Research Integrity Support and Evaluation Procedure

Section 1 - Introduction

(1) The University of Newcastle (University) is committed to ensuring that all research is conducted in accordance with applicable ethical, legal, and regulatory requirements.

(2) This Procedure is a supporting document to the Research Integrity Support and Evaluation (RISE) Policy and should be read in conjunction with that document.

Section 2 - Purpose

(3) RISE supports the University and its Researchers in meeting their obligations under the Australian Code for the Responsible Conduct of Research (the Code). It provides a structured and supportive post approval monitoring program, designed to strengthen responsible research culture, ensure compliance and promote continuous improvement.

(4) This Procedure should also be read in conjunction with the following associated documents:

a. Enterprise Agreements;
b. National Codes:
    i. Australian Code for the Responsible Conduct of Research (the Code);
    ii. National Statement on Ethical Conduct in Human Research;
    iii. Australian Code for the Care and Use of Animals for Scientific Purposes;
c. University policies:
    i. Responsible Conduct of Research Policy;
    ii. Staff Code of Conduct;
    iii. Academic Integrity and Ethical Academic Conduct Policy;
    iv. Student Code of Conduct;
    v. Student Conduct Rule;
    vi. Honorary Academic Titles and Visiting Appointments Policy;
    vii. Ethical Human Research Procedure Manual;
    viii. Animal Research Regulatory Manual;
    ix. Privacy Management Plan;
    x. Records Governance Policy;
    xi. Intellectual Property Policy;
    xii. Intellectual Property Procedure;
    xiii. Research Authorship Procedure;
    xiv. Research Breach Investigation Procedure;
    xv. Research Data and Primary Materials Management Procedure;

xvi. Publication and Dissemination of Research Policy;
xvii. Collaborative Research Procedure;
xviii. Disclosure of Interest Policy;
xix. Disclosure of Interest Procedure;
xx. Public Interest Disclosures Policy;
xxi. Data Breach Policy (Personal and Health Information); and
xxii. Generative AI in Research Guideline.

Section 3 - Scope

(5) This Procedure applies to all approved research conducted under the auspices of the University, regardless of funding source or location of the research activity. This includes all persons who design, conduct, oversee, support, or are otherwise involved in research, including:

a. current academic, teaching or professional staff;
b. students undertaking research (Honours, coursework or HDR);
c. visiting or emeritus appointees; and
d. honorary academic title holders.

Section 4 - Document Specific Definitions

(6) In the context of this document, the following definitions apply:

a. “approved research” – refers to any research project that has been reviewed and formally approved by a University Review Body, or an alternative review body or under delegated authority;
b. Chief Investigator – means any person assigned to a research project with ultimate responsibility for the intellectual, administrative, and ethical conduct of research. Chief Investigators may adopt alternative role titles such as but not limited to, Lead Investigator or Research Supervisor, however, must uphold the responsibilities of Chief Investigator as outlined in this Procedure;
c. “Corrective and preventative actions” - measures that must be implemented to address identified non-compliance and mitigate the risk of recurrence. These may include:
    i. actions required to correct or amend the research record;
    ii. targeted education or training in responsible research conduct; and
    iii. appropriate support measures, such as counselling, mentoring, or guidance;
d. “External regulators” - includes, but is not limited to, relevant national and state or territory regulatory bodies, such as the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC), the Therapeutic Goods Administration (TGA), and the NSW Department of Primary Industries and Regional Development, and any equivalent bodies in other jurisdictions;
e. “Monitoring” – systematic and structured review activities, such as self-assessment, document review, interviews, and site visits, undertaken to assess compliance, identify risks or areas for improvement, and enforce compliance;
f. “Research Integrity Advisor” – a designated University staff member with appropriate expertise in research practice and sound knowledge of the Australian Code for the Responsible Conduct of Research, the Research Breach Investigation Procedure, and the Responsible Conduct of Research Policy, and who provides advice and guidance on research ethics and integrity matters;
g. Research Ethics and Integrity Unit – a business unit located within the Office of the Pro Vice-Chancellor

Research, Research and Innovation Division, responsible for supporting research ethics and integrity functions;

h. Research Integrity Office - a sub-business unit of the Research Ethics and Integrity Unit which is responsible for providing secretariat and administrative support to facilitate the implementation and operation of this Procedure;
i. University Review Body – a committee or body authorised by the University to review and approve research activities, including the University Biosafety Committee, Animal Care and Ethics Committee, Human Research Ethics Committee, and other approved review bodies.

