Scanlon Foundation Research Institute Human Research Ethics Committee Standard Operating Procedures

1. Frequency of Meetings

The Scanlon Foundation Research Institute Ethics Committee (*Scanlon Institute Ethics Committee* or *the Committee*) will meet at least biannually, with additional meetings scheduled as required to ensure the timely review of applications and efficient committee functioning.

2. Attendance at Meetings

a. Members are expected to attend all scheduled meetings.

b. Quorum must include a minimum of eight members, ensuring representation from each NHMRC-required category.

   i. In the event that all members of the Committee cannot attend (less than full attendance), the Chair is to request, in advance of the Committee meeting and in writing (via email), a copy of the absent members position on the project. At a minimum, this should include the member's position on the merit of the project, concerns with ethical conduct in reference to the National Statement, and their views on the project from their perspective relevant to their position on the Committee. This is to be circulated to all members prior to the meeting so the absent member's views can be considered within the discussion.

   ii. A final ethics review decision may only be made at a meeting that is properly constituted in accordance with the National Statement minimum membership requirements. Written comments provided by absent members are advisory only and do not constitute attendance for quorum purposes.

iii. Where there is less than full attendance of members from the minimum membership categories, the Chair must ensure that the views of the absent members have been received in writing and considered by all participating members before any decision is made.

iv. Where the minimum membership requirements are not met for a meeting, the Committee may discuss the matter for preliminary consideration only, but must defer any final decision until:

- The matter is considered at a properly constituted Committee meeting
- The matter is dealt with under an approved delegated review pathway, where delegation is permitted under this SOP.

v. The minutes must record whether the minimum membership requirements were met and, if not, what action was taken.

c. Absences must be communicated in advance, and a record of attendance maintained.

d. Members must send their written comments and questions to the Scanlon Institute Ethics Committee Secretariat one week in advance of any meeting that they are unable to attend.

3. Conduct of Meetings

a. Meetings will be chaired by the appointed Chair or, in their absence, the Deputy Chair.

i. Where the Deputy Chair acts as Chair for a meeting, that person may not simultaneously represent any other minimum membership category for that meeting. If another member is not present to represent that category, the Committee may discuss the matter but may not make a final decision at that meeting.

ii. The procedure outlined in section 2(b)(i) - (v) should be followed in this situation.

b. All deliberations shall be conducted respectfully and collaboratively, in accordance with the National Statement and the Institute's policies.

c. Meetings may be held in person or via videoconference to enable broad participation.

4. Preparation of Agendas and Minutes

a. Agendas are to be prepared by the Scanlon Institute Ethics Committee Secretariat, in consultation with the Chair, and circulated one week prior to the meeting.

b. Agendas will identify all matters for consideration, including new applications, amendments, monitoring reports, adverse events, complaints, delegated decisions, and any matters relating to suspension or withdrawal of approval.

c. Minutes will record:

   i. Attendance, apologies and whether minimum membership/quorum was met

   ii. The membership categories represented at the meeting

   iii. Declarations of interest, recusals, and whether a member was absent from discussion and decision-making

   iv. The key ethical issues discussed

   v. The decision made in relation to each matter

      - Decision will be one of the formal decision categories set out in section 12(e)

   vi. Reasons for the decision

   vii. Dissenting views, if any, and reasons for dissent

   viii. Delegated decisions reported to the Committee

   ix. Actions arising, responsible persons, and due dates.

d. Minutes will be drafted by the Secretariat, approved by the Chair, and distributed to members within one week of the meeting.

5. Timely Distribution of Meeting Papers

a. Meeting papers, including applications, supporting materials, and previous minutes, must be distributed to all members at least ten working days before the meeting.

b. Papers are to be provided via a secure platform to maintain confidentiality.

