VICTORIA UNIVERSITY

VICTORIA UNIVERISTY HUMAN RESEARCH ETHICS COMMITTEE

Standard Operating Procedures

July 2026
Version1.0

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NOTE:
These Standard Operating Procedures provide the operational procedures by which the Victoria University Human Research Ethics Committee (VUHREC) fulfils its responsibilities under the VUHREC Terms of Reference.

Where inconsistencies arise, the Terms of Reference define the Committee's governance, authority, membership and accountability arrangements, while these SOPs provide detailed operational guidance.

Both documents should be read together and interpreted consistently with the National Statement on Ethical Conduct in Human Research (2025).

SOP 1 COMMITTEE ADMINSTRATION

1. Purpose

To define the administrative, procedural, and governance requirements for the effective operation of the Victoria University Human Research Ethics Committee (VUHREC). This SOP ensures consistency, transparency, compliance with the National Statement (2025), and alignment with institutional governance frameworks. This SOP should be read in conjunction with the VUHREC Terms of Reference, which establishes the Committee's authority, membership requirements, delegated responsibilities and reporting obligations.

2. Roles and Responsibilities

2.1 Chair

- Approves agenda and meeting schedule
- Oversees meeting conduct
- Oversees conflict-of-interest declarations
- Makes procedural rulings
- Exercises casting vote
- Approves provisional decisions
- Ensures compliance with National Statement and VU policies

2.2 Deputy Chair

- Acts in Chair's absence
- Supports Chair in managing complex reviews

2.3 Secretary / Ethics Officer

- Manages Quest submissions
- Conducts pre-review screening
- Prepares agenda and meeting papers
- Records minutes
- Processes decisions in QUEST
- Maintains records and correspondence
- Tracks monitoring requirements

2.4 Committee Members

- Review assigned applications
- Declare conflicts of interest
- Attend meetings and contribute to deliberations
- Maintain confidentiality
- Participate in training

3. Meeting Scheduling

3.1 Annual Schedule

- VUHREC meets monthly except for January (minimum 10 meetings per year).
- Schedule published annually on the VU Human Research ethics website.
- Additional extraordinary meetings may be convened by the Chair.

3.2 Submission Deadlines

- Prereview submission deadline: **21 calendar days before meeting**.
- Late submissions accepted only with Chair approval.
- Submissions requiring specialist expertise may be deferred.

4. Agenda Preparation

4.1 Compilation

The Ethics Secretary:

- Extracts all submissions from Quest flagged as “Ready for Review”.
- Confirms screening is complete (see **SOP 4**).
- Categorises items:
    - New applications
    - Withheld applications
- Assigns lead reviewers based on expertise and workload.
- Identifies conflicts of interest using:
    - Quest records
    - Member declarations
    - Institutional relationships

4.2 Chair Review

The Chair:

- Reviews agenda order
- Confirms reviewer assignments
- Approves final agenda

4.3 Distribution

- Agenda and papers distributed **7 days before meeting**.
- Distribution via secure channels

4.4 Late Items

- Late items require Chair approval for inclusion in meeting
- Criteria for acceptance:
    - Time-sensitive research (e.g., clinical trial activation)
    - Institutional priority
- If not accepted, item is deferred to next meeting.

5. Meeting Papers (Operational Requirements)

5.1 Mandatory Components

Each application file must include:

- Application form
- Participant information and consent materials
- Recruitment materials
- External approvals (if applicable)

5.2 Security Requirements

- All papers treated as **CONFIDENTIAL – VUHREC USE ONLY**.

- Digital papers stored in Quest/Research Master with restricted access.

5.3 Version Control

- Secretary ensures version numbers are consistent.

6. Meeting Conduct

6.1 Quorum

- Minimum membership as required by National Statement (2025):
    - Chair or Deputy Chair
    - Lay member
    - Professional care provider
    - Legal or governance member
    - Researcher member
    - VU Quorum for a meeting is 8 members
- If quorum is lost during meeting, decisions cannot be made during that time

6.2 Conflict of Interest Management

- Members declare conflicts at start of meeting.
- Chair determines management action:
    - Declaration and withdrawal for the relevant review
    - No withdrawal (if conflict not material)

6.3 Meeting Etiquette

- Members must:
    - Read papers in advance
    - Speak through the Chair
    - Use respectful language
- Chair may pause meeting to manage conduct.

7. Minutes

7.1 Content Requirements

Minutes must include:

- Date, time, location
- Attendance and apologies
- Conflicts of interest and management
- Summary of discussion
- Decision type
- Conditions of approval
- Action items and responsible persons
- Procedural notes (e.g., quorum changes)

7.2 Drafting Timeline

- Draft minutes prepared within **14 days** of meeting.
- Final minutes approved at next meeting.

7.3 Storage

- Minutes stored in Quest.
- Access restricted to authorised staff.

8. Decision Communications

8.1 Timeline

- Decisions issued within **10 working days** of meeting.
- Sent via Quest

9. Confidentiality Requirements

9.1 Member Obligations

Members must:
- Not disclose application content
- Not discuss deliberations outside meetings

9.2 Breach Management

Breaches may result in:
- Removal from Committee
- Mandatory retraining
- Notification to institutional leadership
- Review under VU misconduct procedures

10. Training

10.1 Mandatory Training

All members must complete:
- Training as required by the Chair

SOP 2 - RISK ASSESSMENT AND REVIEW PATHWAY DETERMINATION

1. Purpose

To provide a detailed, operationalised framework for assessing risk in human research proposals and determining the appropriate review pathway (Low Risk Panel or Full HREC). This SOP ensures consistent application of the National Statement (2025), supports defensible decision-making, and provides clear procedural guidance for staff, reviewers, and investigators. Delegation of review responsibilities to low-risk review pathways is authorised under the VUHREC Terms of Reference.

2. Roles and Responsibilities

2.1 Chair

- Makes final determination on review pathway.
- Escalates applications where risk is underestimated.
- Provides procedural guidance on borderline cases.
- Ensures risk assessment aligns with National Statement (2025).

2.2 Secretary / Ethics Officer

- Conducts initial risk screening.
- Flags risk indicators in Quest.
- Identifies when specialist expertise is required.

