Temperature Controlled Environments Policy

Section 1 - Introduction

(1) The University of Newcastle (the University) is committed to research that delivers innovation and drives global and regional impact. The Responsible Conduct of Research Policy articulates the University's intent to provide systems, facilities, and procedures for the safe and secure storage of research materials and for the maintenance of accurate associated records. The loss of temperature sensitive research materials can have a significant impact on research, the researcher(s), and the University, and cause disruption to the University's research endeavours.

(2) The University is committed to protecting research or teaching materials in temperature controlled environments in accordance with regulatory, commercial and stakeholder requirements.

Section 2 - Definitions

(3) In the context of this policy:

a. “dealing” refers to an interaction with a Genetically Modified Object (GMO). The Gene Technology Act 2000 defines a dealing as meaning: “conduct experiments with the GMO. Make, develop, produce or manufacture the GMO.” (from ogtr.gov.au);
b. “research or teaching materials” refers to materials that:
    i. are used for the purposes of research and/or teaching;
    ii. is / are contained in a temperature controlled environment where the total value of the contents of the device is equivalent to, or greater than $50,000; and may include, but is not limited to:
        - biological samples;
        - chemicals including reagents, kits and research samples;
        - genetically modified materials;
        - plants;
        - radioactive materials;
        - soil and other environmental samples;
        - animals;
        - bio-security materials; and
c. “research group(s)” refers to any group that conducts research under the auspices of the University of Newcastle.

Section 3 - Scope

(4) This policy applies to all temperature controlled environment devices (“device(s)”) that are University assets and are used by the University to store research or teaching materials that are temperature sensitive, including but not limited to:

a. refrigerators;
b. cool rooms;
c. incubators;
d. freezers;
e. liquid nitrogen freezing, cooling and storage systems;
f. plant growth cabinets;
g. glasshouses; and
h. temperature controlled rooms.

(5) Devices may be situated in diverse locations and may also be subject to local infrastructure and support mechanisms in addition to the requirements of this policy.

(6) As this policy also applies to information and contents that are stored in devices, it should also be read in conjunction with:

a. Digital Security Policy and its associated documents;
b. Records Governance Policy and its associated documents;
c. Research Data and Primary Materials Management Procedure; and
d. Guidelines for the Transport, Storage and Disposal of GMOs.

Section 4 - Audience

(7) This policy should be read and understood by:

a. person's holding roles with responsibilities outlined in this policy, or its associated documents;
b. research, college and research group staff who purchase or use devices;
c. students and conjoints who use devices;
d. research supervisors;
e. Security personnel;
f. Digital Technology Solutions staff; and
g. Infrastructure and Facilities Services staff.

Section 5 - Policy

Storage of Temperature Sensitive Research Materials

(8) Research and teaching materials that are temperature sensitive must be stored in a device and in a manner that meets the requirements of this policy.

(9) In the event that research and teaching materials (including Research Higher Degree candidature research materials) of a value less than $50,000 require protection under this policy and a University insurance policy, they must be stored in a device where the total value of the device contents is greater than $50,000.

Purchasing

(10) Purchasing of devices must be in accordance with the University's Procurement Policy.

(11) Devices purchased by the University, regardless of the source of funding, that are to be used to

store temperature sensitive research or teaching materials must:

a. be of a scientific / biomedical grade and be fit for purpose (noting that for liquid nitrogen storage vessels only those capable of being integrated with University monitoring and alarm systems will meet this requirement);
b. contain appropriate shelving and racking, or other suitable features that allow for inventory management;
c. comply with all relevant Australian Standards;
d. be able to:
    i. meet the requirements of the University's Digital Security Policy and its associated documents;
    ii. contribute to the objectives of the University's Environmental Sustainability Plan;
    iii. be connected to the University's alarm monitoring system when stored on a University campus or facility, or allow for a level of monitoring commensurate with the risk of loss of materials if located in a facility owned by a third party; and
e. be compatible with the facility in which it is to be located in terms of access, space, power supply, heat and weight load, work health and safety, and environment.

(12) Devices purchased by the University must be assessed against the requirements of this policy prior to purchase, and purchasing should only proceed where all requirements can be met.

Commissioning

(13) Devices must only be installed on the University premises where it is verified that the requirements of this policy can be met.

