



Cold Storage Management Policy

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DEFINITIONS

OVERVIEW

The University recognises the importance and value of its [Critical Materials](#) required for research and teaching purposes, and is committed to their effective storage and management. [Critical Materials](#) are those 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. Some of this [Critical Material](#), either being actively used or archived, requires cold storage in ultra-cold (-80°C) freezers, -20°C freezers, 4°C fridges and liquid nitrogen vessels.

To support its researchers, the University has developed an '[ABC of Complete Freezer Management](#)', which comprises information about central biobank facilities ('the Biobank'), the University's Laboratory Information Management System ('[FreezerPro](#)'), and local ultra-cold freezer management procedures. The Biobank assists researchers in the secure storage of their samples that are:

- Archival materials (irreplaceable/valuable samples)
- Back-up materials (critical/valuable samples)
- Materials generated from longitudinal and long-term studies

In accordance with the [Research Data and Primary Materials Policy](#), individual researchers have primary responsibility for the management of data and materials related to their research. This Policy is designed to assist researchers in maintaining a high standard of care for refrigerated research materials and ensure that this process is standardised across the University. This initiative is constructed to meet the requirements of the [Australian Code for the Responsible Conduct of Research](#) to establish and maintain good governance and management practices for responsible research conduct, and for researchers to retain clear, accurate, secure and complete records of all research, including research data and primary materials.

SCOPE AND APPLICATION

This Policy, formerly titled 'Research Freezer Management Policy', outlines those principles and procedures associated with the storage, access and management of scientific materials requiring cold storage. It applies to all staff, students, affiliates and titleholders of the University of Adelaide who use such materials in the conduct of research and teaching associated with the University.

When scientific materials requiring cold storage are used for educational purposes, they must be risk-assessed, stored and managed according to the same following principles and procedures as scientific research materials. In such cases the use of the term 'researchers' in this Policy will include academics using scientific materials in educational programs.

RESOURCES

All University staff, students, affiliates and titleholders are encouraged to utilise the guidance available on the [University of Adelaide Biobank](#) website. This includes information about suitable and acceptable material for storage in the Biobank.

POLICY PRINCIPLES

1. All scientific materials, used for research or educational purposes, requiring storage in [Cold Storage Vessels](#) must be assigned a risk impact rating, as per the risk assessment table provided in Appendix 1.
2. All contents stored in ultra-cold -80°C freezers, including non-University owned ultra-cold freezers, must be catalogued in the Laboratory Information System ([FreezerPro](#)) to ensure their contents are accurately recorded and maintained.
3. All [Critical Material](#) stored in -20°C freezers, 4°C fridges and liquid nitrogen vessels must be consolidated into dedicated [Cold Storage Vessels](#) separate from those used for everyday access, and be catalogued in the Laboratory Information System ([FreezerPro](#)).
4. All [Cold Storage Vessels](#) containing [Critical Material](#) must be fitted with an alarm to detect failure of the container, and the alarm must be connected to the University Building Management System or an equivalent monitored alarm system.
5. All local ultra-cold freezers used to store [Critical Materials](#) must be kept in a secure and alarmed room or building and connected to the University Building Management System or an equivalent monitored Building Management System or equivalent independent freezer monitoring system. The room or building must have back-up systems in the event of freezer failure, including the identification of responsible on-call staff.
6. Scientific materials requiring cold storage which are associated with an externally-funded research project must be stored in a manner that fulfils the contractual obligations, principles and guidelines of the external research funding body.
7. All operations of the University Biobank and the Laboratory Information Management System will be conducted in accordance with the [Responsible Conduct of Research Policy](#) and the [Research Data and Primary Materials Policy](#).
8. All working and archival [Critical Materials](#) in ultra-cold freezers with an assigned risk rating of 'Extreme/Irreplaceable' must be stored in the Biobank. If material is in current use, aliquots or duplicates should be stored in the Biobank, where possible. Exceptions to storage in the Biobank can only be made upon the discretion of the Biobank Manager on a case-by-case basis.
9. Access to the Biobank facility will be limited to staff trained and approved by the Biobank Manager.
10. Responsibility for compliance with this Policy rests with the lead researcher or academic who has created or acquired the materials requiring cold storage.
11. Failure to comply with this Policy may mean that financial support is not available from the University's insurance program to assist in re-establishing research. It may also result in the loss of eligibility for funding from the Office of the Deputy Vice-Chancellor and Vice-President (Research) until compliance is met.