2.3 Committee Members

- Contribute to risk determination during meetings.
- Identify overlooked risks or contextual issues.
- Ensure risk assessment is consistent with ethical principles.

3. Risk Assessment Workflow

3.1 Initial Screening (Secretary)

- Initial Review application and protocol.
- Identify risk indicators
- Categorise risk as:
    - Minimal/Low
    - More than low
- Flag any uncertainty for Chair review.
- Send back to researcher if any essential information/attachment appears to be missing
- Assign to Low-Risk Panel or VUHREC review

3.2 Reviewer Assessment

- Review full application and supporting documents.
- Assess:
    - Methodology

    - Participant population
    - Data sensitivity
    - Psychological, physical, social, cultural risks
    - Mitigation strategies
- Compare risk level with National Statement definitions.

4. Risk Categories

4.1 Low Risk Research

Research may be classified as **Low Risk** where the only foreseeable risk is one of inconvenience or mild discomfort to participants (National Statement, 2025).

Examples:

- Short online surveys
- Non-sensitive interviews
- Interviews on non-sensitive personal experiences
- Focus groups discussing general topics
- Observational studies in public settings
- Benign behavioural tasks
- Non-invasive physiological measures (e.g., heart rate monitors)
- Secondary data analysis of de-identified datasets

Indicators:

- No foreseeable harm beyond inconvenience or mild discomfort
- No highly sensitive topics
- Non-sensitive personal questions only
- No vulnerable populations requiring higher-level review
- No deception likely to cause distress
- No invasive physical procedures
- Minimal privacy risks

4.3 More Than Low Risk (Any Plausible Harm)

Examples:

- Trauma-related interviews
- Psychological interventions
- Clinical procedures
- Research involving First Nations communities
- Research involving illegal activities
- Genetic research
- Research with dependent relationships

Indicators:

- Potential for distress, harm, or coercion
- Sensitive topics
- Vulnerable populations
- Deception or concealment
- Physical risk
- Cultural or community-level impact

5. Criteria for Full HREC Review

5.1 Intrusive Techniques

- Invasive medical procedures
- Psychological interventions (e.g., trauma recall, exposure tasks)
- Deception or concealment
- Covert observation
- Use of physiological stressors
- Collection of biological samples

5.2 Sensitive Topics

- Trauma, abuse, violence
- Sexuality or sexual behaviour
- Mental illness
- Substance use
- Illegal activities
- Discrimination or stigmatisation
- Cultural identity or community-level issues

5.3 Vulnerable Populations

- Children and young people
- People with cognitive impairment
- People highly dependent on medical care
- People in dependent relationships (students, employees, patients)
- Aboriginal and Torres Strait Islander Peoples (in some instances)
- People involved in illegal activities
- People in other countries (in some instances)
- Pregnant women and foetuses
- Refugees or asylum seekers
- People experiencing homelessness

5.4 Special Research Types

- Clinical trials
- Innovative therapies
- Human genetic research
- Human tissue research
- Ionising radiation
- Assisted reproductive technology
- Research requiring specialist expertise (e.g., neuroimaging, AI-driven behavioural manipulation)

6. Escalation Procedures

6.1 When Escalation Is Required

Escalation occurs when:

- Risk is underestimated
- New information emerges
- Reviewer identifies additional risk
- Participant population changes
- Protocol changes increase risk
- Investigator experience is insufficient

- Data sensitivity is higher than initially assessed

8. Risk Screening Checklist

8.1 Participant-Related Risks

- Vulnerable population involved?
- Dependent relationship present?
- Cultural considerations required?
- First Nations participants?
- Minors (under 18years) involved?
- People with cognitive impairment?

8.2 Topic-Related Risks

- Sensitive topics?
- Trauma or distress likely?
- Illegal activities?
- Stigmatised experiences?

8.3 Method-Related Risks

- Deception?
- Covert observation?
- Psychological intervention?
- Physical procedures?
- Biological sample collection?

8.4 Data-Related Risks

- Identifiable data collected?
- Sensitive data collected?
- High-risk storage or transfer?
- Cloud storage outside Australia?

8.5 Researcher-Related Risks

- Inexperienced investigator?
- Insufficient supervision?
- Lack of cultural competence?

8.6 Contextual Risks

- International sites?
- Community-level impact?

9. Documentation Requirements

9.1 Required in Quest

- Risk category
- Any Screening notes
- Reviewer comments
- Chair determination

9.2 Required from Researcher

- Where deemed relevant, detailed risk mitigation plan
- Safety procedures
- Distress protocols
- Cultural consultation evidence
- Note: A Data Management Plan is a general research requirement required for **all** researchers conducting research at Victoria University, (not just those conducting research involving human participants)

SOP 3 – COMMITTEE DECISION MAKING

1. Purpose

To provide a comprehensive, operational framework for how the Victoria University Human Research Ethics Committee (VUHREC) makes decisions on human research ethics applications. Decision-making authority derives from the powers delegated to VUHREC through the Terms of Reference and the Deputy Vice-Chancellor (Research & Impact).

This SOP ensures decisions are:

- consistent
- transparent
- defensible
- compliant with the National Statement (2025)
- auditable
- procedurally robust

2. Roles and Responsibilities

2.1 Chair

- Oversees deliberation and ensures procedural fairness.
- Determines when consensus has been reached.
- Calls votes when required.
- Exercises casting vote in ties.
- Ensures decisions are consistent with precedent and policy.

2.2 Deputy Chair

- Supports Chair
- Acts as Chair when Chair is absent.

2.3 Secretary / Ethics Officer

- Records decisions and rationales in minutes.
- Ensures minutes accurately reflect Committee determinations.
- Tracks amendments required and follow-up requirements.
- Ensures decisions are entered correctly in Quest.

2.4 Lead Reviewer(s)

- Present summary of application and key ethical issues in meeting.
- Provide recommendation (approve, modify, defer, reject).
- Identify unresolved ethical concerns.
- Respond to Committee questions.

2.5 Committee Members

- Participate in discussion and deliberation.
- Raise ethical concerns or contextual issues.
- Ensure decisions align with ethical principles and institutional values.

3. Decision Types

3.1 Approved

Application meets ethical requirements with no further changes required.

