Contract Research Procedure

Section 1 - Introduction

(1) This procedure is a supporting document to the Commercial Activities Policy and must be read in conjunction with that document.

Section 2 - Scope

(2) This document applies to any contract research conducted under the auspices of the University of Newcastle (University) where the Commercial Activities Policy directs that this Procedure applies.

(3) This document should be read and understood by all relevant staff of the University.

Section 3 - Definitions

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

Term	Definition
Commercial Activity	As defined by Section 21A of the University of Newcastle Act 1989 a University commercial activity means: i. any activity engaged in, by, or on behalf of the University in the exercise of commercial functions of the University; and ii. any other activity comprising the promotion of, establishment of, or participation in any partnership, trust, company or other incorporated body, or joint venture, by or on behalf of the University, that is for the time being declared by the Guidelines to be a University commercial activity.
Contract Research	means research commissioned by the Australian private sector or an international source as outlined in the Commercial Activities Policy.
Chief Investigator	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, in the context of this procedure must uphold the responsibilities of Chief Investigator as outlined in this document. As the person responsible for the proposed contact research project documentation and ongoing monitoring and review of the research activities the Chief Investigator is the Activity Owner and Responsible Officer as defined in the Commercial Activities Policy.
Due Diligence	The process of investigating and assessing information about a third party who is potentially engaged in a University commercial activity to ensure risks associated with the third party are quantified and understood.
Sponsor	The University staff member who endorses the proposed contract research activity at stage 2 of this Procedure. The Sponsor is the head of the business unit in which the Chief Investigator works – for example, Head of School, Director or equivalent.
Nominated Executive	The member of the Executive Leadership Team, who is not the Sponsor or Delegate and who receives reports for the ongoing monitoring. For contract research this would normally be the College Pro Vice-Chancellor / Division Pro Vice-Chancellor of the Chief Investigator and host School.

Section 4 - Procedure

(5) Each contract research activity that is subject to this Procedure must follow a five-stage life cycle. The five stages are to be completed as follows:

Stage 1	Initiate
Stage 2	Endorse
Stage 3	Negotiate, approve and execute
Stage 4	Manage
Stage 5	Review and Completion

Stage 1 – Initiate

(6) In determining whether an activity is contract research for the purposes of this procedure, the Chief Investigator should first review Section 4 of the Commercial Activities Policy.

(7) If the Chief Investigator is unsure of the application of the Commercial Activities Policy, they should complete the Commercial Activity Decision Tree to determine which category of commercial activity, if any, they are pursuing.

(8) Due diligence assessments must be conducted on the proposed contract research activity and entity funding the research. These assessments will inform the Delegate's decision to approve the contract research. The Delegate will determine if the due diligence is adequate and may request additional information if necessary. A due diligence assessment may consider:

a. Legal: legal and regulatory data and information (corporate structure, environmental and safety compliance, litigations) of the funding entity.
b. Financial: credit watch checks, previous engagement with the University and any payment history of the other funding entity.
c. Financial: fully costed budget including recovery of the direct costs required to deliver the contract research activity, recovery of Chief Investigator time, University indirect costs per the Indirect Cost Recovery Procedure.
d. Strategic: alignment with the University's strategic goals.
e. Risk: foreign interference risk, risk analysis of the contract research activity.

(9) For proposed contract research that satisfies the criteria for Commercial Activities, and is not subject to an alternate procedure, as detailed in the Commercial Activities Policy, a Grant Establishment Form must be completed and submitted to the Sponsor. This must detail evidence of the due diligence undertaken as detailed in clause 8.

Stage 2 - Endorse

(10) Evaluation and endorsement of the proposed contract research activity must be undertaken by the relevant School and College via certification and endorsement of the Grant Establishment Form.

(11) All proposals for contract research are subject to evaluation by the Sponsor against the following criteria as a minimum standard:

a. alignment with the functions described in the University of Newcastle Act 1989 s6(3)a and the current strategic plan;
b. availability and sustainability of the funding source;

c. an identifiable benefit to the University based on sound business case evaluation, risk and return considerations;
d. the accuracy and completeness of the research project plan;
e. feasibility and costs required to conduct the contract research activity including a fully costed budget with indirect cost recovery. In considering the nature of the research activity, the Sponsor or Research and Innovation Division may direct that the budget include appropriate project management resources;
f. appropriate risk mitigation, including but not limited to insurance for management of the identified risks in accordance with the nature and level of the identified risks;
g. declared conflicts of interest and the approval of conflict of interest management plans in accordance with the Disclosure of Interest Policy and its associated procedure;
h. compliance with the University's policies and procedures, applicable laws and regulations; and
i. the principles for 'standard of judgement' as outlined in the Ethical Framework.