Section 5 - Roles

Research Integrity Officers

(7) In the context of this Procedure, Research Integrity Officers must:

a. coordinate and administer reviews in accordance with this Procedure;
b. ensure consistent application of this procedure;
c. maintain complete and accurate records of all monitoring activities, decisions, and outcomes;
d. implement escalation processes as determined by the Senior Manager, Research Integrity;
e. coordinate communication and formal notifications to stakeholders;
f. support readiness by ensuring documentation is complete and accessible; and
g. advise the Pro Vice-Chancellor (Research) of any findings that present an immediate risk to participants, Researchers, or the University, or where there is a potential breach of the Australian Code for the Responsible Conduct of Research.

Senior Manager, Research Integrity

(8) The Senior Manager, Research Integrity must:

a. review and formally approve all RISE findings and recommendations;
b. determine whether escalation is required; and
c. approve all formal RISE correspondence prior to its release.

Research Integrity Advisor

(9) RIA's must:

a. lead monitoring activities within their respective College in accordance with this procedure, ensuring that all information is managed sensitively and in accordance with confidentiality requirements;
b. identify potential risks and recommend escalation where required;
c. prepare draft findings and recommendations; and
d. oversee the implementation of any corrective and preventative actions.

(10) As an RISE reviewer, with authority to carry out functions under this Procedure, the RIA must:

a. act promptly and cooperatively, so as not to hinder research projects, while complying with the requirements of review timeframes;
b. act fairly, reasonably, and without bias;
c. promptly disclose any actual or potential conflicts of interest and manage or resolve that conflict appropriately and in accordance with the Disclosure of Interest Policy;

d. treat all matters under this Procedure as confidential and not discuss them with anyone else, except on a 'strictly need to know' basis; and
e. approach the process as an information-gathering exercise, rather than adversarial.

Chief Investigators

(11) Chief Investigators have a responsibility to:

a. ensure full compliance with this Procedure;
b. ensure all information provided is complete, accurate, and not misleading;
c. respond to all RISE requests within required timeframes;
d. ensure all research team members comply with RISE requirements; and
e. implement all required corrective and preventive actions.

Researchers

(12) Researchers have a responsibility to:

a. comply with this Procedure, including cooperating with any assessment, and monitoring under it.

Pro Vice-Chancellor Research

(13) The Pro Vice-Chancellor (Research) is responsible for executive oversight of RISE findings that involve:

a. immediate or significant risk to research participants, animals, Researchers, or the University; or
b. potential breaches of the Code.

(14) The Pro Vice-Chancellor (Research) is accountable for ensuring that appropriate institutional responses are initiated when serious non-compliance is identified, including escalation, risk mitigation, and stakeholder engagement.

(15) The Pro Vice-Chancellor (Research) must ensure that relevant internal stakeholders are informed in accordance with the severity and nature of the risk, which may include Legal Counsel, Human Resource Services, College Pro Vice-Chancellors, Heads of School, and relevant committees.

Section 6 - Research Integrity Support and Evaluation Process

Project Selection

(16) Selection of projects is performed by the Research Integrity Office.

(17) Selection of projects is designed to ensure proportional, risk-based, and representative oversight across the University's research portfolio. Selection may occur through one or more of the following mechanisms:

a. Random selection – to support broad coverage of all research projects:
    i. random selection will be conducted from a register of approved research projects, ensuring adequate coverage across research types, disciplines, and approval categories;
    ii. a register of active grants is owned by the Research Grants Office.
b. Risk-based or for-cause selection – where research projects present elevated or emerging risk, including but not

limited to a history of unexpected adverse events, compliance concerns, repeated errors, or associated research integrity matters. Such risks could impact the University across one or more of the following domains:

i. financial – exposure to potential loss of funding, fines or financial penalties;
ii. reputational – damage to the University's reputation, including loss of public trust;
iii. human – actual or potential harm to individuals, including research participants, staff, students or visitors;
iv. animal – significant risks to the ethical treatment and welfare of animals used in research, including non-compliance with applicable standards, guidelines or approvals;
v. environmental – activities that may result in serious environmental damage or hazards.