3.2 Minor or Major Amendments required

Application is ethically acceptable subject to specific conditions, such as:

- minor wording changes
- clarification of procedures
- updated consent materials
- additional safety measures

3.3 Withheld

When an application cannot be approved in its current form and requires significant further information, clarification, or amendments before it can be reconsidered. The revised application must return to the full Committee.

Used when:

- Significant clarification is required
- required documents are missing or incomplete
- risk mitigation strategies require further detail or strengthening
- recruitment, participant information, or consent processes require clarification and amendment
- aspects of the research design or protocol require modification
- the Committee requires additional information to determine whether the ethical requirements for approval have been met

3.4 Rejected

Application cannot be ethically approved. Used rarely and only when:

- risks cannot be mitigated
- methodology is fundamentally unethical
- participant welfare cannot be protected
- research contravenes National Statement principles

This must be reported in annual government reports

4. Decision-Making Workflow

4.1 Presentation of Application

- Lead reviewer presents summary.
- Secondary reviewer adds comments
- Chair invites input from members.

4.2 Deliberation

- Chair facilitates structured discussion:
  - Ethical issues
  - Risk mitigation
  - Participant welfare
  - Consent processes
  - Data security
  - Cultural considerations
- Members raise concerns or request clarification.
- Chair confirms whether consensus is emerging.

4.3 Determination of Decision Type

- Chair proposes a decision type.
- Committee indicates agreement or disagreement.
- If consensus is not reached, Chair calls a vote.

4.4 Voting Procedure

- Simple majority required.
- Chair has deliberative vote.
- Chair has casting vote if tied.
- Secretary records:
  - vote outcome
  - any abstentions
- Members may abstain if:
  - They feel insufficiently informed
  - They have minor conflict concerns
  - They are uncomfortable with the decision but not opposed

4.5 Finalisation

- Chair states final decision.
- Secretary records decision and rationale.

4.6 Submission of Comments

Absent members may submit written comments:

- via email to Secretary
- ≥48 hours before meeting

4.7 Use of Comments

- Comments inform deliberation.
- Comments do not constitute a vote.
- Comments must be recorded in minutes.

SOP 4 – SUBMISSION REQUIREMENTS AND PRE-REVIEW

1. Purpose

To ensure all human research ethics applications submitted to VUHREC are complete, compliant, and ready for review. This SOP provides detailed operational guidance for:

- researchers preparing submissions
- Ethics Officers conducting screening
- Chairs determining review pathways
- Committee members relying on accurate pre-review checks

This SOP ensures consistency, efficiency, and compliance with the National Statement (2025) and VU governance requirements.

2. Roles and Responsibilities

2.1 Researchers

- Submit complete, accurate applications.
- Ensure all required documents are uploaded.
- Respond promptly to queries.
- Provide evidence of approvals, checks, or training.
- Ensure version control across all documents.

2.2 Secretary / Ethics Officer

- Conduct detailed pre-review screening.
- Verify completeness and compliance.
- Identify conflicts of interest.
- Determine eligibility for low-risk review.
- Flag issues requiring Chair attention.
- Document screening outcomes in Quest.

2.3 Chair

- Confirms review pathway.
- Resolves borderline eligibility cases.
- Determines whether specialist expertise is required.
- Approves deferral of incomplete submissions.

3. Submission Requirements

Researchers must submit the following documents **in Quest**, with correct version numbers and clear file naming conventions:

3.1 Core Documents

- Completed VU HREC Application Form
- Participant Information Sheet (PIS)
- Consent Form (CF)
- Recruitment materials (emails, posters, scripts)
- Distress Protocol (if applicable)

- Cultural consultation evidence (if applicable)
- Insurance documentation (if required)
- Contract documentation (if applicable)

3.2 Additional Documents (Conditional Requirements)

3.2.1 For research involving children

- Working with Children Check (WWCC)
- Child-safe procedures
- Parental consent processes

3.2.2 For research involving First Nations participants

- Evidence of cultural consultation
- Community engagement plan
- Indigenous governance approval (if required)

3.2.3 For clinical or medical research

- Investigator qualifications
- Safety monitoring plan
- Adverse event reporting procedures

3.2.4 For international research

- Local ethics approval (if applicable)
- Translation certificates (if applicable)
- Local cultural risk assessment

3.2.5 For research involving sensitive data

- Data encryption plan
- Secure storage location details
- Access control procedures

4. Pre-Review Screening Workflow

4.1 Initial Assessment and Pathway Determination

The Secretary undertakes an initial assessment of each application and, where required, consults with the Chair to determine the appropriate review pathway.

The assessment considers:

- risk category
- participant population
- topic sensitivity
- methodology
- data sensitivity
- researcher experience
- any other matters relevant to ethical review

Where the appropriate pathway is unclear or concerns are identified, the Secretary refers the application to the Chair for further consideration.

SOP 5 - EXTERNAL HUMAN RESEARCH ETHICS APPROVAL

1. Purpose

This Standard Operating Procedure (SOP) describes the process for the review, acceptance and oversight of human research projects that have received ethics approval from an external Human Research Ethics Committee (HREC) and require consideration by the Victoria University Human Research Ethics Committee (VUHREC). This SOP supplements Section 12 of the VUHREC Terms of Reference relating to external researchers and recognition of external ethics approvals.

This SOP applies to:

- externally approved research involving VU participants
- externally approved research involving VU staff and/or students as investigators
- externally approved research conducted by external investigators seeking access to VU participants, facilities, data or resources
- research reviewed by VUHREC on behalf of external organisations under a formal agreement with the University.

