CONTROLLED ENVIRONMENTS PROCEDURE

SCOPE

This procedure applies to all staff and students for the management of controlled environments to protect research material at Monash University Australia, Monash University Malaysia and Monash Suzhou.

PROCEDURE STATEMENT

Effective management and oversight of controlled environments is critical for the protection of all research material. The University is committed to providing infrastructure, facilities and systems to enable the protection and safe storage of all research materials.

This procedure outlines the safeguards that must be implemented to protect research materials in controlled environments at the University.

1. Controlled Environments and Research Materials

1.1 Effective management of research materials housed in and/or reliant on controlled environments is essential to:

- the University's commitments as a leading research institution;
- facilitating research activity in accordance with the Australian Code for the Responsible Conduct of Research and Malaysian Code of Responsible Conduct in Research;
- protecting the integrity and capabilities of individual research endeavours; and,
- mitigating financial losses as a result of the damage to or destruction of research materials.

1.2 Controlled environments include all forms of infrastructure, facilities and equipment that require a controlling mechanism (such as temperature, pressure, humidity or dark/light cycles) to protect the housed research materials. Examples of controlled environments include oxygenated fish tanks, cold storage (freezers, cold rooms, dewars or specialised rooms housing -80 C freezers), animal houses, greenhouses, specialised equipment rooms and incubators.

1.3 All controlled environments housing research material, including all samples and materials used in conducting research and education must be managed in accordance with this procedure.

1.4 The University provides infrastructure, systems and processes to enable researchers, research support teams and faculties to protect research materials for the duration of research.

1.5 All goods and/or infrastructure purchased with research grant funds are deemed to be University property, and must adhere to the requirements set out in this procedure.

1.6 Researchers should be aware of the short and long term consequences, including reputational damage from the loss of material. A researcher who is in breach of a requirement set out in this procedure may not be insured in the event of a loss. Additionally, individual researchers failing to comply with this procedure may be in breach of the Australian Code for the Responsible Conduct of Research or Malaysian Code of Responsible Conduct in Research.

2. Procurement requirements

2.1 The procurement of all controlled environments must be undertaken in accordance with the University's Procurement Policy.

2.2 Prior to the purchase of any controlled environment, researchers and staff must ensure that the device or environment is:

- fit for purpose and its cost is proportionate to the research purpose;
- capable of meeting all alarming, monitoring, and oversight requirements as set out in this procedure; and
- consistent with the University's Environmental Sustainability Policy.

2.3 Any ultra-cold freezers, laboratory grade freezers and scientific fridges used for the storage of critical material must be purchased from the recommended suppliers as advised by Strategic Procurement.

2.4 Staff who procure or purchase any controlled environment with a total value of less than $5000 must email the relevant local area support team to record the relevant asset details, for example, unique identifier, description, equipment barcode number, and/or serial number.

3. Management of controlled environments

Installation

3.1 The local area support team must submit a request to the Buildings and Property Division (BPD) or Facilities Management for Monash University Malaysia and Monash Suzhou, for connection to the University's approved back to base alarm system and back up power prior to installing the Controlled Environment.

3.2 Prior to submitting a request, the local area support team may require that the Chief Investigator and/or lead researcher determines a risk rating of the research material in accordance with the Risk Assessment process outlined at Table 1 below.

3.3 The local area support team must record the relevant information into the faculty repository, including the location, controlled environment details and if applicable, BAS port number. Researchers should contact their local area support team for more information.

Maintenance

3.4 All controlled environments containing critical material must be maintained in accordance with manufacturer's specifications to ensure they are in optimal condition and regularly serviced to minimise malfunctions.

3.5 Additional local maintenance of the environments must be undertaken on a regular basis, for example, cleaning, disposal of redundant samples, defrosting, de-icing freezer doors and preventative maintenance.

Risk assessment for research material housed in controlled environments

3.6 The Chief Investigator and/or approved lead researcher must determine the risk rating of the research material in accordance with the Risk Assessment process outlined in Table 1 below. A risk rating of Major (level 4) or Extreme/Irreplaceable (level 5) means that 'material' requires additional safeguards, as set out at 3.9 below.

3.7 The ratings outlined in Table 1 relate to the level of impact on a research project, or wider research activities, if the associated materials were lost.