c. Governance referral – at the request of the Chair of the Human Research Ethics Committee and Animal Care and Ethics Committee, or Heads of School.
d. Context-based selection – informed by project characteristics such as complexity or novelty of the research, experience level of the research team, or involvement of vulnerable populations.
e. Proactive requests – made by project Chief Investigators.
f. Exclusions – research projects will not be selected for monitoring where an active suspension is in place, or where the project is subject to an open research integrity matter.

(18) The selected research project team and RISE reviewer will not be notified of the pathway selection for the review.

(19) For each selected project, the Research Integrity Office will document:

a. the selection method (e.g. random, risk-based, governance referral, context-based consideration); and
b. rationale for project selection, demonstrating why the project was selected for review.

RIA selection

(20) RIA's will be appointed to a project for RISE review by the Senior Manager, Research Integrity, based on the following criteria:

a. alignment of the project with the RIA's relevant expertise, knowledge, and experience appropriate to the project or discipline; and
b. ability to ensure independence. RIA's must not be appointed to oversee monitoring activities where they have direct involvement, supervisory responsibility, or an actual, potential, or perceived conflict of interest;
c. Researchers subject to a RISE review must be given the opportunity to declare any actual, potential, or perceived conflict of interest with the appointed RIA.

Project Risk Assessment

(21) For each selected project, the RIA must conduct and document a risk assessment that includes:

a. risk factors considered (e.g. project type, involvement of vulnerable populations, investigator experience, prior compliance history);
b. risk rating assigned (e.g. low, medium, high).

(22) Risk rating criteria:

a. Low risk - the identified risk factors indicate a low likelihood of non-compliance. Routine monitoring is likely to be sufficient.
b. Medium risk - the identified risk factors indicate a moderate likelihood of non-compliance. Targeted monioring or further review may be warranted.

c. High risk - the identified risk factors indicate a high likelihood of non-compliance. Enhanced monitoring, active oversight, or early intervention may be required.

Scope of Review

(23) RISE reviews are conducted to reflect the diversity, scale, and complexity of research activities conducted across the University. The scope of each review will be context-specific and may include, but is not limited to, the following areas:

a. Ethics and Regulatory Compliance
    i. Animal Ethics
    ii. Human Ethics
    iii. Indigenous research
    iv. Clinical trials
    v. Safety and related approvals
b. Research Governance and Management
    i. Research data management
    ii. Industry and engagement and partnerships
    iii. Intellectual property management
    iv. Conflicts of interest declaration and management
    v. Publications and dissemination practices
c. Funding
    i. Grants and financial management
    ii. Researcher Capability
    iii. Training, skills, and competency

Monitoring Approach and Frequency

(24) Monitoring activities must be conducted in a manner that:

a. is proportionate to risk;
b. ensures independence and objectivity; and
c. enables verification of compliance.

(25) The scope and selection of monitoring activities are determined at the discretion of the RIA reviewer but must address any specific risk or referral identified in project selection.

(26) Monitoring activities may include one or more of the following approaches, applied proportionately, based on the nature, complexity, and risk profile of the research project. This may include:

a. investigator self-assessment, conducted using a standardised self-assessment checklist;
b. desktop (document) review;
c. virtual or in-person interviews with research teams;
d. observation of research processes; and
e. site visits (physical or virtual).

(27) Frequency should reflect the degree of risk to research participants, animals and the environment and any regulatory requirements.

(28) The RISE review process is applicable upon arrival of a research project and continues throughout the entire research lifecycle, encompassing project delivery, completion, dissemination of results and publication of research outcomes.

Process Timeframes

(29) Where practicable, a RISE review should be completed within three months of its commencement. A RISE review is considered completed once the review process has concluded and the outcome, including any findings and recommendations, have been formally documented and issued to the relevant parties.

(30) The process timeframes outlined below must be complied with unless otherwise approved by the Senior Manager, Research Integrity.

RISE Review Initiation

(31) The Research Integrity Office must notify the Chief Investigator of the project's selection for RISE review.