This SOP aims to:

- ensure compliance with the National Statement on Ethical Conduct in Human Research and University requirements
- avoid unnecessary duplication of ethics review where appropriate ethics approval has already been granted by another HREC
- ensure VU-specific governance, participant welfare and local context considerations are addressed
- establish consistent processes for recognition of external ethics approvals
- define monitoring and reporting requirements for externally approved research

2. Roles and Responsibilities

2.1 Chair

The Chair:

- determines whether external HREC approval may be accepted by VU
- considers local context issues relevant to VU participants, facilities and services
- determines the appropriate review pathway
- imposes site-specific conditions where required
- refers applications to the full Committee where additional ethical review is required
- approves externally reviewed projects on behalf of the Committee where appropriate

2.2 Secretary / Ethics Officer

The Secretary:

- receives and screens all applications seeking recognition of external approval
- verifies documentation and approval status
- confirms completeness of submissions
- coordinates communication with researchers, sponsors and external institutions
- prepares applications for Chair review

- maintains monitoring and reporting records

2.3 VU Sponsor

Where the research is conducted by external investigators, a VU Sponsor:

- must be a current VU staff member
- acts as the primary liaison between VU and the external researcher
- provides advice regarding the VU context
- ensures compliance with applicable VU policies and procedures
- assists in managing ethical issues arising at the VU site
- supports participant welfare and appropriate conduct of the research at VU

2.4 Researchers

Researchers:

- provide all required documentation
- ensure external ethics approval remains current throughout the project
- comply with all conditions imposed by VUHREC
- report amendments, adverse events and complaints as required
- comply with VU governance, privacy and data management requirements

3. Research Requiring VUHREC Review

VUHREC review is required for the following externally approved research activities.

3.1 Externally Approved Research Involving VU Participants

Research approved by another HREC that proposes to recruit or involve:

- VU students
- VU staff
- VU alumni
- participants accessed through VU services, programs or networks

3.2 Externally Approved Research Involving VU Staff or Students as Investigators

Research approved by another appropriately constituted HREC where a VU staff member and/or student is named as an investigator.

3.3 Externally Approved Research Conducted by External Investigators

Research conducted by external investigators seeking access to:

- VU participants
- VU facilities
- VU services
- VU resources

Such projects require a VU Sponsor and approval by the Chair of VUHREC before commencement.

3.4 Review of Research for External Organisations

VUHREC may review research proposals for external organisations where a formal agreement exists and appropriate arrangements have been approved by the University.

4. Assessment Criteria for Acceptance of External Approval

Before external approval can be accepted, VUHREC (through the Chair) must be satisfied that:

4.1 External Approval is Current and Valid

The researcher must provide:

- the full external HREC Application including all relevant attachments
- the external HREC approval letter
- evidence that approval remains current
- details of any conditions imposed by the approving HREC
- details of approved amendments

4.2 Documentation is Complete

The submission must include:

- approved protocol
- participant information materials
- consent materials
- recruitment materials (where applicable)
- site-specific documentation relevant to VU
- sponsor confirmation (if required)
- details of approved amendments (if applicable)

4.3 Local Context Requirements are Addressed

VUHREC must be satisfied that:

- recruitment methods are appropriate
- participant welfare is adequately protected
- privacy and confidentiality requirements are addressed
- cultural considerations have been considered
- data storage and management arrangements comply with VU requirements
- any sponsor requirements have been met

4.4 Ethical and Governance Requirements are Satisfactory

VUHREC must be satisfied that:

- the approved research is suitable for implementation at VU where relevant
- no additional risks arise because of the VU context
- participant protections remain appropriate
- University governance requirements have been met

5. Review Workflow

5.1 Submission

The researcher submits:

- the external ethics approval documentation
- all approved study documents
- any required VU forms
- supporting governance documentation

5.2 Administrative Screening

The Chair verifies:

- approval authenticity
- approval dates and status
- document completeness
- sponsor requirements
- applicability to the VU context

5.3 Local Context Assessment

The Chair assesses:

- participant population
- recruitment methods
- consent arrangements
- privacy and confidentiality considerations
- data management arrangements
- any VU-specific risks

5.4 Chair Review

The Chair reviews:

- screening notes
- local context assessment
- risk considerations
- documentation provided

The Chair determines whether:

- external approval may be accepted
- conditions are required
- additional information is required
- a VU application and referral to the full Committee is necessary

5.5 Notification

The Secretary:

- records the determination
- issues written notification to the researcher
- communicates any conditions of approval

6. Review Outcomes Outlined

6.1 External Approval Accepted

The external approval is recognised, and the project may proceed

6.2 External Approval Accepted with Conditions

The project may proceed subject to specified conditions determined by VUHREC (through the Chair).

6.3 Further Information Required

Additional information, clarification or documentation is required before a determination can be made.

6.4 Referred to a Full Committee

The application is referred to a full VUHREC where:

- significant ethical issues are identified
- local context concerns require consideration
- additional expertise is required
- reliance on the external approval is uncertain

6.5 External Approval Not Accepted

VUHREC determines that the external approval cannot be relied upon for the proposed activities at VU and may require a separate ethics application.

7. Sponsor Responsibilities

Where a VU Sponsor is required, the Sponsor must:

- confirm acceptance of the sponsorship role
- act as the principal contact person for VU
- assist with communication between VU and the researcher
- advise on local organisational requirements
- ensure compliance with VU policies
- assist in managing participant welfare concerns and ethical issues arising at VU

8. Monitoring and Reporting

Researchers must:

- maintain current ethics approval throughout the project
- report approved amendments
- report adverse events and participant complaints
- comply with all reporting requirements imposed by VUHREC
- submit progress and final reports where required

Additional monitoring activities may include:

- requests for supplementary reports
- audits of documentation
- review of data management arrangements
- review of compliance with approval conditions

9. Records Management

The research record must include:

- external HREC approval documentation
- approved protocol and supporting documents
- local context assessment
- sponsor documentation
- Chair or Committee determination
- correspondence and conditions
- monitoring and reporting records

10. Commencement of Research

Research involving VU participants, facilities, services or resources must not commence until written confirmation has been issued by Research Ethics and Integrity Office following completion of the review process.

SOP 6 – MONITORING OF APPROVED RESEARCH

1. Purpose

To provide a detailed operational framework for monitoring human research approved by the Victoria University Human Research Ethics Committee (VUHREC). Monitoring functions are undertaken pursuant to the responsibilities assigned to VUHREC under the Terms of Reference.

Monitoring ensures:

- ongoing compliance with approved protocols
- protection of participant welfare
- adherence to VU policies and the National Statement (2025)
- early identification of risks, deviations, or adverse events
- transparent and auditable oversight

This SOP applies to all research approved by VUHREC or the Low-Risk Panel conducted at VU.

2. Roles and Responsibilities

2.1 Chair

- Oversees monitoring strategy and escalations.
- Determines when additional monitoring is required.
- Approves suspension or withdrawal recommendations.
- Reviews serious non-compliance cases.