6. Timely Consideration of Applications

a. The Committee will meet at least biannually and may convene additional meetings, including by videoconference, where necessary, to ensure timely review of applications. Where the next scheduled meeting falls more than four

weeks after receipt of a complete application requiring full Committee review, the Chair may convene an additional meeting or place the matter before the next available properly constituted meeting.

b. Minor amendments and other matters listed in section 6(c) may be dealt with by delegated review in accordance with this SOP. Where there is uncertainty about whether a matter is suitable for delegated review, the Chair will refer it to the full Committee.

c. The Committee may delegate administrative handling of minor matters to the Secretariat, but any delegated ethics review or ethics decision must be undertaken by the Chair, Deputy Chair, or one or more nominated Committee members. Examples of matters that may be delegated include:

    i. Minor amendments that do not alter risk, participant population, consent processes, study aims, or data use in a material way

    ii. Administrative corrections

    iii. Responses satisfying conditions previously set by the Committee

    iv. Specified monitoring actions where no new ethical issue arises.

d. Matters that must not be finally determined by delegated review include:

    i. New applications requiring full Committee review

    ii. Substantial amendments that may alter the risk-benefit assessment

    iii. Rejection of an application

    iv. Withdrawal of ethics approval

    v. A recommendation to suspend research activities or institutional authorisation, other than urgent interim action taken for participant safety pending full Committee review

    vi. Any matter raising a new or unresolved ethical issue

e. Delegates may approve, request further information, or refer the matter to the full Committee. All delegated actions must be reported to the next Committee meeting. The Committee will determine which delegated actions require formal ratification and which are to be noted only.

7. Methods of Deliberation and Decision-Making

a. Decisions are made by consensus; unanimity is not required but efforts will be made to reach general agreement.

b. Diverse views are to be recorded in the minutes, and deviation from consensus will be recorded.

c. If consensus cannot be reached, the Chair may defer the decision to a later date or note a majority view with a record of dissent. This will be relayed in correspondence to the applicant.

8. Reviewing Applications from Unaffiliated Researchers

a. Applications from unaffiliated researchers will be reviewed under the same ethical criteria.

b. The Scanlon Institute Ethics Committee may charge a fee-for-service and require evidence of ethical training or governance frameworks.

c. All unaffiliated researchers must formally acknowledge the Institute's policies and conditions of approval.

9. Disclosure of Interests and Management of Conflicts

a. At the start of each meeting, members must disclose any actual, potential, or perceived conflicts of interest.

b. Conflicted members must abstain from the review and discussion of the relevant application and leave the meeting if required.

c. All disclosures and recusals will be documented in the minutes.

d. In the event that the Chair has a conflict of interest and must abstain from deliberation, the position of Chair will be held by the Deputy Chair for deliberation and communication related to the proposal.

10. Confidentiality of Applications and Deliberations

a. Members are bound by confidentiality obligations and must not disclose any information about applications, deliberations, or decisions outside the committee.

b. All members must sign a Deed of Confidentiality upon appointment.

11. Prompt Notification of Decisions

a. Applicants will be notified of the outcome of their submission within five working days of the meeting. Notifications will include the information set out in section 12(f), as applicable.

b. Decisions will be formally documented in accordance with section 12, including the reasons for the decision, any conditions, required actions, and applicable review or appeal options.

12. Communicating with Researchers

a. The Scanlon Foundation Research Institute website will provide the Secretariat's email address for users to contact. There will also be clear instructions provided for users regarding the application process, expected wait times, and communication that they should expect from the committee in potential outcome scenarios.

b. All communication must be respectful, constructive, and clear.

c. Feedback to researchers should be specific, referencing relevant ethical guidelines, and include suggestions for amendments where appropriate.

d. Researchers may request clarification and/or appeal decisions by contacting the Secretariat. Where possible, the Committee will endeavour to meet with the researcher in a face-to-face meeting to clarify the Committee's decision and resolve issues the applicant may have raised in their appeal.