(32) The notification must include relevant information regarding the purpose and requirements of the review, including any documentation to be completed and applicable timeframes.

(33) Upon request by the Chief Investigator, the commencement of the review may be deferred for a period of up to 3 months.

(34) Flexibility in the response timeframes outlined below may be granted where the Chief Investigator is on approved leave or managing competing deadlines.

(35) The Chief Investigator must acknowledge and respond to the notification within five working days.

Self-Assessment

(36) The Chief Investigator will be provided with a self-assessment checklist relevant to their research context for completion at the commencement of the review. The purpose of the self-assessment checklist is to:

a. support preparation for the RISE review;
b. promote reflective research practice; and
c. identify potential gaps or issues prior to monitoring activities.

(37) The self-assessment checklist must be completed by the Chief Investigator within ten working days of receipt.

(38) The assigned RIA must review the completed self-assessment checklist and identify any areas requiring further or focused review.

RISE Review

(39) The RIA will then undertake a review of the relevant project materials and records. The Research Integrity Office will facilitate access to relevant documentation required to support the review.

(40) Where appropriate, the Research Integrity Office may coordinate a site visit or virtual engagement with the research team. This may include:

a. discussions with members of the research team; or
b. engagement with research participants or collection of participant feedback.

Finalisation of Review

(41) To finalise the review, the RIA will prepare a report using a standardised reporting template, including:

a. findings;
b. supporting rationale;
c. draft determinations and actions, in accordance with Table 1; and
d. proposed corrective and preventative actions (CAPA), designed to address identified issues, prevent recurrence, and support improvements in research practice, where relevant.

(42) The RIA reviewer may also identify and document any instances of exemplary or best practice observed throughout the review.

(43) The draft report will be provided to the Research Integrity Office for review and endorsement.

Determination Outcomes and Actions

(44) Outcomes will be determined as one of the following, in accordance with Table 1:

a. no issues;
b. minor or moderate issues;
c. serious issues.

Table 1- Determination Outcomes and Actions

	Determination Outcome	Actions
1	No issues identified. No instances of non-compliance identified.	The Research Integrity Office issues written confirmation to the research team advising of the outcome.
2	Minor or moderate issues identified. Minor instances of non-compliance or not meeting best practice across a range of activities reviewed.	The Research Integrity Office will provide the research team with a recommended CAPA.
3	Serious issues identified. Findings indicate potential breaches of the Code.	The findings must be escalated to the Research Integrity Office for review under the Research Breach Investigation Procedure.

(45) Where it becomes apparent that there is serious or systemic non-compliance with a potential risk of harm, escalation is required, regardless of the stage of review. The Senior Manager, Research Integrity will notify the Pro Vice-Chancellor (Research), to enable prompt action to mitigate the risk.

Actions

(46) The Senior Manager, Research Integrity will consider the report and determine the review findings and recommendations.

(47) Following determination, the Research Integrity Office will issue a formal letter advising of the review outcome via email, accompanied by a CAPA form, where applicable.

(48) CAPA forms are used to document identified issues, outline required corrective actions to address non-compliance or deficiencies and establish preventative measures to mitigate the risk of recurrence, including assigned responsibilities and timeframes for completion.

(49) The Chief Investigator and research team will be offered the opportunity to meet with the RIA to:

a. discuss the RISE findings;
b. seek guidance on CAPA; and
c. access appropriate support.

(50) Where a CAPA form is issued, the Chief Investigator must complete and submit the form to the Research Integrity Office within three months of its issue.

(51) Where CAPA are required:

a. the Chief Investigator must implement actions within required timeframes;
b. the RIA must monitor progress of completion; and
c. the Research Integrity Officer must verify completion and maintain records.

(52) The RISE review must not be closed until all required actions have been verified as complete by the Research Integrity Officers, or Senior Manager, Research Integrity.

(53) Findings from RISE activities will be used to inform continuous improvement of institutional research governance, including identifying trends, informing targeted education, awareness initiatives, and guiding the review and enhancement of relevant policies, procedures, and guidance as well as broader University-wide actions to strengthen research integrity culture and practice.