2.2 Secretary / Ethics Officer

- Issues reminders and escalation notices.
- Maintains monitoring records.

2.3 Researchers

- Submit annual and final reports on time.
- Report adverse events promptly.
- Maintain compliance with approved protocol.
- Notify VUHREC of any deviations or amendments.
- Cooperate with monitoring activities.

3. Monitoring Framework Overview

Monitoring consists of:

- Annual Reports
- Final Reports
- Non-Compliance Management
- Adverse Event Oversight **(see SOP 8)**
- Recordkeeping and documentation

Monitoring requirements apply for the entire duration of the approved project.

4. Annual Reports

4.1 Submission Timeline

- Due every **12 months**
- Due annually until project completion.
- Reminders issued at:
    - 1 month before due date
    - Due date
    - 1 month overdue
    - 2 months overdue

4.2 Required Content

Annual reports must include:

4.2.1 Project Progress

- Activities completed
- Recruitment numbers
- Any delays or changes
- Any deviations from protocol

4.2.2 Compliance

- Confirmation that research is conducted as approved
- Any amendments submitted
- Any deviations not previously reported

4.2.3 Participant Welfare

- Any adverse events
- Any complaints
- Any withdrawals and reasons

4.2.4 Data Security

- Storage location
- Access controls
- Any breaches or near misses

4.2.5 Future Plans

- Activities planned for next reporting period
- Any anticipated amendments

4.3 Review Process

Secretary:

- Reviews report for completeness.
- Flags issues for Chair or reviewer.

5. Final Reports

5.1 Submission Timeline

- Due within **3 months** of project completion.
- Required for all projects

5.2 Required Content

The Annual Report and Final reports should include:

- project title and ethics approval number
- reporting period
- current project status
- recruitment numbers and participant demographics (where relevant)
- summary of research activities undertaken during the reporting period
- progress against project objectives
- details of amendments approved since the previous report
- details of any adverse events, complaints or protocol deviations
- confirmation of ongoing compliance with ethics approval conditions
- anticipated completion date
- any emerging ethical issues or risks

6. Non-Submission Escalation Workflow

6.1 Escalation Steps

1. **1 Month Overdue**
    - First reminder issued.
    - Quest status updated to “Overdue – Level 1”.

2. **2 Months Overdue**
    - Second reminder issued.
    - Quest status updated to “Overdue – Level 2”.
    - Researcher warned of possible suspension.
    - Chair determines whether withdrawal of approval is required.

6.2 Suspension Requirements

Suspension letter must include:

- Reason for suspension
- Required actions
- Deadline for compliance
- Consequences of continued non-compliance

SOP 7 – AMENDMENTS TO APPROVED RESEARCH

1. Purpose

To provide a detailed operational framework for the submission, classification, review, approval, and implementation of amendments to human research previously approved by VUHREC or the Low-Risk Panel. This SOP ensures:

- amendments are reviewed proportionate to risk
- participant welfare remains protected
- approved protocols remain current and compliant
- changes are documented, auditable, and transparent
- researchers understand what constitutes an amendment and how to submit one

This SOP applies to all approved research, including external projects conducted at VU.

2. Roles and Responsibilities

2.1 Chair

- Determines amendment suitability
- Approves amendments
- Determines review pathway for major amendments
- Escalates amendments/or requests new application submitted when deemed relevant (change in risk level, significant amendment requested requiring additional review process)
- Oversees urgent amendment procedures.

2.2 Secretary / Ethics Officer

- Conducts initial amendment screening.
- Ensures amendment documentation is complete.
- Assigns amendments to Chair
- Tracks amendment outcomes in Quest.

2.4 Committee Members

- Review major amendments requiring a new application at full HREC meetings.
- Participate in deliberation and decision-making.
- Ensure applications align with ethical principles.

2.5 Researchers

- Submit amendments before implementing changes.
- Provide updated documents with correct version numbers.
- Explain rationale for changes.
- Ensure changes are not implemented until approved.
- Notify VUHREC of urgent safety-related amendments immediately.

3. What Constitutes an Amendment

An amendment is **any change** to an approved research project that affects:

- protocol

- methodology
- participant population
- recruitment
- consent materials
- data collection
- data storage
- safety procedures
- investigator team
- project timeline

4. Amendment Types

4.1 Moderate Amendments (Ethical Review Required)

Examples:

- Changes to recruitment materials
- Changes to consent forms
- Addition of new data collection instruments (non-sensitive)
- Changes to participant reimbursement
- Changes to inclusion/exclusion criteria (non-vulnerable populations)
- Addition of new sites (non-high-risk)
- Changes to data storage location (within VU systems)

Characteristics:

- Minor impact on risk
- Minor impact on participant experience
- No introduction of vulnerable populations
- No introduction of sensitive topics

4.3 Major Amendments may require new Application (Full HREC Review Required)

Examples:

- Changes to methodology
- Introduction of sensitive topics
- Introduction of vulnerable populations
- Introduction of deception
- Introduction of intrusive procedures
- Significant changes to data sensitivity
- Addition of international sites
- Addition of First Nations participants
- Major changes to safety procedures
- Major changes to recruitment strategy
- Major changes to consent processes
- Changes that increase risk level

Characteristics:

- Significant impact on risk
- Significant impact on participant welfare
- Requires full ethical deliberation

5. Amendment Submission Requirements

Researchers must submit:

5.1 Mandatory Documents required for Chair

- Summary of changes
- Rationale for changes
- Updated protocol (if applicable)
- Updated PIS/CF (if applicable)
- Updated recruitment materials (if applicable)

Researchers may implement changes **only after approval**.

SOP 8 – ADVERSE EVENTS

1. Purpose

To provide a detailed operational framework for identifying, reporting, assessing, and responding to adverse events occurring in human research approved by VUHREC or the Low-Risk Panel. The Committee's authority to require corrective actions, suspension or withdrawal of approval is established in the VUHREC Terms of Reference.

This SOP ensures:

- participant safety is prioritised
- adverse events are managed promptly and effectively
- reporting is consistent, transparent, and auditable
- risks are mitigated and monitored
- compliance with the National Statement (2025) and VU policies

This SOP applies to all research conducted at VU or by VU researchers, including external projects.