e. The Committee may make one of the following decisions in relation to a submission:

    i. Approve

    ii. Approved subject to conditions or modifications

    iii. Request further information or clarification

    iv. Defer pending reconsideration at a future meeting

    v. Reject

    vi. Recommend suspension of research activities or institutional authorisation to the responsible institution

    vii. Withdraw ethics approval

f. Written notification to researchers will include, as applicable:

    i. The decision and date of decision

    ii. The reasons for the decision

    iii. Any conditions to be met and relevant timeframes

    iv. The approved document versions, where approval is granted

    v. Any ongoing monitoring or reporting requirements

    vi. Any right to seek clarification, reconsideration, appeal or make a complaint

g. Where proposals are rejected, or approval is withdrawn, the Committee's reasons for rejecting the proposal will be communicated to the researcher via an electronic letter (PDF) which explicitly states that the proposal did not meet the requirements of the National Statement with reference to specific clauses.

    i. Where proposals are rejected, the Committee will provide, in writing, a rationale for why the project does not meet either the provisions set out in the National Statement, or the Committee's Terms of Reference (i.e., the scope of research areas that will be considered by the Committee), or the Scanlon Foundation Research Institute's policies and procedures. The Committee will always endeavour to, if it is an in-scope research project and does not conflict with the Institute's policies, provide guidance on ethical research procedures to applicants and request modifications and/or meet with applicant. The Committee will always state in any letter of rejection of this sort that the applicant is welcome to request clarification or appeal a decision, as outlined in section 12(d).

    ii. Where approval is withdrawn, the Committee will provide, in writing, a rationale for why the project's ethics approval has been withdrawn with specific reference to why the Committee has reason to believe that any prior suspension and requested changes were not appropriately applied (if applicable) or if there is reason to believe that there are immediate safety concerns for the participants. The researcher will be made aware that if the research is to continue, they must reapply to the Committee and is subject to reapproval.

        - The Committee will notify the responsible institution of the research (e.g., the NGO or government body) that the ethics approval has been withdrawn, effective immediately, and the institution must ensure that the research is promptly halted. Furthermore, the institution will be informed of their requirement to ensure the safety of any impacted participants is secured and that the institution has an obligation to ensure the researcher has taken these steps.

h. Similarly, where proposals are approved, the Committee's reasons for approval will be communicated to the researcher via an electronic letter (PDF) that states the proposal did meet the requirements of the National Statement.

    i. Where proposals are approved, a letter of approval will be sent to the applicant from the Chair and/or Secretariat on behalf of the Committee.

    ii. The information will include reasons for approval (i.e., noting the benefit of the research considering the risks), an outline of why the risk mitigation

strategies are sufficient to protect participants (i.e., risk protocols in situations of distress). Additionally, it will also outline requirements for ongoing reporting, reporting of adverse events, safety reports, request procedures for minor or major amendments, and requirements to report any changes to the project. It will outline the situations where suspension of research activities or institutional authorisation may be recommended to the responsible institution, or where ethics approval may be withdrawn.

i. Where proposals are approved subject to conditions or modifications, the Committee's reasons for approval and ongoing conditions or modifications required will be communicated to the researcher via an electronic letter (PDF) that states the proposal did meet the requirements of the National Statement.

    i. The information will include reasons for approval (i.e., noting the benefit of the research considering the risks), an outline of why the risk mitigation strategies are sufficient to protect participants (i.e., risk protocols in situations of distress).

    ii. It will explicitly state the conditional nature of the approval and the modifications required for approval to be valid. Researchers will be made aware that if these conditions or modifications are not adhered to, their ethics approval may be suspended or withdrawn.

    iii. Additionally, it will also outline requirements for ongoing reporting, reporting of adverse events, safety reports, request procedures for minor or major amendments, and requirements to report any changes to the project. It will outline the situations where suspension of research activities or institutional authorisation may be recommended to the responsible institution, or where ethics approval may be withdrawn.

