Cold Storage Procedure

Version	Approved by	Approval date	Effective date	Next review
1.0	Pro-Vice-Chancellor (Research Infrastructure)	13 September 2018	13 September 2018	September 2021

Procedure Statement

Purpose	The purpose of this Procedure is to provide an overarching framework for reliable and efficient storage of refrigerated samples to ensure a world class research environment. The framework comprises a collection of principles, responsibilities and authorities to govern the integrity of Cold Storage Services (CSS) provided at UNSW and: • ensure that the University complies with applicable standards and regulations regarding cold storage services • outline the responsibilities and authorities governing cold storage services at UNSW facilities • define cold storage equipment, facilities and storage environments at UNSW • depict a typical research sample life cycle and prescribed sample management system • provide guidance to Estate Management with respect to cold storage requirements • define the minimum criteria for insurance eligibility for cold storage equipment and stored research material.	
Scope	This Procedure applies to staff, students and affiliates of all UNSW Faculties and Schools regarding cold storage services.	
Are Local Documents on this subject permitted?	☒ Yes, subject to areas specifically restricted within this Procedure.	☐ No

Procedure Processes and Actions

Contents

1. Introduction

This Procedure outlines the principles, responsibilities, and authorities governing Cold Storage Services (CSS) at UNSW.

Cold storage technology holds high value samples and assets across the University which support substantial research incomes and outcomes. It is therefore imperative that services and investment are coordinated, and high standards are maintained so research output is not compromised.

CSS are fundamental for the support of world class UNSW research facilities; reliable cold storage infrastructure is essential for maintaining the integrity of samples, reagents and experiments across more than 120 research groups at UNSW.

Failure to comply with this Procedure may result in unsuccessful insurance claims and/or loss of eligibility for cold storage funding until compliance is met.

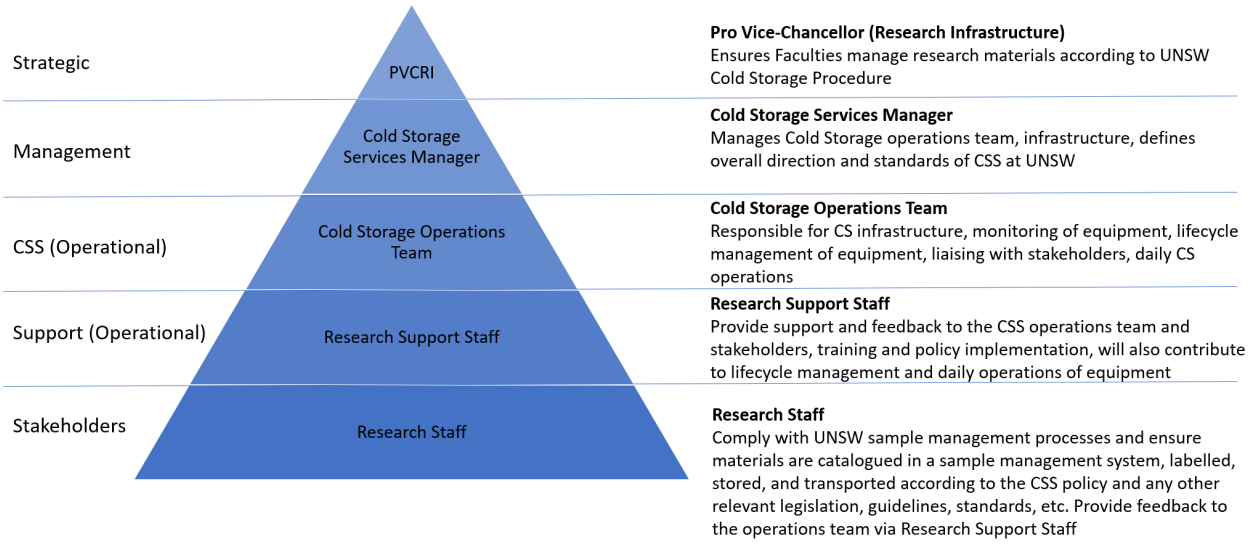
1.1. Research and Sample Integrity

The integrity of research material (including research samples), supported by cold storage, is intrinsically linked to Research Integrity at the University. Research integrity encompasses responsible research conduct and is comprehensively covered under the University Research Integrity Policies and Procedures. A robust cold storage procedure for effective management will include:

1. World class cold storage in terms of:
    a. Sample integrity
    b. High-quality equipment
    c. Cold storage equipment monitoring
    d. Facilities, infrastructure, management and maintenance
2. Sample management with respect to:
    a. Inventory identification and tracking
    b. Minimised contamination and degradation
    c. Compliance with relevant legislation, guidelines, ethics and retention periods
    d. Protection via quantifiable and agreed insured value.

1.2. Governance

This section defines the overall governance for Cold Storage at UNSW.



Further, the associated Service Catalogue defines the roles, responsibilities and services available within CSS.