2. Roles and Responsibilities

2.1 Chair

- Oversees adverse event management.
- Determines severity classification.
- Approves required actions (modification, suspension, withdrawal).
- Tracks follow-up actions and deadlines.
- Escalates serious events to institutional leadership.
- Ensures Committee review of serious events.

2.2 Secretary / Ethics Officer

- Receives adverse event reports.
- Ensures reports are complete.
- Logs events in Quest.
- Coordinates with Chair

2.4 Researchers

- Identify adverse events promptly.
- Report events within required timeframes.
- Implement immediate safety actions.
- Submit follow-up reports.
- Cooperate with monitoring and investigation.

5. Reporting Timeframes

5.1 Adverse Events

Must be reported within:

- **24 hours** for life-threatening or severe events
- **72 hours** for all other serious events

6. Adverse Event Reporting Workflow

6.1 Identification

Researcher identifies:

- adverse event
- near miss
- protocol deviation

6.2 Immediate Actions

Researcher must:

- ensure participant safety
- stop procedures if necessary
- provide support or referral
- document event details
- contact the Chair and update them verbally or by email as soon as possible

6.3 Submission

Researcher submits Adverse Event Report to Chair

- description of event
- timeline
- participant impact
- immediate actions taken
- proposed protocol changes
- risk mitigation strategies

6.4 Review

Chair determines:

- severity classification
- need for urgent meeting with researcher
- need for additional monitoring
- need for protocol modification
- need for suspension

6.5 Follow-Up

Researcher must:

- submit follow-up report within **14 days**
- implement required changes
- provide evidence of mitigation

7. Emergency Escalation Procedures

7.1 When Required

- life-threatening events
- severe psychological distress
- serious cultural harm
- significant data breach
- legal risk to participant

7.2 Immediate Steps

Researcher must:

- stop research procedures
- ensure participant safety
- contact emergency services (if required)
- notify VUHREC (through the Chair) within **24 hours**
- document all actions

7.3 Chair Response

Chair may:

- suspend project immediately
- require urgent meeting
- notify institutional leadership
- require external reporting (e.g., police, health services)

SOP 9 — COMPLAINTS MANAGEMENT

1. Purpose

To provide a detailed operational framework for receiving, documenting, investigating, responding to, and resolving complaints related to human research approved by VUHREC or the Low-Risk Panel. The management of complaints forms part of VUHREC's oversight responsibilities established under the Terms of Reference.

This SOP ensures:

- complaints are handled promptly, fairly, and transparently
- participant welfare is protected
- researchers receive clear guidance
- institutional and National Statement (2025) requirements are met
- complaint processes are auditable and defensible

This SOP applies to complaints from:

- participants
- researchers
- third parties (e.g., family members, community members, external organisations)
- VU staff or students
- external researchers conducting research at VU

2. Roles and Responsibilities

2.1 Chair

- Oversees complaint management.
- Determines whether research must be suspended.
- Escalates serious complaints to institutional leadership.
- Ensures Committee review of unresolved or serious complaints.

2.2 Researchers

- Respond promptly to complaint enquiries.
- Provide requested documentation.
- Cooperate with investigations.
- Implement required corrective actions.

2.3 Complaint

Any expression of dissatisfaction or concern about:

- conduct of research
- behaviour of researchers
- participant experience
- consent processes
- recruitment practices
- data handling
- cultural safety
- privacy or confidentiality
- protocol deviations

- communication issues

2.4 Chair Review

Chair determines:

- complaint classification
- investigation requirements
- need for suspension
- need for Committee review
- need for external reporting (e.g., police, cultural bodies)

3. Complaints About the Conduct of VUHREC in Reviewing Research Proposals

3.1 Purpose

To establish a clear, fair, and transparent procedure for receiving, documenting, investigating, responding to, and resolving complaints concerning the conduct, decisions, processes, or behaviour of the Victoria University Human Research Ethics Committee (VUHREC) in its review of research proposals. This section ensures:

- complainants have an accessible and impartial avenue for raising concerns
- VUHREC operations remain accountable, procedurally sound, and aligned with the *National Statement on Ethical Conduct in Human Research (2025)*
- institutional confidence in ethics review processes is maintained
- complaints are managed in a way that protects the integrity of the Committee and the welfare of researchers and participants

This section applies to complaints from:

- researchers (internal or external)
- supervisors
- research administrators
- VU staff or students
- external organisations or partners

3.2 Scope of Complaints About VUHREC Conduct

A complaint may relate to any concern about the Committee's conduct, including:

- procedural fairness or transparency in review processes
- communication quality, tone, or professionalism
- perceived bias, conflict of interest, or inconsistency
- application of the National Statement or institutional policies
- adequacy of feedback or decision rationale
- behaviour of Committee members during meetings or correspondence
- administrative handling of submissions

Complaints **must not** be used to challenge the scientific merit of a decision or to appeal an ethics outcome.

3.3 Receiving Complaints

Complaints may be received via:

- email to the Research Ethics inbox researchethics@vu.edu.au
- direct communication to the Chair
- communication to the Senior Manager, Research Ethics and Integrity
- formal letters from researchers or external organisations

Upon receipt:

- all complaints must be acknowledged within **3 business days**
- the complaint must be logged in the **Complaints Register**
- the Chair must be notified unless the complaint concerns the Chair (see 3.7)

Acknowledgement must include:

- confirmation of receipt
- outline of next steps
- expected timeframes
- request for any additional information if required

3.4 Initial Assessment

The Chair (or delegate) conducts an initial assessment to determine:

- **classification** (minor, moderate, serious)
- whether the complaint relates to:
    - procedural matters
    - conduct/behaviour
    - conflict of interest
    - misapplication of policy
- whether immediate action is required
- whether the complaint may be resolved informally
- whether the complaint requires formal investigation

Timeframe: **10 business days** from receipt.