(14) The installation of devices must ensure:

a. connection of the device to an appropriate alarm monitoring system in accordance with Clause 11d iii;
b. optimal operation of the device accounting for temperature / air changes and consideration of other equipment in the area;
c. compliance with the University's Digital Security Policy and its associated documents;
d. restricted access wherever possible;
e. safe and effective management of unplanned spills and/or device failure;
f. that effective maintenance and testing of the device can be carried out;
g. inclusion of the device in the University Disaster Recovery plan;
h. for liquid nitrogen devices, a provision to reduce any risk of oxygen depletion and pre-approval via Health Safety and Wellbeing Safety (HSW) Clearance of location before the purchase of the device; and
i. that if storing genetically modified organisms (GMO) outside of an authorised certified physical containment facility, the storage device must be kept locked, and access to the GMOs must be restricted to only a person or class of persons deemed in the Safety Clearance by the Institutional Biohazard Committee (IBC) as having appropriate training and competency in this area.

Device Accountability

(15) A University staff member must be identified as holding accountability for the device, at the time of commissioning. This person will be contacted in the event of an alarm response, and is accountable for taking action should they receive notification that the device has failed, or has otherwise been impacted.

(16) Clear signage must be applied to the device to identify the accountable person for the device, and clearly show their name and contact phone numbers during business hours and after hours.

Device Maintenance Planning

(17) At the time of commissioning, a maintenance schedule must be documented to ensure that:

a. the device is maintained in accordance with the products recommended maintenance activities and schedule;
b. person's responsible for undertaking maintenance, and their contact details, are able to be identified; and
c. Standard Operating Procedures (SOP(s)) for undertaking maintenance are developed.

Device Monitoring

(18) At the time of commissioning, SOPs in accordance with Clause 26, must be documented to ensure that on a regular basis:

a. the alarm monitoring system is tested to verify that the internal alarm system generates a signal;
b. the device is subject to regular disaster recovery testing;
c. operating temperatures are monitored;
d. the device's operation is reviewed and tested; and
e. the signage on the device is current and up to date (see Clause 16, 23 to 25).

Device Failure Planning

(19) At the time of commissioning, a SOP must be developed to establish actions required in the event of failure of the device. Failure of the device should include consideration of a device defect or malfunction and any outside events that may prevent access to or operation of the device. In addition to Clause 26 requirements, this SOP should include:

a. an alternate mechanism to achieve the required temperature, or identification of a suitable alternative space to re-store the device's inventory according to its needs;
b. procedures to respond to the device failure;
c. communication protocols in the event of device failure;
d. person's responsible for responding to the device failure; and
e. person's to be notified in the event of device failure.

(20) A SOP for device failure must be developed in accordance with the College, School, division or unit's Business Continuity Plan.

Device Signage

(21) In addition to Clause 16, devices must be appropriately labeled to:

a. identify the device's asset number;
b. clearly display appropriate biological hazard signage of a hazard diamond or pictogram if storing biological materials;
c. clearly display signage to identify the presence of stored genetically modified material;
d. clearly display the certification signage if the device is:

    i. a certified physical containment facility with the Office of the Gene Technology Regulator; or
    ii. a Biosecurity Facility (Approved Arrangement) with the Department of Agriculture.

(22) At each occurrence where new material is placed into the device, the signage must be reviewed to ensure it is appropriate to meet any safety or compliance requirements relating to that material.

Device Management

(23) A person holding technical responsibilities ("technical officer") must be appointed to the device for the purposes of ensuring appropriate maintenance, monitoring, and failure planning in accordance with this policy.

(24) Colleges and research groups using devices must maintain a register of all devices under their oversight. The register will identify:

a. the Technical Officer for each device;
b. the device maintenance schedule and arrangements; and
c. the contents of the device and the value of the contents.

(25) Devices not included on the above register, or materials without adequate protection, will not be subject to an insurance claim by the University in the event of a device outage.

Standard Operating Procedure Inclusions

(26) SOPs for maintenance, monitoring, and failure planning must identify:

a. the device that they apply to, its location, and its alarm point;
b. the person accountable for the device;
c. any applicable service agreements;
d. when the SOP should be implemented, and if on a cycle, what the agreed cycle is;
e. the role responsible for undertaking the procedure;
f. the steps involved in carrying out the procedure;
g. any work health and safety and regulatory compliance considerations;
h. the steps required to record evidence of actions undertaken; and
i. the person responsible for updating the SOP when changes occur, and on a regular review cycle.