Table 1: Risk assessment for research material housed in controlled environments:

Rating	Impact Description	Examples
5 – Extreme / Irreplaceable	• Disastrous impact on research activities; • serious reduction in research activity/output; • serious problems for a number of students, teaching or research samples; and/or • serious impact on the reputation of the affected researcher(s) and/or University	Material that is impossible to replace/collect again due to: • declared or danger of extinction; • irreplaceable clinical samples; • current ethical considerations; • long-term living organisms in clinical studies that cannot be repeated.
4 – Major	• Critical event or circumstance that can be endured with proper management; • major impact on research activity over a sustained period; • major problems meeting research targets; and/or, • serious impact on the reputation of the affected researcher(s)	Material that can be replaced but with major impact in loss of research funds and time, e.g: • repeating a long-term animal/clinical study to collect and analyse new samples • high-cost laboratory reagents
3 – Moderate	• significant event or circumstance that can be managed under normal circumstances • significant impact on research activity over a sustained period	Material that can be replaced but with moderate impact in loss of research funds and time, e.g. repeat a short term study to collect and analyse new samples

	• significant problem meeting research targets	
2 – Minor	• Event with consequences that can be easily absorbed but requires management effort to minimise the impact; • minor impact on research activity; and/or • temporary problems meeting some research targets	Material that can be easily replaced with minor impact in loss of research funds and time, e.g. • re-extract DNA/RNA/protein • re-run a PCR
1 – Insignificant	• Some loss; existing controls and procedures should cope with circumstance or event • Negligible impact on research activity or achievement of teaching/research targets	Material that can be easily replaced with no impact in loss of research funds and time, e.g. • duplicate of samples • consumable items

Housing of critical research material

3.8 Researchers requiring storage of critical research material in an accredited ISO20387 biobank should contact an appropriate accredited biobank for access requirements.

3.9 All research material associated with an externally-funded research project must be housed in a manner that fulfils the contractual obligations and requirements of the external research funding body.

3.10 All controlled environments containing critical material (risk rating of level 4 or level 5) must have additional safeguards, as follows:

- connection to an approved back-to-base alarm that is capable of detecting a change in the environment and is monitored 24 hours a day, for example, BAS or approved wireless technology and should be connected to emergency power or have adequate battery back-up to enable ongoing power supply in the event of an extended power outage;
- back-up power in the event of a loss of regular power to the environment;
- clearly displayed contact details of the research group's on-call list in the event of alarm activation;
- clear signage on all electrical sockets supplying freezers that contain critical material indicating that the supply must not be switched off or unplugged without informing the responsible person; and,
- where there is no such infrastructure available to provide power back-up, an appropriate, faculty endorsed risk management strategy must be in place.

3.11 Where possible, all researchers must maintain back-up duplicates or aliquots of critical research materials housed in alternate controlled environments. Researchers should contact the relevant local area support team to access alternate controlled environments.

Valuation of research materials

3.12 All researchers must determine a financial value (insurable value) for their research materials using the University's Project Costing and Pricing Model as requested by the local area support team and/or on an annual basis. The insurable value is the cost to recreate or replace the material. Researchers should refer to the Research Material Valuation Methodology for valuation principles and contact Research Finance for assistance in calculating the insurable value of research materials.

3.13 The risk rating and associated valuation must be recorded with their inventory list and provided to the local area research support team upon request.

3.14 In the event of a loss of research materials, the insurable value will be calculated in reference to the cost to recreate or replace the materials as set out below at 4. Reporting an adverse event and loss of research material.

Disposal of research materials

3.15 Staff and researchers must destroy and/or dispose of research material housed in controlled environments in accordance with the following:

- Requirements of the Australian and Malysian Code for the Responsible Conduct of Research and the National Statement on Ethical Conduct in Human Research (NHMRC);
- The University's Recordkeeping policy and procedure and Research Data Management policy and procedure;

- Australian and Malaysian Biosafety, Biosecurity and GeneTechnology regulations; and,
- The University's Occupational Health & Safety Policy and associated procedures, including the Disposal of Radioactive Procedure.

4. Reporting an adverse event and loss of research material

4.1 Controlled environments must be maintained to ensure accuracy, reproducibility and integrity of research results and reporting.

4.2 Researchers must contact their local area support team or school manager in accordance with the local area emergency contact process immediately upon becoming aware of any change in the condition of a controlled environment, for example, variation in temperature, humidity etc that is outside of the set parameters.

4.3 Researchers, Chief Investigators and staff must report any loss of research materials due to failure or malfunction of controlled environments to the relevant school or department manager via email immediately after becoming aware of the loss.

5. Controlled Environments located at third-party locations

5.1 Researchers and staff who are engaged in research that is conducted for and/or on behalf of the University at off-site location or premises, for example, hospitals or at third party institutions should refer to the terms of any applicable agreement for the management of controlled environments.

5.2 The local area support team must ensure that the minimum requirements for the management of controlled environments containing critical material at third party institutions are met prior to any storage of critical materials. The minimum requirements for the management of controlled environments include:

- connection to a monitored building management system or equivalent;
- connection to a backup power supply appropriate to the building;
- access to alternate controlled environments in case of an emergency;
- emergency management plans;
- regular professional maintenance; and
- located in a controlled environment with appropriate fire detection.

5.3 If the minimum requirements outlined above cannot be met, the relevant local area support team will conduct a risk assessment and consult the Risk and Compliance Unit to determine an alternative solution.