PROCEDURES

1. Compliance

- 1.1 Researchers and academics using materials for research or educational purposes, requiring cold storage must assign a risk rating to the materials, as per the risk assessment table provided in Appendix 1 and ensure that the materials are stored in accordance with the requirements of this Policy.

Responsibility: Chief Investigator or Lead Researcher on a Project

- a) Ensure that a risk rating is assigned to all scientific materials requiring cold storage.
- b) Authorise a member of the research group to bear responsibility for the storage and cataloguing of refrigerated research materials.

Responsibility: Executive Deans and Heads of School

- a) Ensure that all Schools manage relevant [Critical Materials](#) in line with the requirements of this Policy.
- b) Certify compliance with this Policy and the [ABC of Complete Freezer Management](#) guidelines.

Responsibility: Approved Researcher

- a) Determine those items used for research and educational purposes which are to be considered [Critical Materials](#) under this Policy.
- b) Assign a risk rating for all scientific materials stored locally in cold storage or in the Biobank, and ensure compliance with this Policy for new materials created or acquired that require cold storage.

2. Biobank Access and Management

- 2.1 For all [Critical Materials](#), researchers are strongly encouraged to have backup duplicates or aliquots stored in the Biobank.
- 2.2 For materials stored in ultra-cold freezers or [cold storage vessels](#) that are not owned by the University, researchers are strongly encouraged to have backup duplicates or aliquots stored in the Biobank regardless of the risk rating.
- 2.3 Access to and use of the Biobank is strictly regulated by the Biobank Manager, who will conduct a monthly review of the access list to the Biobank to ensure that only those employees and contractors who require it have access.
- 2.4 Research Grant Acceptance Forms issued by the University include a specific requirement that confirms the cataloguing and appropriate storage of research samples in accordance with this Policy.
- 2.5 All scientific materials must be catalogued at the sample level in [FreezerPro](#) before samples will be transferred from local freezers for storage in the Biobank.
- 2.6 Only material that is owned by the University of Adelaide, where responsibility also rests with the University of Adelaide, may be stored in the Biobank. Any material that does not fit this criterion can be stored subject to negotiation with the Biobank Manager on a case-by-case basis, giving consideration to capacity, risk and cost recovery.

Responsibility: Biobank Manager

- a) Oversee the collection of any materials for Biobank storage, or transfer of any materials in and out of the Biobank, ensuring the transfer process found on the [University Biobank website](#) is strictly followed.
- b) Send an annual report to each Chief Investigator for a review of [Critical Materials](#) they have stored in the Biobank.
- c) Conduct a biennial audit to assess compliance of randomly selected research groups (with prior notice). The audit is to assess whether [FreezerPro](#) has been updated to match local cold storage contents, and whether researchers are meeting the requirements of this Policy and the [ABC of Complete Freezer Management](#) guidelines.

Responsibility: Chief Investigators

- a) Ensure that all the necessary approvals (both external and internal) for storage and transport of their materials are in place prior to the transfer to the Biobank, and provide written evidence of such approvals.
- b) Complete a University [‘Biobank Transfer Authorisation’](#) acknowledging that their samples meet the requirements of this Policy, in order to receive final approval to transport samples to the Biobank.
- c) Retain all data and documents associated with the materials transferred to the Biobank. This includes grant details, contract details, ethics approvals, participant approvals, confidentiality agreements, legal agreements, deeds, etc.
- d) Where research is funded by the NHMRC, ensure compliance with the [NHMRC National Statement on Ethical Conduct in Human Research \(2007 updated 2018\)](#), and in particular, [Chapter 3.2 Human Biospecimens in laboratory based research](#).

