated to the Safeguarding Committee.
- b. **Progress reporting:** The lead researcher shall provide verbal or written progress reports to the HREC Chair, including any amendments or adverse events, in accordance with established reporting timelines.

vii. Amendments and Protocol Changes:

- Any significant proposed amendments or changes to the multicentre research project should be submitted to the HREC in writing for review and approval before implementation.

viii. Completion and Closure:

- Upon the completion of the multicentre research project, the lead investigator shall provide a final report to the HREC, summarising any issues.

7. Access to the HREC by Unaffiliated Researchers

- Unaffiliated researchers shall have the right to request the ethical review of their research proposals by the HREC. Procedures for submitting and reviewing research proposals from unaffiliated researchers shall be regularly updated and published on Includovate website.

8. Administrative Support:

- The HREC shall have access to administrative support staff designated to assist in its functions. The roles and responsibilities of administrative support staff, as well as those of HREC members, shall be clearly defined in the Standard Operating Procedures.

9. Appeals and Complaints:



- The HREC has established a transparent process for addressing appeals and complaints related to its decisions or actions. This process shall ensure that concerns and grievances are addressed promptly and fairly.

The transparent process for addressing appeals and complaints:

i.Submission of Appeals and Complaints:

- Open channels:** Includovate shall maintain open and accessible channels for individuals or organisations to submit appeals or complaints related to HREC decisions, actions, or processes. These channels may include email to Includovate Grievance Committee (Grievances@includovate.com), online forms, or designated contact persons.
- Submission timelines:** Appeals and complaints should be submitted within a reasonable timeframe (up to maximum 30 days) following the decision or action in question. The appeal or complaint will be addressed by an independent Grievance committee according to procedures as specified in Includovate Grievance policy.

ii.Initial review and acknowledgment:

- Receipt confirmation:** Includovate shall promptly acknowledge the receipt of appeals and complaints, providing a reference number or acknowledgment email to the complainant.
- Initial review:** An impartial Grievance Committee shall conduct an initial review to determine the validity and relevance of the appeal or complaint.

iii.Mediation and Resolution:

- Mediation attempt:** If appropriate and agreed upon by all parties, an initial attempt at mediation may be made to resolve the issue informally and promptly.
- Resolution process:** If mediation is not successful or if the issue cannot be resolved informally, a formal resolution process shall be initiated. This process may involve a designated committee.

iv.Investigation and Review:

- Comprehensive review:** The designated committee shall conduct a comprehensive and impartial review of the appeal or complaint. This may involve a review of relevant documentation, interviews with involved parties, and any necessary consultations.
- Timely review:** The review process should be conducted in a timely manner, with reasonable deadlines established for each stage of the investigation.



v. Decision and Recommendations:

- a. **Decision:** The designated committee shall make a decision based on the findings of the investigation. This decision may uphold the original HREC decision, modify it, or provide an alternative resolution.
- b. **Recommendations:** The committee may provide recommendations for process improvements or corrective actions if deemed necessary.

vi. Notification:

- Includovate shall communicate the decision or recommendations to the complainant in writing, outlining the reasons for the decision and any follow-up actions required.

vii. Right to Escalate:

- If the complainant remains dissatisfied with the resolution, they shall have the right to escalate the matter to a higher authority or external oversight body, if applicable.

viii. Documentation and Reporting:

- a. **Records:** Includovate shall maintain records of all appeals and complaints, including documentation of the resolution process, findings, and decisions.
- b. **Reporting:** Periodic reports summarising the number and nature of appeals and complaints, as well as their resolutions, shall be prepared and made available to the relevant oversight bodies.

ix. Continuous Improvement:

- Feedback from appeals and complaints shall be considered in ongoing efforts to improve HREC processes, policies, and decision-making.

10. Accountability and Reporting

- The HREC shall be accountable for its decisions and actions. It shall provide regular reports to Includovate's leadership, NHMRC and relevant oversight bodies, outlining its activities, decisions, and any issues or challenges encountered.

11. Document Control:

- The HREC shall implement document control procedures to maintain the integrity and confidentiality of sensitive information, including research proposals, meeting minutes, and



correspondence. These procedures shall encompass version control, access restrictions, and secure storage practices adhering to data protection principles. HREC Members are required to sign non-disclosure agreements and will be trained on safe data protection during initial training.