(12) In endorsing the contract research activity, the Sponsor is accepting that their business unit may bear any cost overruns from their operating funds on delivery by the Chief Investigator or any failure to pay by the funding entity. The subsequent recovery of funds from any existing or future work of the Chief Investigator is then a matter for the Sponsor to resolve.

(13) A Sponsor is restricted from endorsing any contract research where they will be engaged in the research. An alternate Sponsor to endorse the research activity must be identified.

Stage 3 – Negotiate, Approve and Execute

(14) The next stage is to negotiate a research agreement (in whatever form is appropriate) and have it executed by the appropriate Delegate in accordance with the requirements of the Delegation of Authority Framework.

(15) Contract research must not commence before formal approval has been obtained from the relevant Delegate via a fully executed research agreement.

(16) All contract research agreements must be properly structured from a legal, tax, regulatory or other perspective in line with any recommendations given by Legal and Governance Services, legal or other professional advisers, and documented.

(17) The following issues should be considered by the Chief Investigator at a minimum when preparing a contract research agreement to govern the contract research:

a. Which stakeholders need to be consulted on and approve the terms of the arrangement?
b. Is there a University template agreement that can be used?
c. Who will negotiate the arrangement with the funding entity?
d. If the University is granting ownership and/or use of intellectual property, has Knowledge Exchange & Enterprise been consulted?
e. Has the full scope of the engagement (including deliverables and milestones) been included and clearly articulated in the arrangement?
f. How will research data and materials be managed in accordance with the relevant University Procedure, including security and confidentiality of records, compliance with privacy laws for handling of personal information or health information, public right of access to information?
g. How will the research findings be disseminated and are there any delays or other restrictions from the funding entity on releasing the research results?
h. Is any additional due diligence or documentation required at the point of execution?
i. Who is the appropriate Delegate who can sign the agreement?

(18) Before signing the agreement, contract or similar, the Delegate must receive the recommendation from Research and Innovation Division to execute and ensure that all required stakeholders have been consulted and the necessary endorsement from the Sponsor to proceed with the research activity has been obtained.

(19) The following items will be considered by the Research and Innovation Division at a minimum prior to recommending execution of an agreement for contract research;

a. Has the Chief Investigator reviewed and endorsed the agreement, including milestones and deliverables?
b. Do the agreement terms align with the University's preferred terms as set out in the template University research agreements? If not and the value of the contract research is over the minimum value set for review by Legal and Governance Services, then the agreement will be referred to Legal and Governance Services for review if this has not already been undertaken.
c. Do the intellectual property terms in the agreement align with the University preferred terms as set out in the template University research agreements? If not, then the agreement will be referred to Knowledge Exchange & Enterprise for review if this has not already been undertaken.
d. Financial terms – review of the invoicing schedule, financial due diligence check on the funding entity, and Indirect Cost recovery.
e. Are there appropriate exit arrangements including termination to protect the interests of the University?
f. Has the School and College approved Grant Establishment Form been received and reviewed, and have any issues flagged within the Grant Establishment Form been resolved or can they be managed? This could include that declared Conflicts of Interest have been approved and actioned in accordance with the University procedure.
g. Is the research activity covered by the University's insurance?
h. Are there any research integrity or ethical matters which need to be considered and have these been addressed?

(20) A Delegate is restricted from approving any research agreement where they will be engaged in the research activity. An alternate Delegate with authority to approve the contract research agreement must be identified.

(21) Where the Delegate determines that a prepared research proposal is outside the University's risk appetite then the Delegate may:

a. reject the proposed research activity; or
b. escalate the proposed research activity to be considered for approval by the Vice-Chancellor.

(22) The Research and Innovation Division shall notify the Chief Investigator of the approval (or otherwise) of the contract research.

Stage 4 - Manage

(23) Upon execution of the contract, the Research and Innovation Division is responsible for the provision of all necessary information to ensure that the Contract Register is kept up to date.

(24) Following execution, the contract research needs to be managed in a manner that provides assurance that the contract research complies with:

a. the University's legal rights and obligations;
b. the agreement that it is subject to;
c. applicable policies and procedures of the University; and
d. any conditions of approval imposed by the Delegate.

(25) Ongoing management and monitoring should also ensure that the University achieves optimal benefits from the activity while minimising the risks to the University.

(26) The Chief Investigator is responsible for:

a. managing and regularly monitoring the contract research throughout the total activity life to ensure the ongoing viability of the research activity;
b. Implementing the Project Management Plan (if applicable);
c. completing all deliverables, including reporting, as outlined in the research agreement;
d. engaging with Financial Services and completing any required activity to ensuring timely invoicing and payments;
e. reporting any proposed variations to the research activity including the timing of deliverables to the Research and Innovation Division. Depending on the nature of the variation this may require endorsement by the Sponsor, and the research agreement may need to be varied, and approved and executed by the Delegate.