Responsibility: Laboratory Manager or Approved Researcher

- a) Ensure all boxes are dated and labelled before transport to the Biobank. Labels must be permanent (i.e. able to withstand temperature changes).
- b) Where Genetically Modified Organisms are stored, label them in accordance with the [OGTR Guidelines for the Transport, Storage and Disposal of GMOs](#) current at the time of storage, and notify the University’s Institutional Biosafety Committee of the change in storage location.
- c) Where microorganisms and/or infectious substances are to be stored, label them with a biological hazard symbol in accordance with the [AS/NZS 2243.3:2010](#) as well as any other information or labels as per any other related regulatory requirements.

3. Laboratory Information Management System ‘FreezerPro’

3.1 The Biobank Manager will have ‘administrative’ rights to [FreezerPro](#).

3.2 Users including Laboratory/School administrators and researchers will have designated access rights to FreezerPro for their local cold storage management, and ‘view only’ access to their group’s [FreezerPro](#) contents stored in the Biobank.

3.3 In addition to the requirements of Principle 2, all researchers are encouraged to use [FreezerPro](#) to catalogue materials from 4°C fridges, -20°C freezers and liquid nitrogen storage that have a risk rating lower than ‘Major’.

Responsibility: Laboratory Manager or Approved Researcher

- a) Ensure all the contents of local ultra-cold freezers and [Critical Materials](#) stored in 4°C fridges, -20°C freezers and liquid nitrogen are catalogued in [FreezerPro](#) and identify material to be sent to the Biobank. Compulsory data for all materials to be catalogued comprises:
 - Chief Investigator details
 - Research Group details
 - Research grant ID (e.g. NHMRC/ARC/GRDC) and/or PeopleSoft Project code
 - Ethics Approval Numbers
 - School details
 - Existing local freezer storage details
 - Box type
 - Risk rating
 - Sample name and type
 - Details of storage chemicals/ hazard class
 - Original storage date
 - Required legal/contractual time for sample to be kept (‘end date’)
 - Biobank Storage (Yes or No)

Responsibility: Biobank Manager

- a) Allocate access to [FreezerPro](#) via a licence to the Laboratory Manager and/or Approved Researchers of each research group upon completion of a FreezerPro training course.

4. Cold Storage Management

4.1 All local freezers must be managed in accord with this Policy in order to keep [Critical Materials](#) secure, keep the freezers in optimal condition, minimise freezer malfunctions and ensure insurance standards are met.

4.2 All local ultra-cold freezers must be connected to a backup power supply, which may be electrical or CO₂ as appropriate to the building. Where possible, critical -20°C freezers should also be connected to a backup power supply. Where there is no such infrastructure available, an appropriate, endorsed risk management strategy must be in place.

4.3 Freezer facilities containing [Critical Materials](#) must be air-conditioned (temperature controlled) and have appropriate fire detection.

4.4 Each research group must identify staff responsible for the local freezers they use and the contents of those freezers.

4.5 Each research group must maintain local on-call lists of staff to attend freezers in the case of failure. Contact details must be clearly displayed on each freezer.

4.6 Spare ultra-cold freezers must be available to provide space for defrosting of ultra-cold freezers and for emergency use.

4.7 New ultra-cold freezers and laboratory grade -20°C freezers used for the storage of critical material must be purchased from the recommended suppliers and brands chosen by Procurement Services and the Biobank Manager.

Responsibility: Faculty and/or School Research Support team

- a) Ensure all local ultra-cold and -20°C freezers containing [Critical Material](#) have regular “local” maintenance which includes:
 - i. Defrosting and/or de-icing the doors at a minimum of once per month.
 - ii. Conducting a full defrost if directed by maintenance technicians in the inspection cycles.
- b) Ensure all local ultra-cold and -20°C freezers containing [Critical Material](#) have professional maintenance by an appropriate service technician with documented records at a minimum of once per year.
- c) Ensure the room in which a local freezer is kept is air-conditioned (temperature controlled) and has appropriate fire detection.
- d) Ensure all local ultra-cold freezers and freezers with [Critical Material](#) have up-to-date, primary and secondary emergency contact details printed and attached to the front of the freezer, along with an on-call list for staff to attend the freezer in case of failure.
- e) Ensure that spare ultra-cold freezers are available for use as emergency backups and to provide space for defrosting of local ultra-cold freezers.