2. Cold Storage Equipment and Facilities

2.1. Equipment and Facilities covered under this Procedure

- Cryogenics (vapour-phase and liquid)
- Cold storage cabinets (+4°C fridges, -20°C, -30°C, -40°C, and -80°C freezers)
- (+4°C) Walk-in Cool Rooms and (-20°C) Walk-in Freezer Rooms
- Cold Storage Cabinet Facilities/Cold Storage Rooms (Secure, alarmed, temperature-controlled facility used to accommodate cold storage cabinets)
- Supporting infrastructure and equipment.

2.2. Equipment Acquisition, Procurement, and Replacement Program

As a guide, freezers purchased to house critical research material must be fit-for-purpose (i.e. scientific grade equipment), and able to be connected to existing temperature monitoring facilities at the University, to ensure consistent lifecycle management of samples.

Cold storage equipment testing results along with data recorded by the Independent Data Logging and Alarm System (IDLAS), will contribute to an approved vendor list within UNSW Procurement. CSS will replace equipment from the approved vendor panel, funded through the CSS replacement program (budget dependent). Replacement and disposal will be based on freezer reliability, efficiency and overall life cycle management.

2.3. Equipment Monitoring

CSS will implement a rigorous program to ensure that UNSW researchers and other stakeholders meet their responsibilities to protect high-value samples. This will be undertaken in-part by investment in monitoring. It is a requirement that newly purchased freezers can be integrated into the University's equipment/sample monitoring systems.

2.3.1. The Building Management System (BMS)

The UNSW BMS forms part of UNSW's infrastructure. This hard-wired system communicates equipment alarms to selected personnel via email and/or SMS.

The existing BMS shall remain in place for all Ultra-low (-80°C) and other selected refrigerated cabinets across campus. Selected newly-acquired refrigerated cabinets are also to be connected to the BMS. In addition, these cabinets shall be monitored via an Independent Data Logging and Alarm System (IDLAS).

2.3.2. The Independent Data Logging and Alarm System (IDLAS) – Wireless monitoring

The IDLAS is a centralised, wireless monitoring technology which will operate in parallel with the BMS, thereby acting as a second level of redundancy. The IDLAS will monitor equipment temperature, power consumption and door opening/closing. Equipment alarms will be communicated by the IDLAS to selected personnel via email and/or SMS.

All refrigerated cabinets containing critical samples and operating at -30°C or below, will be monitored via the IDLAS. Selected scientific-grade refrigerated equipment will be monitored by the IDLAS as required, in consultation with CSS and in conjunction with a sample risk assessment.

The IDLAS will reduce the risk to cold storage assets, demonstrate compliance for the purposes of Research Integrity, maintain sample integrity and inform CSS for the purposes of the equipment replacement program.

2.4. Equipment Maintenance

The University is committed to scheduled equipment maintenance to ensure reliability, efficiency and longevity for researchers. CSS will determine the maintenance items to be performed by laboratory staff and an approved maintenance contractor, respectively. Laboratory level maintenance may include activities such as cleaning filters and undertaking regular defrosting procedures.

2.4.1. Preferred Maintenance Contractors

Maintenance contractors will be selected and managed by CSS to ensure maintenance is consistent and reliable in conjunction with UNSW Procurement policies and procedures. Maintenance which involves testing or measurement of electrical or refrigerator components shall be performed by a selected maintenance contractor.

2.5. Equipment Audits

CSS will undertake a comprehensive freezer audit each year, to ensure accurate records of all cold storage equipment are maintained.

3. Sample Management

Cold storage devices with valuable (insurable) contents are required to have sample management which identifies the contents, owner and age of the sample. Sample management by the stakeholder will assist in determining a quantifiable insured value calculated by researchers from labour and other associated costs. Sample management will determine which samples can be archived or disposed of (see figure 1). All samples require a risk rating as per risk assessment.