(27) If required by the Sponsor or Delegate, the Chief Investigator will provide monitoring reports annually to the Sponsor and Nominated Executive using the Contract Research Activity Report.

(28) Regular monitoring seeks to provide assurance to the University of:

a. compliance with the University's obligations as a public authority;
b. compliance with any conditions of approval for the contract research;
c. compliance with all relevant University policies and procedures;
d. compliance with all contractual and legislative obligations;
e. prompt notification of any changes that materially impact commercial or financial viability;
f. ongoing assessment of risks, risk reporting and notification of any changes in risk ratings.

(29) The Sponsor, Nominated Executive, Research and Innovation Division or Financial Services may escalate to an appropriate Delegate to seek suspension of a contract research where there are identified changes to the risks associated with activity.

(30) Where any significant changes to the contract research activity are identified, including changes to the risks associated with the activity, the Contract Research Activity Report is to be completed, and Research and Innovation Division are to be notified within 60 calendar days of identifying the change. The completed Contract Research Activity Report must be provided to the Nominated Executive and approval must be sought for the proposed management plan. The research agreement may need to be varied, approved and executed by the Delegate.

Stage 5 - Review and Completion

(31) The Chief Investigator for any contract research activity exceeding four years is responsible for completing the Contract Research Activity Report on that activity at least once every 4 years, unless requested sooner by the Nominated Executive or Delegate, in order to:

a. assess the ongoing viability of the contract research activity, including whether the activity has achieved the object for which it was originally established;
b. assess compliance with relevant law, policy and standards; and
c. provide a recommendation about what, if any, action (continue until end of term/terminate early/renew) should be taken in light of the review.

(32) The Chief Investigator for each contract research activity must provide a copy of the review report to the

Nominated Executive at least 1 month before the expiry of the 4 year review period.

(33) Once the contract research activity is completed and all payments are received and expenditure processed, Financial Services will identify if a surplus has been derived from the contract research.

(34) A surplus is calculated by the following formula, where:

> revenue – (labour + direct costs + indirect costs + intellectual property (IP) commitments) = surplus

(35) If there is a surplus, Research and Innovation Division will identify if the University can retain any surplus or whether the agreement requires that these funds are returned to the funding entity.

(36) Where the University can retain any surplus, and no obligation has been placed on these by the Sponsor or Delegate, then the Chief Investigator may elect for a surplus to be distributed to the Support Account in accordance with the Support Account Procedure.

(37) If it is determined that there is a cost overrun or there is a failure to pay by the funding entity, then in accordance with:

a. the Support Account Procedure this may be charged to the Chief Investigator's Staff Support Account;
b. (12) above, will be charged to the Sponsor operating funds if not resolved until 37a. The subsequent recovery of funds from any existing or future work of the Chief Investigator is then a matter for the Sponsor to resolve.

Section 5 - Exit or Termination of Activity

(38) Exit or termination of a contract research activity may be considered when:

a. the activity has fulfilled its purpose/objective; or
b. the activity has failed/is failing to meet its objective/purpose; or
c. the activity's residual risk rating is high or extreme; or
d. there is another legitimate reason for exiting the contract research activity.

(39) A request to terminate a contract research activity ahead of completion is to be prepared by Research and Innovation Division, including consideration of the financial, commercial and legal aspects, and submitted to the appropriate Delegate for consideration and approval.

Section 6 - Appendices

(40) Contract Research Activity Report

Status and Details

Status	Current
Effective Date	2nd July 2025
Review Date	6th March 2028
Approval Authority	University Secretary
Approval Date	2nd July 2025
Expiry Date	Not Applicable
Responsible Executive	Craig Simmons Deputy Vice-Chancellor (Research and Innovation)
Enquiries Contact	Research and Innovation Division

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 appetite" - Risk appetite is the amount and type of risk that an organisation (or individual) is willing to accept or pursue in order to achieve its objectives.

"Personal information" - Has the same meaning as in the Privacy and Personal Information Protection Act 1998 (NSW).

"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.

"School" - An organisational unit forming part of a College or Division, responsible for offering a particular course.

"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.

"Foreign interference" - Foreign interference occurs when activities are carried out by, or on behalf of, a foreign actor that are coercive, clandestine, deceptive or corrupting and are contrary to Australia’s sovereignty, values and national interests.

"Delegate" - (noun) refers to a person occupying a position that has been granted or sub-delegated a delegation of

authority, or a committee or body that has been granted or sub-delegated a delegation of authority.