Responsibility: Biobank Manager

- a) Review the University Asset Register, School asset registers and the Equipment Register against existing [FreezerPro](#) reports every six months to ensure effective oversight and monitoring of ultra-cold freezers. Local managers are responsible for the accuracy of content data in the registers.

5. Management of Ultra-cold Freezers Located at Third Party Institutions

5.1 Minimum requirements for the management of ultra-cold freezers containing [Critical Material](#) utilised by University researchers in a third party institution include:

- i. Connection to a monitored Building Management System or equivalent
- ii. Connection to a backup power supply appropriate to the building
- iii. Access to backup freezers in case of emergency
- iv. Emergency management plans
- v. Regular professional maintenance
- vi. Housing in an air-conditioned (temperature controlled) facility with appropriate fire detection,

This requirement includes both University-owned ultra-cold freezers and those owned by third-party institutions being used by University researchers.

5.2 Where University standards are unable to be met, the relevant School will conduct a risk assessment (found on the [Biobank website](#)) and consult with the Biobank Manager to determine an appropriate alternative solution.

Responsibility: Faculty and/or School Research Support Team

- a) Ensure that new or existing facilities utilised by University researchers for housing of ultra-cold freezers meet the minimum requirements.
- b) If the minimum requirements are unable to be met, perform a risk assessment and consult Legal and Risk and the Biobank Manager to determine an alternative solution.

6. Disposal of Biobank materials

6.1 If research data or primary materials stored in the Biobank are no longer required to be retained to satisfy the [Australian Code for the Responsible Conduct of Research, Research Data and Primary Materials Policy](#), [NHMRC National Statement on Ethical Conduct in Human Research](#), [Australia code for the care and use of animals for scientific purposes](#), or the guidelines of the external research funding body associated with the research project, they may be destroyed or disposed of having regard to the [University Records Policy](#), or any procedures on destruction or disposal that may be determined by the University from time to time. Such disposal must take into account any specific requirements of the [NHMRC National Statement on Ethical Conduct in Human Research](#), including Chapter 4.7: Aboriginal and Torres Strait Islanders.

Responsibility: Chief Investigator

- a) Ensure that materials that no longer satisfy Procedure 6.1 are removed from the Biobank and destroyed or disposed of in the appropriate manner.

7. Reporting losses of cold storage Critical Materials

7.1 Any loss of cold storage scientific materials due to failure or critical malfunction of ultra-cold freezers, -20°C freezers, 4°C fridges or liquid nitrogen storage must be reported as soon as possible to Legal and Risk (helpdesklegal@adelaide.edu.au), the Biobank Manager and the relevant Faculty or School Manager via the Loss and Damage Report located on the [Biobank website](#).

Responsibility: Chief Investigator

- a) Ensure that the Loss and Damage report is accurately completed and submitted to Legal and Risk, the Biobank Manager and the relevant School Manager.

DEFINITIONS

Aliquot is a specific sample or volume that is taken as portion of a larger sample or volume.

Approved Researcher is a member of a research group that is given authorisation by the Chief Investigator to bear responsibility for the storage and cataloguing of refrigerated scientific materials.

The Biobank is an ultra-cold biorepository for critical research and education materials that are not reasonably expected to be required to be accessed for a period of 12 months or more. The facility is built to a PC2 standard. It is primarily designed for the secure storage of archival materials (past activity), as a back-up for current critical materials (current activity), and for materials used in longitudinal and long-term studies (potential future activity).

The Biobank Manager is the officer responsible for management of the University Biobank facilities. The Biobank Manager is also the FreezerPro administrator and is responsible for transfers and storage of Critical Materials in the Biobank facility.