3.5 Investigation Process

Where formal investigation is required, the Chair (or delegate) will:

- appoint an **independent reviewer** (e.g., another senior ethics officer, external HREC Chair, or institutional governance representative)
- gather relevant documentation (submission history, correspondence, meeting minutes, reviewer comments)
- interview relevant parties if required
- ensure procedural fairness for all involved
- assess whether:
    - VUHREC processes were followed
    - communication was appropriate
    - conflicts of interest were managed
    - decisions were consistent with policy and the National Statement

Investigations should be completed within **30 business days**, unless complexity requires extension.

3.6 Outcomes and Corrective Actions

Possible outcomes include:

- complaint not substantiated
- complaint substantiated in part
- complaint substantiated in full

Corrective actions may include:

- providing additional explanation or clarification to the complainant
- issuing an apology
- revising Committee procedures
- retraining or guidance for Committee members
- adjusting communication templates or workflows
- updating policy interpretation guidance
- referring matters to institutional leadership if serious

All outcomes must be:

- documented
- communicated to the complainant
- recorded in the Complaints Register

3.7 Complaints Concerning the Chair

If the complaint concerns the Chair:

- the Senior Manager, Research Ethics and Integrity will conduct the initial assessment
- investigation will be undertaken by an independent reviewer external to VUHREC
- the Chair will not participate in any part of the process
- outcomes will be reported to the Deputy Vice-Chancellor, Research & Impact

3.8 Committee Review

The full Committee must review:

- serious complaints
- complaints involving alleged bias or conflict of interest
- complaints that identify systemic issues
- complaints where the complainant disputes the investigation outcome

Committee review must be minuted and may result in:

- procedural amendments
- guidance to members
- escalation to institutional governance bodies

3.9 Communication with Complainants

All communication must be:

- respectful
- clear
- timely
- consistent with privacy and confidentiality requirements

Complainants must receive:

- acknowledgement
- investigation summary
- outcome and rationale
- information on further escalation pathways (e.g., institutional governance, external bodies where appropriate)

3.10 Recordkeeping and Reporting

Research Ethics and Integrity must maintain:

- the Complaints Register
- investigation documentation
- outcome records
- corrective action logs

3.11 Principles

All complaints about VUHREC conduct must be managed according to:

- procedural fairness
- transparency
- independence
- confidentiality
- respect for all parties
- alignment with the National Statement (2025)
- institutional governance requirements

SOP 10 - RECORDKEEPING & CONFIDENTIALITY

1. Purpose

To provide a detailed operational framework for the creation, management, storage, retention, access, and disposal of records relating to human research ethics applications reviewed by VUHREC or the Low-Risk Panel. This SOP supports the Committee's accountability obligations established in the Terms of Reference.

This SOP ensures:

- compliance with the National Statement (2025)
- compliance with VU information governance and privacy policies
- secure and auditable recordkeeping
- protection of confidentiality and sensitive information
- consistent and defensible administrative practice

This SOP applies to all records generated or received by VUHREC, including both digital and physical records.

2.Roles and Responsibilities

2.1 Chair

- Ensures Committee compliance with recordkeeping and confidentiality requirements.
- Approves access to restricted records (e.g., serious adverse events, complaints).
- Oversees confidentiality breach management.
- Ensures records support defensible decision-making.

2.2 Secretary / Ethics Officer

- Maintains all VUHREC related records in Quest and VU drives.
- Ensures version control across all documents.
- Manages access permissions.

2.3 Committee Members

- Maintain confidentiality of all records.
- Access records only as required for review.
- Do not store records on personal devices.

2.4 Researchers

- Maintain records required for monitoring and compliance.
- Provide updated documents with correct version control.
- Ensure data storage complies with VU requirements.

3. Confidentiality Requirements

3.1 Committee Confidentiality

Committee members must:

- not disclose application content
- not discuss deliberations outside meetings
- not store documents on personal devices
- not forward documents to unauthorised persons

3.2 Researcher Confidentiality

Researchers must:

- protect participant data
- comply with VU data storage requirements

3.3 Confidential Information Categories

Confidential information includes:

- participant data
- sensitive topics
- cultural information
- adverse events
- complaints
- investigator identities
- proprietary methodologies
- unpublished research findings

3.4 Breach Management

Confidentiality breaches must be:

- reported immediately to Chair
- addressed with corrective actions

4. Record Retention Schedule

4.1 Standard Records

Retain for at least **7 years** after project completion:

- applications
- decisions
- amendments
- monitoring reports
- adverse events
- complaints

4.2 High-Risk Records

Retain for at least **15 years**:

- First Nations research
- clinical trials
- genetic research
- research involving vulnerable populations (including children)

- serious adverse events
- serious complaints

4.3 Administrative Records

Retain for at least **7 years**:

- meeting minutes
- agendas
- training records
- SOP versions

4.4 Disposal

After retention period:

- digital records securely deleted
- physical records shredded
- disposal logged

SOP 11 — SUSPENSION OR WITHDRAWAL OF APPROVAL

1. Purpose

To provide a detailed operational framework for the suspension or withdrawal of ethics approval for human research previously approved by VUHREC or the Low-Risk Panel. The authority to suspend or withdraw ethics approval is delegated to VUHREC through the Terms of Reference.

This SOP ensures:

- participant safety is protected
- non-compliance is managed promptly and transparently
- decisions are consistent, defensible, and auditable
- researchers understand their obligations
- institutional and National Statement (2025) requirements are met

This SOP applies to all approved research, including external projects conducted at VU.

2. Roles and Responsibilities

2.1 Chair

- Determines whether suspension or withdrawal is required.
- Approves urgent suspensions.
- Oversees investigation of non-compliance and refers suspected breaches of research integrity to the Senior Manager, Research Ethics and Integrity.
- Escalates serious cases to institutional leadership.
- Ensures Committee review of withdrawal decisions.

2.2 Secretary / Ethics Officer

- Receives reports of non-compliance.
- Logs issues in Quest.
- Maintains records as instructed by the Chair

2.3 Researchers

- Comply with suspension or withdrawal instructions.
- Cease research activities immediately when required.
- Provide requested documentation.
- Implement corrective actions.
- Cooperate with investigations.

3. Conditions for Suspension or Withdrawal

Approval may be suspended or withdrawn when there is:

- Non-Compliance with Approved Protocol
- Participant Welfare at Risk
- Failure to Meet Monitoring Requirements
- Serious Adverse Events
- Serious Complaints
- Misconduct or Ethical Breach

4. Suspension vs Withdrawal

4.1 Suspension

Temporary cessation of research activities until issues are resolved.