j. In the case of requested modifications, the Chair and/or Secretariat (on behalf of the Committee) may informally request a researcher via email or other correspondence to make a modification.

    i. Where only a minor further amount of information is requested, the applicant will be contacted and requested to make a modification. This could include things such as additional details about the research team, formatting issues, or minor referencing issues, or something similar that would not prevent the project from being approved.

    ii. Where a more substantial modification is required, the applicant will be contacted by the Chair and/or Secretariat requesting a meeting with the researcher and outlining the amendments required for the project to be

approved. The Committee believes that promoting transparency between the ethics application process and review process is fruitful for promoting better ethical conduct in research. If the applicant prefers to complete the amendment without meeting the Committee, they may do so.

k. Records of correspondence with researchers regarding minor modifications will be maintained in a secure spreadsheet specifically created for the proposal.

l. Communication between the Scanlon Institute Ethics Committee and research sponsors, including the Scanlon Foundation Research Institute, will be restricted so that it does not inappropriately influence the review, monitoring, suspension, withdrawal, or other ethics decision-making processes. This does not prevent the Committee from notifying the responsible institution, sponsor, or other relevant body where required for research governance, participant safety, adverse event management, complaints handling, suspension, withdrawal of approval, or other obligations under these SOPs or the National Statement.

13. Record Keeping

a. The Committee will maintain secure and complete records of:

   i. All submitted applications and supporting documents

   ii. Agendas, meeting papers and minutes

   iii. Attendance records, including membership categories represented

   iv. Declarations of interest and recusals

   v. All decisions, reasons, conditions and correspondence with researchers

   vi. Approved versions of study documents

   vii. Delegated decisions and any ratification by the Committee

   viii. Monitoring reports, annual reports, final reports and closure notifications

   ix. Protocol deviations, adverse events, complaints and investigations

   x. Any recommendation to suspend research activities or institutional authorisation, any urgent interim action, any withdrawal of ethics approval, and any associated notification to institutions or other bodies

b. Records will be stored securely, access will be limited to authorised persons, and records will be retained and disposed of in accordance with institutional policy and applicable legal requirements.

c. Proposals will be given a project number. Within the project number folder, sub-folders will be created titled:

i. Application

ii. Key information

iii. Amendments

iv. Communication

v. Meeting minutes relevant to proposal

d. For each research proposal, the minimum amount of information that will be recorded and stored in the 'Key Details' folder listed in section 13(c) is as follows:

i. Name of the institution responsible for which any ethics approval is applicable

ii. Project identification number

iii. Title of the project

iv. Name of the principal researcher/s

v. Any correspondence between the Committee and the researcher regarding the review, either ongoing or following a decision

vi. Outcome of the decision made by the Committee (i.e., approval, request for modification) and any amendments made following approval

vii. Terms and conditions, if applicable, to the approval of the proposal or amendment

viii. Duration of the approval

ix. Proposed date of the completion of the project

x. Progress reports

xi. Name of any other review body whose opinion was considered

xii. Approved mechanisms to be used to monitor the conduct of the research

xiii. Record of assessments relating to relevant Commonwealth, state or territory legislation regarding the privacy and security of personal information.

e. As stated above, for each proposal, the Secretariat will create a working spreadsheet that will log all communications with researchers over the course of the Committee's deliberation, approval or rejection. This also includes initial correspondence researchers make while submitting their proposal.

f. Records will be retained for a minimum of five years, or longer where required by law, institutional policy, funding agreement, regulatory requirement or the nature of the research.