Cold Storage Vessels include ultra-cold (-80°C) freezers, -20°C freezers, 4°C fridges and liquid nitrogen vessels.

Critical Materials are those 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, tissues, blood, faeces, urine samples and their derivatives.

FreezerPro is the University's Laboratory Information Management System used to manage and catalogue University Cold Storage Vessels and their contents including the Biobank and local freezers.

Institutional Biosafety Committee is a University body that is required to assist researchers with compliance to relevant legislation on genetic manipulation work, including the Gene Technology Act 2000, Gene Technology Regulations 2001, OGTR Guidelines and also accreditation by the Gene Technology Regulator.

Laboratory Information Management System users are laboratory managers or researchers who hold a licence for FreezerPro and are able to access and edit the catalogues for their frozen materials.

Local Freezers are those used by researchers within their laboratories or research facilities.

Non University-owned freezers are those owned by a third party company or institution (e.g. a hospital, SAHMRI, SA Museum).

Procurement Services is a University department that negotiates with suppliers and creates a structure in which goods and services can be obtained for the best quality and value.

Ultra-cold freezers are -80°C freezers.

RMO File No.	F. 2019/3666
Policy Custodian	Deputy Vice-Chancellor and Vice-President (Research)
Responsible policy officer	Director, Adelaide Microscopy and Biobank
Endorsed by	Academic Board on 4 September 2019
Approved by	Vice-Chancellor and President on 4 September 2019
Related Documents and Policies	<i>Research Data and Primary Materials Policy</i> <i>University Records Policy</i> <i>Risk Management Policy / Framework</i> Australian Code for the Responsible Conduct of Research NHMRC National Statement on Ethical Conduct in Human Research Australia code for the care and use of animals for scientific purposes ABC of Complete Freezer Management
Related Legislation	<i>OGTR Guidelines for the Transport, Storage and Disposal of GMOs</i> <i>Australian New Zealand Standard AS/NZS 2243.3:2010</i>
Superseded Policies	Research Freezer Management Policy
Effective from	5 September 2019
Review Date	5 September 2022
Contact for queries about the Policy	Dr Georget Reaiche-Miller, Biobank Manager, 831 34807 or georget.reaiche@adelaide.edu.au

Appendix 1

Risk Assessment: Impact ratings for research and educational material housed in cold storage

This rating relates to the level of impact on a research project or wider research activities if the associated scientific materials were lost.

Rating	Impact Description	Examples
5 Extreme/irreplaceable	<ul style="list-style-type: none"> Potentially disastrous impact on research activities Serious reduction in research activity/output Serious problems reaching a number of students, teaching or research samples Serious impact on the reputation of the affected researcher(s) 	Material that is impossible to replace/collect again due to: <ul style="list-style-type: none"> Already extinct Danger of extinction Current ethical considerations Long-term animal/clinical study that cannot be repeated
4 Major	<ul style="list-style-type: none"> 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 Serious impact on the reputation of the affected researcher(s) 	Material that can be replaced but with <u>major impact in loss of research funds and time</u> , e.g.: <ul style="list-style-type: none"> Repeat a long-term animal/clinical study to collect and analyse new samples High-cost laboratory reagents
3 Moderate	<ul style="list-style-type: none"> Significant event or circumstance that can be managed under normal circumstances Significant impact on research activity over a sustained period Significant problem meeting research targets 	Material that can be replaced but with <u>moderate impact in loss of research funds and time</u> , e.g.: <ul style="list-style-type: none"> Repeat a short term study to collect and analyse new samples
2 Minor	<ul style="list-style-type: none"> Event with consequences that can be easily absorbed but requires management effort to minimise the impact Minor impact on research activity Temporary problems meeting some research targets 	Material that can be easily replaced with <u>minor impact in loss of research funds and time</u> , e.g.: <ul style="list-style-type: none"> Re-extract DNA/RNA/protein Re-run a PCR
1 Insignificant	<ul style="list-style-type: none"> 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 <u>no impact in loss of research funds and time</u> , e.g.: <ul style="list-style-type: none"> Duplicate of samples