Used when:

- corrective actions may resolve issues
- participant safety can be restored
- non-compliance is significant but remediable

4.2 Withdrawal

Permanent removal of ethics approval.

Used when:

- risks cannot be mitigated
- serious misconduct occurred
- researcher fails to comply with suspension conditions
- external approval withdrawn and cannot be replaced
- research is fundamentally unethical

4.3 Follow-Up in the case of removal of ethics approval

Researcher must:

- cease all research activities immediately
- implement corrective actions
- submit evidence of compliance

SOP 12 — DEFINITIONS & INTERPRETATION

1. Purpose

To provide clear, operational definitions and interpretation rules for terms used throughout the VUHREC Standard Operating Procedures (SOPs). This SOP ensures:

- consistent understanding of key concepts
- clarity for researchers, reviewers, and administrators
- alignment with the National Statement (2025)
- defensible decision-making
- transparent application of ethical principles

This SOP applies to all VUHREC processes, decisions, and communications.

2. Definitions

The following definitions apply across all SOPs. Where definitions differ from external sources, the National Statement (2025) prevails.

2.1 Human Research

Research conducted **with** or **about** people, their data, or their biological materials, including:

- surveys, interviews, focus groups
- behavioural experiments
- observational studies
- clinical trials
- genetic research
- research using identifiable or re-identifiable data
- research using human tissue or biological samples
- research involving digital platforms or AI systems interacting with participants

Operational Note: If a project involves identifiable human data, it is human research even if no direct interaction occurs.

2.2 Participant

Any individual who:

- takes part in research activities
- provides data, tissue, or biological samples
- is observed or recorded
- is affected by research procedures
- is recruited or approached for participation

Includes:

- active participants
- passive participants (e.g., observed individuals)
- individuals whose data is used without direct contact

2.3 Minimal and Low Risk

Research involving no more than inconvenience and/or discomfort, where any foreseeable risk is limited and unlikely to cause harm. Low risk research involves no foreseeable risk of harm, and any discomfort must be transient, reversible, and not expected to have lasting impact. Examples include:

- short surveys or questionnaires
- non-sensitive interviews
- benign behavioural tasks
- low-impact observational studies
- non-sensitive personal questions
- studies involving mild psychological discomfort (e.g., reflecting on everyday experiences)
- studies involving minor physical discomfort (e.g., wearing a wrist sensor, pedometer)

Examples of inconvenience and discomfort may include:

- time spent completing a survey
- minor scheduling inconvenience
- brief interruption to routine
- embarrassment
- fatigue
- mild anxiety
- minor physical strain

This category is assessed through the low-risk review pathway.

2.5 More Than Low Risk

Risk involving **any plausible harm**, including:

- physical harm
- psychological harm
- social harm
- cultural harm
- economic harm
- legal harm

Examples:

- trauma recall
- invasive procedures
- sensitive topics
- vulnerable populations
- deception
- significant privacy risks

2.6 Vulnerable Populations

Groups requiring additional protections due to increased risk of coercion, harm, or disadvantage, including:

- children and young people
- people with cognitive impairment

- people highly dependent on medical care
- people in dependent relationships (students, employees, patients)
- Aboriginal and Torres Strait Islander Peoples
- people involved in illegal activities
- people in other countries
- pregnant women and foetuses
- refugees or asylum seekers
- people experiencing homelessness

2.7 Adverse Event

Any undesirable experience affecting a participant during research, including:

- physical discomfort
- psychological distress
- social or cultural harm
- privacy breach
- data breach
- unexpected withdrawal

2.8 Serious Adverse Event

An adverse event requiring:

- medical intervention
- psychological intervention
- hospitalisation
- legal intervention
- cultural governance intervention

Or causing:

- significant distress
- significant privacy breach
- significant data breach
- community-level harm

2.9 Protocol

The approved plan describing:

- research aims
- methodology
- participant population
- recruitment
- consent processes
- data collection
- data storage
- safety procedures
- risk mitigation

Operational Note: Any deviation from protocol requires an amendment (**see SOP 7**).

2.10 Primary Chief Investigator (CI)

The researcher responsible for:

- overall project conduct
- compliance with approved protocol
- participant welfare
- data management
- reporting requirements
- communication with VUHREC

2.11 Delegated Review

Review conducted by the Low-Risk Panel or designated reviewer for:

- minimal risk research
- low risk research

2.12 Confidential Information

Any information that:

- identifies participants
- relates to sensitive topics
- relates to cultural knowledge
- relates to adverse events or complaints
- relates to investigator identities
- relates to proprietary methodologies
- relates to unpublished research findings

2.13 Local Context

VU-specific considerations affecting ethical review, including:

- participant demographics
- cultural considerations
- recruitment environment
- data storage requirements
- institutional policies
- community expectations

2.14 Suspension

Temporary cessation of research activities due to:

- safety concerns
- non-compliance
- serious adverse events
- serious complaints

2.15 Withdrawal of Approval

Permanent removal of ethics approval due to:

- serious misconduct
- unmitigable risk
- repeated non-compliance
- external approval withdrawal

3. Interpretation Rules

3.1 National Statement Prevails

Where ambiguity exists, the National Statement (2025) overrides:

- SOP definitions
- Committee interpretations
- researcher interpretations

3.2 Plain Language Interpretation

Terms must be interpreted using:

- ordinary meaning
- common usage
- context within SOPs

3.3 Contextual Interpretation

Interpretation must consider:

- participant population
- cultural context
- research methodology
- institutional environment

3.4 Risk-Sensitive Interpretation

Where definitions relate to risk, interpretation must:

- err on the side of participant safety
- consider worst-case plausible harm
- consider cumulative risk

3.5 Precedent

Committee decisions establish interpretive precedent unless:

- National Statement changes
- SOPs are updated
- new information emerges

3.6 Chair Authority

The Chair has authority to:

- interpret definitions
- resolve ambiguity

- determine classification
- escalate issues to full HREC

4. Updating Definitions

Definitions may be updated when:

- National Statement changes
- VU policies change
- Committee identifies ambiguity
- new research methodologies emerge
- new cultural considerations arise