14. Monitoring of Approved Research

a. All approved or authorised research will be monitored in a way that is proportionate to risk, but the responsible monitoring body will depend on which body conducted the substantive review and which institution holds governance responsibility.

    i. Low risk research reviewed and approved by an authorised single reviewer will be monitored through the delegated review pathway (see Section 1 of the Committee's Terms of Reference for review pathways). Monitoring will be proportionate to risk and may include amendment review, annual progress reports for multi-year projects, receipt of final reports, review of complaints, adverse events, protocol deviations, and requests for extension. Matters raising significant ethical concerns, participant safety issues, serious or continuing non-compliance, or possible recommendation to suspend research activities or institutional authorisation, or withdrawal of ethics approval must be escalated to the Chair and, where appropriate, the full Committee.

    ii. Greater than low risk research reviewed and approved by the full Committee will be monitored through the full Committee. Routine monitoring matters may be initially reviewed by the Chair or the Secretariat where the matter does not raise a new or significant ethical issue. Monitoring will include amendment review, annual progress reports for multi-year projects, receipt of final reports, review of complaints, adverse events, protocol deviations, and requests for extension. Matters raising significant ethical concerns, participant safety issues, serious or continuing non-compliance, or possible recommendation to suspend research activities or institutional authorisation, or withdrawal of ethics approval must be escalated to the full Committee.

b. Where the Committee or its delegate has not conducted a substantive ethics review (for example, where the project was authorised through an institutional governance process rather than reviewed by the Committee or an authorised Committee delegate), the Committee will not accept a delegated monitoring role; instead, monitoring must be undertaken through the responsible institution's governance arrangements.

c. Monitoring of approved research will be proportionate to the level of risk and nature of the project. Monitoring may include review of annual progress reports,

final reports, amendments, protocol deviations, serious or unexpected adverse events, complaints, requests for extension, safety reports, audit findings and any evidence of non-compliance.

d. Monitoring matters may be reviewed by the Chair or delegate where appropriate, but any matter raising a significant ethical issue, participant safety concern, or non-compliance that may affect participant safety, participant rights, or the ethical acceptability of the research must be escalated to the Chair and, where appropriate, referred to the full Committee. Matters involving possible recommendation to suspend research activities or institutional authorisation, or withdrawal of ethics approval must be referred to the full Committee.

e. Following review of monitoring information, the Committee or delegate may, within the limits of their authority under these SOPs:

    i. Note the report

    ii. Request further information

    iii. Require corrective action or modification

    iv. Impose conditions on continued approval

    v. Refer the matter to the full Committee for consideration of a recommendation to suspend research activities or institutional authorisation, or withdrawal of ethics approval

    vi. Take urgent interim action where necessary to protect participant safety, pending full Committee review

    vii. Notify the responsible institution or other relevant body where required

f. Researchers whose research is monitored by the Committee or through a Committee delegated review pathway are required to submit:

    i. Annual progress reports (for multi-year projects) including information on:

        - Progress to date or outcome if the project has been completed
        - The security of project-related data and information
        - Compliance with approved proposal
        - Compliance with any conditions of approval

    ii. Final reports upon completion

    iii. Amendments prior to implementation, submitted by researchers

    iv. Internal project audit reports or any audits of research documentation conducted by institutions or review bodies

g. The Committee will record meetings with researchers and monitor any actions arising from meetings.

h. Where interviews with research participants are conducted, the Committee will also monitor feedback from participants where provided. This will be requested from the researchers where applicable.

i. The Committee may request project updates or conduct audits if concerns arise.

j. In the event that researchers require ethics approval to continue after the original term of approval has expired, the researchers must request extension in writing to the Secretariat which will be forwarded to the Chair. In turn, the Chair will:

    i. Ensure that the researcher understands they must continue to conduct their research in a manner compliant with the original ethics approval granted by the Committee

    ii. Ensure the researcher understands they must continue to submit amendment requests to the Committee, including, but not limited to:

        - Those that may decrease immediate risks to participants
        - Those that may increase the risk to participants
        - Those that may change the scope of the project

    iii. In the event that the Chair understands that a major amendment must be made to the project for approval to continue, the researcher will be made aware of this in writing and will be required to submit a major amendment to the Committee.

k. If a project is to be discontinued before the expected date of completion, the researcher must contact the Secretariat in writing alerting the Committee to this, explaining explicitly why the project has been discontinued.