Escalation criteria

(54) Escalation must occur where:

a. serious or systemic non-compliance is identified:
    i. serious is an instance of non-compliance with research approval requirements, policies, procedures, or regulatory standards that pose material risk to participants, animals, the environment, or the University's legal or reputational standing;
    ii. systemic is indicative of patterns or repeated instances of non-compliance indicating underlying process failures, instances of non-compliance indicating underlying process failures, Inadequate controls, or a culture of non-adherence, rather than isolated or incidental issues.
b. a potential breach of the Code has been identified; or
c. there is unacceptable risk to participants, animals, or the University.

(55) Escalation process:

a. the RIA identifies a potential serious or systemic non-compliance arising from an RISE review, and recommends escalation of the matter to the Research Integrity Office;
b. the Senior Manager, Research Integrity considers the RIA's recommendation and determines whether escalation is warranted;
c. where escalation is required, the Senior Manager, Research Integrity must refer the matter to the Pro Vice-Chancellor (Research).

Notifications

(56) The relevant Head of School will be notified upon commencement of RISE review activities for awareness and oversight.

(57) The relevant Head of School will be responsible for providing local oversight and must support the implementation of CAPA, where required.

(58) For serious findings, notification must be provided by the Research Integrity Office to the Pro Vice-Chancellor (Research), and relevant stakeholders which may include but is not limited to Legal Counsel, Human Resource Services, Communications, College Pro Vice-Chancellors, and relevant committees.

Section 7 - Obligations

(59) Participation in RISE monitoring activities is a condition of approval for all research conducted under the auspices of the University.

(60) All persons involved in any part of the process under this Procedure (including staff and students) must:

a. cooperate fully and in good faith;
b. not withhold, conceal, or misrepresent information; and
c. comply with confidentiality requirements.

(61) Non-compliance with this Procedure may result in the suspension of research by the Pro Vice-Chancellor (Research), exercised in accordance with their delegated authority.

Section 8 - Potential Breaches and Non-Compliance

(62) Potential or actual breaches identified through RISE must be managed in accordance with the Research Breach Investigation Procedure and Responsible Conduct of Research Policy.

(63) The RISE review process does not replace or duplicate formal breach processes.

Section 9 - Record Management

(64) All records relating to the monitoring of projects must be maintained and confidentially documented within the University's record management system (TRIM) and maintained in accordance with the Records Governance Policy.

(65) Information provided as part of an RISE review may be subject to audit and regulatory review and may be accessed for these purposes.

Status and Details

Status	Current
Effective Date	10th September 2026
Review Date	10th September 2029
Approval Authority	Academic Senate
Approval Date	11th August 2026
Expiry Date	Not Applicable
Responsible Executive	Craig Simmons Deputy Vice-Chancellor (Research and Innovation)
Enquiries Contact	Jodie Marquez Director, Research Ethics & Integrity

Glossary Terms and Definitions

"University" - The University of Newcastle, a body corporate established under sections 4 and 5 of the University of Newcastle Act 1989.

"Risk" - Effect of uncertainty on objectives. Note: An effect is a deviation from the expected, whether it is positive and/or negative.

"Risk assessment" - The overall process of risk identification, risk analysis, and risk evaluation.

"Working day" - Any day other than Saturday, Sunday, or a public holiday in Newcastle, on which business may be conducted.

"Student" - A person formally enrolled in a course or active in a program offered by the University or affiliated entity.

"Intellectual property" - Intellectual property (IP), as defined by the World Intellectual Property Organisation, refers to creations of the mind: inventions; literary and artistic works; and symbols, names and images used in commerce. Intellectual property is divided into two categories: Industrial property includes patents for inventions, trademarks, industrial designs and geographical indications; and Copyright covers literary works (such as novels, poems and plays), films, music, artistic works (e.g. drawings, paintings, photographs and sculptures) and architectural design. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and broadcasters in their radio and television programs.

"Research" - As defined in the Australian Code for the Responsible Conduct of Research, or any replacing Code or document.

"Staff" - Means a person who was at the relevant time employed by the University and includes professional and academic staff of the University, by contract or ongoing, as well as conjoint staff but does not include visitors to the University.

"College" - An organisational unit established within the University by the Council.

"Delegated authority" - refers to the specific description of the authority that is delegated or sub-delegated to a holder.