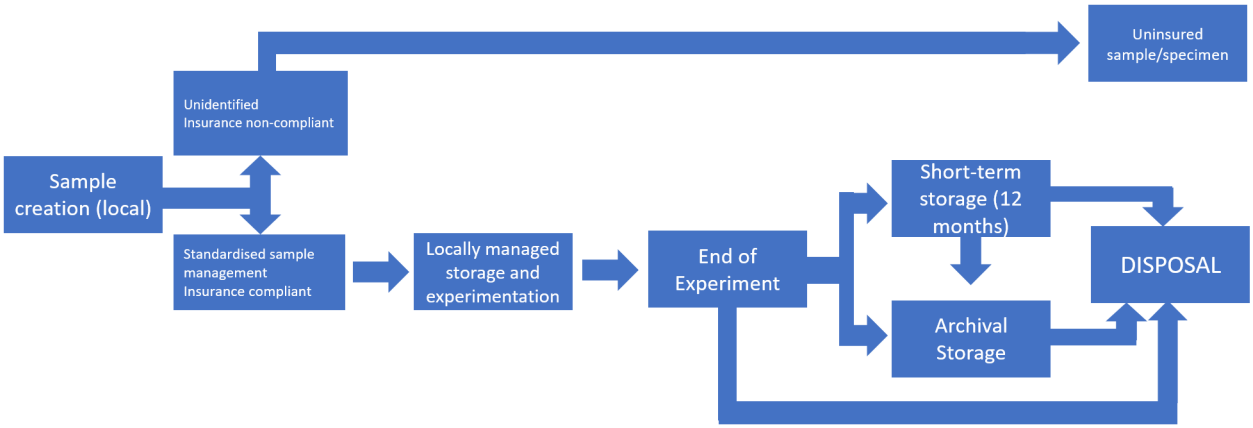


Figure 1: Lifecycle of a Sample

3.1. Prescribed Sample Management System

Samples should be identifiable down to a minimum of box-level or tube level at the discretion of the researcher.

All stakeholders should ensure that sample management endeavours include capturing and cataloguing research material on a UNSW supported database, once established. This measure is vital to ensuring sample integrity, as it identifies the sample throughout its lifecycle and satisfies value and insurance requirements. Currently, significant volumes of research material are catalogued in Microsoft Excel programs (47% as indicated in the 2017 -80 Freezer Survey), which is not intended for use as a rigorous sample management database.

4. Biorepository

Cold storage facilities at lab level are intended for short-term storage. Older samples shall be archived or discarded, where appropriate.

The UNSW Biorepository provides a complete service for the life cycle of specimens (planning, collection/processing, storage, retrieval, and disposal). The Biorepository contains biospecimens, including blood and tissue samples (DNA and RNA extraction services available), from both healthy individuals and patients diagnosed with cancer and other diseases in line with relevant legislation, codes and other regulations.

Clinical information from the donors is also collected and linked to the specimens via a secure, web-accessible database. The Biorepository offers monitored long-term storage to maintain specimen integrity and a rapid on-demand specimen retrieval service, allowing investigators to focus on their research and avoid unnecessary investment in equipment, staffing and storage facilities.

4.1. Biobank (Future state)

Samples which require long-term or archival storage will be managed by a central UNSW Biobank, once established. An expiry date will be required on submission of the sample. Storage of the sample will be free of charge until its expiry date, at which time a prescribed fee is required for it to be retained. This scheme is designed to ensure that redundant samples are not kept indefinitely. It is expected that samples which enter the biobank are not required or accessed within 12 months from the time of placement in the UNSW Biobank.

It is envisaged that the Biobank and Biorepository will be managed by the Biobank/repository manager.

5. Floorspace Utilisation

CSS will advise on approved equipment brands and models, consistent with efficient space utilisation of research facilities.

6. Estate Management

Estate Management (EM) shall comply with endorsed guidelines provided by CSS regarding cold storage requirements for new or upgraded facilities including, but not limited to, new and re-purposed buildings, renovations, and provision of maintenance and required services. Further, EM will provide services, utilities (such as air-conditioning and electricity supply) and maintenance for existing and future approved cold storage infrastructure.

7. Cold Storage Website

Stakeholders should utilise the Cold Storage Website, once established, to inform themselves on all matters concerning cold storage. The website is intended for use as a working tool for researchers and lab managers, to provide a source of centralised information and to instil confidence and share knowledge. The website will be accessible to persons who have fulfilled access requirements as determined CSS.

8. Grants and Insurance

The criteria for insurance of equipment (refrigerated cabinets) and research material (samples, precursors, etc.) will be contingent on meeting minimum insurance standards as defined by UNSW insurers.

Minimum standards will include:

- Temperature monitoring and alarms
- Power monitoring and alarms
- Identification of contents (sample management)
- Smoke detection
- Periodic emergency response training
- Retrofitting of captive plugs
- A robust, current and verifiable value estimate of the contents of each individual cold store.

Factors considered in sample valuation should include the cost of acquisition and work required to reproduce the sample to its current state. Consideration of these factors will generate a “sample replacement value” for insurance purposes.

Insurance exclusions or sublimits may apply to equipment and samples which fail to meet minimum insurance criteria.

Accountabilities	
Responsible Officer	Pro-Vice-Chancellor (Research Infrastructure)
Contact Officer	Cold Storage Services Manager
Supporting Information	
Legislative Compliance	Nil.
Parent Document (Policy)	Handling Research Material and Data Procedure
Supporting Documents	UNSW Cold Storage Service Catalogue
Related Documents	Australian Code for the Responsible Conduct of Research Office of the Gene Technology Regulator, Guidelines for the Transport, Storage and Disposal of GMOs AS/NZS Standards AS/NZS 60079.29.2:2016 AS/NZS 2243.3-2010
Superseded Documents	Nil.
File Number	2018/26945

Revision History

Version	Approved by	Approval date	Effective date	Sections modified
1.0	Pro-Vice-Chancellor (Research Infrastructure)	13th September 2018	13 September 2018	New Procedure