15. Reporting and Handling of Adverse Events

a. Researchers must report serious or unexpected adverse events, serious breaches and urgent participant safety concerns to the Secretariat (ethics@scanloninstitute.org.au) as soon as possible and within 72 hours. The Secretariat will immediately notify the Chair.

b. The Chair will conduct an initial assessment of the reported event and determine whether:

    i. No immediate action is required, and the matter can be considered through routine monitoring

ii. Further information is required urgently

iii. Immediate interim action is necessary to protect participants

c. Where there is an immediate safety concern, the Chair may take interim action, including requiring temporary suspension of recruitment or study procedures, pending review by the Committee at the earliest practicable opportunity.

d. The Committee will then determine whether to:

i. Continue approval unchanged

ii. Continue approval subject to conditions

iii. Require amendment or corrective action

iv. Recommend suspension of research activities or institutional authorisation to the responsible institution

v. Withdraw ethics approval

vi. Notify the responsible institution, sponsor, or relevant authority where required

e. Refer to Section 12 of the SOP for guidelines for communication with researchers, which will be followed in the case of an adverse event.

16. Receiving and Handling Complaints

Complaints about the conduct of research

a. Complaints about the conduct of approved research may be made by participants, researchers or third parties and should be directed to the Secretariat at ethics@scanloninstitute.org.au. The Secretariat will acknowledge receipt within five working days and refer the matter to the Chair for preliminary assessment.

b. Depending on the nature of the complaint, the matter may be:

i. Resolved through clarification

ii. Referred to the researcher for response

iii. Referred to the full Committee for consideration

iv. Referred to the responsible institution or another appropriate authority for investigation

c. Complaints that cannot be resolved through clarification or researcher communication will be referred to the Committee. Referral to the full Committee

and the calling of a special meeting if required will be at the discretion of the Chair's determination of the severity of the complaint.

d. The Chair or the full Committee will determine whether the complaint shows the researcher (including but not limited to):
    i. Has deviated from the approval protocol and research
    ii. The research has exceeded risk thresholds outlined in the research
    iii. The research has undergone an adverse event that was not reported to the Committee
    iv. Has breached the standards outlined in the National Statement
e. In all above situations, the complaints will be handled directly in accordance with the National Statement.
f. If the review concludes the complaint is legitimate and demonstrates one of the cases outlined above, the Committee will contact the researcher, provide details of the complaint as appropriate, seek a response, and then determine the outcome of the investigation.
    i. The investigation may result in a recommendation to suspend research activities or institutional authorisation, or withdrawal of ethics approval, in line with the processes outlined in section 17 and communicated to the researcher in line with section 15.
g. The Committee will protect the complainant's identity to the fullest extent possible, consistent with a fair and proper investigation of the complaint.
h. The outcome of the complaint will be communicated via email in written form to the complainant, explaining the reasons for the decision that has been made, and contacts for other relevant services if required.

Complaints about the conduct of the Committee

a. Complaints about the conduct of the Committee, a reviewer, or the ethics review process should be directed to the Institute's contact officer at info@scanloninstitute.org.au, who is independent of the Committee's decision-making in the matter. Such complaints will be managed separately from the Committee review of the project.
b. The complainant will be advised of the outcome and of any available further review pathway. A complainant must not be disadvantaged for making a complaint in good faith.