Inventory Management

(27) Materials stored in devices must:

a. be appropriately assessed prior to storage in a device, to identify and manage:
    i. work health and safety risks including selection of appropriate storage containers compatible with the sample and the storage conditions;
    ii. compliance and regulatory risks including those related to Genetically Modified Organisms, radiation and other regulated material including S8 drugs, and prohibited and restricted carcinogens;
    iii. obligations;
    iv. risks to the devices operation in the event of spillage; and
    v. please also refer to Clause 22 of this policy, the Responsible Conduct of Research policy, and Managing Health and Safety Risks and Health and Safety - Laboratory Safety;
b. be appropriately marked to enable identification of:
    i. information regarding the research that it relates to (e.g. a G-number or a Safety Clearance Reference Number for genetically modified material, radiation sources, risk group 2 microbiological materials and other high risk or regulated material/s). An approved arrangement (AA) reference number and import permit number must also be displayed for biosecurity material;
    ii. the material owner;
    iii. the date it was first stored in the device;

iv. a review date for when the materials continued usefulness will be assessed;
v. a disposal date for all research or teaching materials that relate to completed or published research, in accordance with the Records Governance Policy; and
vi. an expiry date for all GMO dealings stored that matches the relevant HSW Safety clearance expiry.

c. be managed in accordance with the Research Data and Primary Materials Management Procedure, where relevant;
d. not be stored for a period greater than required by relevant legislation, unless:
   i. prior agreement has been approved by the relevant School / Institute; or
   ii. an exemption has been granted by the appropriate School / Institute; and
e. be disposed of after the required retention period has been reached, and in accordance with relevant legislation, unless agreement or exemption has been obtained as outlined in Clause 27c (please refer to the Records Governance Policy and/or Research Data and Primary Materials Management Procedure.

(28) Where the owner of the material is no longer associated with the University the material must be "handed over" to ensure continuity of management. The material label must be updated accordingly when this occurs.

(29) GM material must be disposed of in accordance with the Guidelines for the Transport, Storage and Disposal of GMOs before the owner leaves the University, unless the material is approved by the IBC to be transferred to a new dealing under another staff member.

(30) A SOP should be developed to document how inventory stored in the device is managed including steps for storing, recording a chain of custody, and disposal.

(31) A drug register of usage is required to be kept up to date for relevant scheduled poisons / drugs stored in a device.

Decommissioning

(32) Decommissioning of the device or facility must meet the relevant University requirements, including where applicable:

a. the University's requirements for e-waste; and
b. the Decommissioning Laboratory and Associated Facilities Procedure including specified decontamination and sign off of the equipment if it has held genetically modified, risk group 2 biological, or radiation material.

Section 6 - Training

(33) Persons holding roles that are accountable for devices, and Technical Officers assigned to devices must, as a minimum, complete the Temperature Controlled Environment Training Module to ensure that the requirements of this policy and the requirements of each device for which they are accountable for are understood, as well as undertake any further necessary training.

(34) Persons accessing devices must undergo training to ensure that SOPs are clearly understood and able to be implemented.

(35) Persons storing materials in devices must complete applicable training regarding safe material management (see Laboratory Safety Training and the OGTR Certified Facility Authorised Person Form for GM Material.

(36) Training, as outlined in Clause 33 to 35, must be undertaken at least every two years.

(37) Records of training completed must be maintained, and made available to the following when requested:

a. Deputy Vice-Chancellor (Research and Innovation);
b. Insurance Officer;
c. Internal Auditors;
d. the assigned Technical Officer (see Clause 23); and
e. the person accountable for the device (see Clause 15).

Section 7 - Responsibilities

(38) The Deputy Vice-Chancellor (Research and Innovation) will be responsible for monitoring compliance with the policy.

(39) The College Pro Vice-Chancellors will be responsible for:

a. ensuring that a complete and accurate college register, as outlined in Clause 24, is:
    i. maintained; and
    ii. provided to the University's insurance team in Governance and Assurance Services by 15 July each year;
b. responding to and rectifying matters that are identified to be non-compliant with this policy or its associated documents; and
c. providing an annual attestation to the Deputy Vice-Chancellor (Research and Innovation) confirming compliance with this policy for all devices and materials contained within each device.

Section 8 - Essential Supporting Documents

(40) Temperature Controlled Environment Training Module

Status and Details

Status	Current
Effective Date	18th September 2023
Review Date	18th September 2026
Approval Authority	Vice-Chancellor
Approval Date	21st August 2023
Expiry Date	Not Applicable
Responsible Executive	Warwick Dawson Deputy Vice-Chancellor (Research and Innovation)
Enquiries Contact	Jodie Marquez Director, Research Ethics & Integrity 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.

"Asset" - Any tangible or intangible item (or group of items) that the University owns or has a legal or other right to control and exploit to obtain financial or other economic benefits.

"Campus" - means any place or premises owned or controlled by the University, but may also specifically refer to a designated operating location such as the Callaghan Campus.

"Candidature" - The period of time between acceptance of offer and termination, withdrawal from, or completion of a higher degree by research program, including periods when a candidate is not enrolled.

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

"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.