6. Roles and responsibilities

Chief Investigator and/or Approved Researcher

6.1 The Chief Investigator and/or Approved Researcher is responsible for managing local controlled environments and all materials housed within those environments, as follows:

- assigning a risk rating in accordance with Table 1 and ensuring all information relied on is true and correct;
- compliance with requirements for the storage, maintenance, monitoring and disposal of research materials as outlined in this procedure;
- ensuring the requirements for the management of research materials associated with an externally-funded research project;
- maintenance of inventory lists and associated valuations;
- adhering to any additional control mechanisms as advised by the local area support team and/or BPD or Facilities Management; and,
- taking reasonable care when using controlled environments.

Local area support teams

6.2 The local area support team is responsible for supporting the Chief Investigator and/or research team with the management of controlled environments. Local area support teams are also responsible for:

- supporting researchers with the monitoring and maintenance of non-fixed or portable asset controlled environments in accordance with the requirements with this procedure, including servicing of environments in accordance with manufacturer specifications, and displaying of emergency contact details on controlled environments;
- the establishment of a response plan for the management of (non-fixed or portable asset) controlled environments in the event of a failure; and,
- providing alternate (spare) controlled environment (where practicable) space for emergency use; and,
- updating the insurance survey annually.

School and Department Manager(s) and School Senior Managers

6.3 The establishment of processes for the management of controlled environments, and responsibility for monitoring compliance with this procedure is overseen as follows:

- For Monash University Australia: School and Department Managers
- For Monash University Malaysia: School Senior Managers
- For Monash Suzhou: Suzhou Managers

Buildings and Property Division and Facilities Management

6.4 The University's Buildings and Property Division at Monash University Australia and Facilities Management at Monash University Malaysia and Monash Suzhou is responsible for:

- the monitoring and maintenance of controlled environments that are a fixture and/or fixed controlled environments in a building attached to back to base alarm, for example, BAS or generators (asset and/or infrastructure), in accordance with the requirements with this procedure;
- facilitating the engagement and programming of back to base alarms, as required;
- maintaining a documented protocol, responsibility and planned schedule for maintenance and servicing of built controlled environments;
- monitoring of back to base alarms, facilitate servicing in accordance with manufacturers specifications and annual testing;
- facilitating the servicing of building backup power sources in accordance with manufacturer specifications; and
- undertaking the review of power requirements against available backup generator supply every six months. and
- in consultation with the School or Department Manager, establish a response plan for the management of fixed asset controlled environments in the event of a failure, including communication and/or notifications to local support areas.

DEFINITIONS

Back to base alarm	Alarms that are monitored 24 hours a day and must be capable of detecting a change in the environment.
Biological samples	Mostly derived from non-human subjects in relation to the fields of biochemistry, cell biology, virology, bacteriology (infection and immunity) animal parasitology, and microbiology.
Cold storage	Includes ultra-cold (-80°C) freezers, -20°C freezers, 4°C fridges, cold rooms and liquid nitrogen vessels or dewars.
Critical materials	Items used for research and educational purposes which have a risk impact rating of major or extreme/irreplaceable. The risk rating relates to the level of impact on a research or educational program if the materials were lost or damaged. These may include, but are not limited to, animals, living organisms, tissues, blood, faeces, urine samples and their derivatives.
Insurable value	The cost to replace an item.
Local area support team	Lab groups, school-or departments within faculties or portfolios.
Local Controlled Environments	Equipment (eg. Freezers, fridges, incubators) that are owned or used by researchers within their laboratories or research facilities.
Medical samples	May be collected as a part of baseline or longitudinal human health studies, clinical trials, cancer or other human health research including infectious and lifestyle diseases. In some instances, these studies will involve the use of animals and involve the storage of primary tissue samples (human and animal), DNA, RNA, blood, urine and other samples
Plant, environmental and engineering samples	May relate to a broad selection of research topics ranging to marine, estuarine and freshwater ecology and environmental biology wheat and barley breeding, grain quality, potato production and supply, molecular plant pathology, transgenic plants, gene discovery and functional genomics

Primary samples	Can be either collected or created. They are then subject to analysis and key elements of the sample extracted (for example DNA or RNA) which is then kept as a product of the research to support results and research outcomes (secondary or test samples). Primary samples can be categorised into Medical, Biological or Plant, environmental and engineering samples.

GOVERNANCE

Parent policy	Responsible Conduct of Research Policy
Supporting schedules	N/A
Associated procedures	Responsible Conduct of Research: Procedure for Investigating Code Breaches Procurement Procedure
Related legislation	N/A
Category	Academic
Approval	Monash University Research Committee 6 August 2020 MEETING NUMBER 6/2020 / AGENDA ITEM 7.1
Endorsement	Vice-Provost and Senior Vice-Provost (Research) 27 July 2020
Procedure owner	Director, Platform Operations & Strategy
Date effective	13 October 2020
Review date	13 October 2023
Version	1.0
Content enquiries	platforms@monash.edu