c. Complaints will be sent for review to the CEO of the Scanlon Foundation Research Institute, noting the CEO of the Institute is external to the ethics Committee.
d. The Committee will not be notified of the complaint until investigated by the CEO in the first instance. The CEO will determine whether the complaint:
    i. Relates to ethical review processes
    ii. Requires escalation to the Institute's legal team
e. Following initial investigation and communication with the complainant, the CEO will attempt to resolve the issue between the complainant and the Committee through convening a special meeting.
    i. This will only occur if the complainant is willing to discuss and meet with the Committee
        - In the event the complainant does not want to discuss the matter with the Committee, the complaint may be referred to an external assessor.
    ii. This special meeting will be convened and conducted by the CEO of the Institute
f. In the case that conflict resolution cannot be reached through communication between the Committee and the complainant, the Institute may refer the complaint to an external assessor.
g. Where the CEO has an actual, potential or perceived conflict of interest, the complaint will be referred to an independent external assessor or other appropriately independent person.
h. The outcome of the investigation will be communicated via email in written form to the complainant, explaining the reasons for the decision that has been made, and contacts for other relevant services if required.

17. Decisions to Suspend or Withdraw Approval

a. The Committee may consider whether research activities or institutional authorisation should be suspended by the responsible institution, and/or whether ethics approval should be withdrawn by the Committee, where it has reason to believe that:
    i. Continuation of the research may compromise participant welfare
    ii. Participant safety is at risk
    iii. The research is not being conducted in accordance with the approved protocol, project description, conditions of approval, or reporting requirements

iv. Required reporting has not occurred

v. Serious or continuing non-compliance is identified

vi. There has been a serious or unexpected adverse event, serious breach, protocol deviation, or complaint that affects the ethical acceptability of the research

vii. New information changes the risk-benefit assessment or ethical acceptability of the project

viii. Amendments required to protect participants have not been made, are not sufficient, or cannot adequately address the concerns identified

b. Concerns that may give rise to suspension or withdrawal may be identified through monitoring reports, annual or final reports, adverse event reports, complaints, audit findings, protocol deviation reports, researcher correspondence, information from the responsible institution, or any other credible source.

c. Where a concern is identified, the Chair will conduct an initial assessment to determine whether:

i. No immediate action is required, and the matter can be managed through routine monitoring

ii. Further information is required from the researcher, responsible institution, sponsor, or another relevant party

iii. Corrective action or amendment may be sufficient to address the concern

iv. Urgent interim action is required to protect participant safety or welfare

v. The matter must be referred to the full Committee for consideration of suspension or withdrawal of approval

d. The Chair may require urgent interim action where necessary to protect participant safety or welfare, including temporary suspension of recruitment, data collection, contact with participants, or other research activities. Any urgent interim action taken by the Chair must be referred to the full Committee for review at the earliest practicable opportunity.

e. Where suspension of the research is considered necessary, the instruction to stop research activities will be issued by the management of the responsible institution. The Committee may recommend suspension or require the matter to be escalated to the responsible institution, but the instruction to stop research activities must come from the responsible institution.

f. Except for urgent interim action taken to protect participant safety or welfare, a decision to recommend suspension of research activities or institutional authorisation to the responsible institution, or to withdraw ethics approval, must be made by the full Committee. Such decisions must not be finally determined by delegated review.

g. Before making a final decision to recommend suspension of research activities or institutional authorisation to the responsible institution or withdraw ethics approval, unless immediate action is required to protect participants, the Committee will provide the researcher with:

    i. Written notice of concerns

    ii. The information on which the concerns are based, to the extent appropriate and lawful

    iii. An opportunity to respond or provide further information

    iv. Any proposed corrective actions, amendments, or conditions that may be required

    v. The time frame for the response

h. The Committee will consider any response provided by the researcher before making a final decision. The Committee will ensure that the researcher and others involved in the project are treated fairly and with respect.

i. Following consideration of the matter, the Committee may decide to:

    i. Allow the research to continue unchanged

    ii. Allow the research to continue subject to conditions

    iii. Require further information

    iv. Require corrective action

    v. Require submission of an amendment

    vi. Require increased monitoring or more frequent reporting

    vii. Recommend suspension of research activities or institutional authorisation to the responsible institution

    viii. Withdraw ethics approval

    ix. Notify the responsible institution, sponsor, or relevant body where required

j. Where suspension of research activities or institutional authorisation is recommended to the responsible institution:

    i. The researcher, the responsible institution, and, where possible and appropriate, participants will be informed of the suspension

    ii. The responsible institution must ensure that the researcher promptly suspends the relevant research activities

    iii. Arrangements must be made to protect the welfare, rights and interests of participants, including appropriate support, referral, counselling, continued standard care, or other measures where relevant

    iv. The Committee will specify the reasons for suspension, the activities that must stop, any activities that may continue for participant safety or welfare, any corrective actions required, and the process for seeking reinstatement of approval

    v. The research must not resume unless the Committee is satisfied that the concerns that led to suspension have been adequately addressed, the research will not compromise participant welfare, and the responsible institution authorises continuation

k. A recommendation for suspension may be withdrawn, and the responsible institution may authorise research to recommence, where:

    i. The researcher has provided sufficient information to address the Committee's concerns

    ii. The project has been modified to provide sufficient protection for participants

    iii. Required corrective actions or amendments have been completed and approved

    iv. The Committee is satisfied that continuation of the research is ethically acceptable

    v. The responsible institution authorises the continuation of the research

l. Where the Committee determines that suspension, amendment, corrective action or additional conditions cannot adequately protect participants or address the ethical concerns, the Committee may withdraw ethics approval.

m. Where ethics approval is withdrawn:

    i. The researcher, the responsible institution, and where possible and appropriate, participants will be informed of the withdrawal

ii. The researcher must promptly halt the research

iii. The researcher must make arrangements to protect the welfare, rights and interests of the participants, including appropriate support, referral, counselling, continued standard care, or other measures where relevant

iv. The researcher must notify the responsible institution(s) that the research has been halted and that participant welfare arrangements have been made

v. The research must not continue under the withdrawn approval

vi. Continuation or recommencement of the research will require submission of a new ethics application and re-approval by the Committee or other appropriate review body before any research activities recommence

n. Written notice of a recommendation to suspend research activities or institutional authorisation, or a decision to withdraw ethics approval, will include:

i. The decision and date of decision

ii. The reasons for decision, including reference to relevant ethical concerns and where applicable, relevant provisions of the National Statement

iii. Any immediate actions required

iv. Any requirements for participant safety, welfare, communication or support

v. Any corrective actions, amendments, conditions or reporting requirements

vi. Whether and how the recommendation for suspension may be withdrawn, and how research activities or institutional authorisation may be reinstated, in the case of suspension

vii. Whether a new ethics application and re-approval is required, in the case of withdrawal

viii. Any opportunity to seek clarification, reconsideration, appeal or make a complaint

o. Any recommendation to suspend research activities or institutional authorisation, or any withdrawal of ethics approval, including the reasons for the decision, actions required, correspondence with the researcher, notification to the responsible institution or other body and any participant welfare

arrangements, must be recorded in the Committee's minutes and retained on the Committee file in accordance with section 13.

p. Where a project has been approved through a delegated review pathway, any concern that may require suspension or withdrawal must be escalated to the Chair and referred to the full Committee, except where urgent interim action is necessary to protect participant safety or welfare pending full Committee review.

q. This section should be read together with section 14 on monitoring, section 15 on adverse events, section 16 on complaints, and section 12 on communication with researchers.

18. Attendance of Non-Members at Meetings

a. Non-members (e.g. researchers, experts, observers) may attend by invitation from the Chair.

    i. Individuals with specialised scholarly expertise (including research methods)

    ii. Individuals with specialised technical expertise, such as statisticians

    iii. Individuals with expertise related to participant groups, including participant advocates

    iv. Individuals with expertise related to research contexts, such as community care

b. Non-members may provide advice or information when invited by the Chair but must not participate in Committee deliberations or decision-making.

c. Non-members must:

    i. Declare any conflicts of interest

    ii. Sign a confidentiality agreement

    iii. Only be present for relevant agenda items