Research Freezer Management Policy

OVERVIEW

The University recognises the importance and value of its research materials and is committed to their effective management. Some of this research material, either being actively used or archived, requires refrigerated storage, including the use of ultra-cold (-80^{0}C) freezers, -20^{0}C freezers, 4^{0}C fridges and liquid nitrogen storage.

To support its researchers, the University has developed an 'ABC of Complete Freezer Management', which comprises central biobank facilities ('the Biobank'), an information management system ('FreezerPro') and local freezer management procedures. Researchers are able to benefit from use of the Biobank which is a highly specialised facility, and offers long-term protection and storage for valuable refrigerated research materials.

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 requirement of the *Australian Code for the Responsible Conduct of Research* that all data storage and management processes must be accessible, easy to use, affordable, auditable, flexible, sufficient and secure.

SCOPE AND APPLICATION

This Policy outlines those principles and procedures associated with the storage, access and management of research materials requiring refrigerated storage. It applies to all staff, students, affiliates and titleholders of the University of Adelaide who are involved in the conduct of research associated with the University.

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 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*.

2. All materials stored in freezers must fulfil the contractual obligations, principles and guidelines of the external research funding body associated with the research project.

3. Grant acceptance procedures will include the requirement for all materials requiring ultra-cold storage generated from new grants to be catalogued in FreezerPro, and stored in the Biobank where required.

4. All refrigerated research materials must be assigned a risk rating, as per the risk assessment table provided in Appendix 1.

5. All working and archival research materials in ultra-cold freezers with an assigned risk rating of '*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.

6. Details of all working materials placed in local ultra-cold freezers, including non-University owned ultra-cold freezers, must be catalogued in FreezerPro to ensure their contents are accurately recorded and maintained.

7. All materials stored in 4^0C fridges, -20^0C freezers or liquid nitrogen that are rated as '*Irreplaceable'* or *'Major'* (as per the risk assessment table in Appendix 1) must be catalogued in FreezerPro.

8. Where relevant, Schools must make available liquid nitrogen storage vessels that are alarmed. Cryo-material rated as '*Irreplaceable'* or '*Major'* must be stored in the alarmed vessels.

9. Where relevant, Schools should make available 4^0C fridges and -20^0C freezers that are alarmed and connected to the University Building Management System or equivalent monitored alarming system. Materials that are stored at 4^0C or -20^0C and are rated as 'Irreplaceable' or 'Major' should be stored in the alarmed freezers.

10. All local ultra-cold freezers must be kept in a secure and alarmed room or building and connected to the University Building Management System or equivalent monitored Building Management System or equivalent independent freezer monitoring system, with back-up systems in the event of freezer failure, including the identification of responsible on-call staff.

11. Access to the Biobank facility will be limited to the trained Biobank Manager. Approved back-up staff will be given access by Security as required. Access to the Benham Biobank will be controlled by the University's secure card key system and access to the Waite Biobank will be controlled by the University's secure key system.

12. Failure to comply with this Policy may mean there is no financial support 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 Provost and Deputy Vice-Chancellor and Vice-President (Research) until compliance is met.

PROCEDURES

1. Compliance

1.1 For research materials with an assigned risk rating of '*Major'*, researchers are strongly encouraged to have backup duplicates or aliquots stored in the Biobank.

1.2 Materials stored in non-University-owned freezers are strongly encouraged to have backup duplicates or aliquots stored in the Biobank regardless of the risk rating.

1.3 Existing samples stored in ultra-cold freezers in each research group must be catalogued at a minimum of 50% of total occupied freezer space by March 2017, and the remaining 50% must be completed by March 2018.

Responsibility: Executive Deans and Heads of School

a) To ensure that all Schools manage relevant research material in line with the requirements of this Policy.
b) To certify compliance with this Policy and the ABC of Complete Freezer Management guidelines.

Responsibility: Laboratory Manager or Approved Researcher

a) Assign a risk rating for all research materials stored in the Biobank and a local freezer.

Responsibility: Biobank Manager

a) Send an annual report to each Chief Investigator for a review of research material they have stored in the Biobank.
b) 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 freezer contents, and whether researchers are meeting the requirements of this Policy and the *ABC of Complete Freezer Management* guidelines.

2. Biobank Access and Management

2.1 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 Benham Biobank to ensure that only those employees and contractors who require it have access.

2.2 Storage of materials in the Biobank will incur service fees as listed on the University Biobank website.

2.3 Research Grant Acceptance Forms issued by the University will include a specific requirement that confirms the cataloguing and appropriate storage of research samples in accordance with this Policy.

2.4 All research materials must be catalogued in FreezerPro before archive samples will be transferred from local freezers for storage in the Biobank.

2.5 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 criteria can be stored subject to negotiation by facility management 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 out of the Biobank, ensuring the transfer process found on the University Biobank website is strictly followed.

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 revised NHMRC *National Statement on Ethical Conduct in Human Research* (2007), and in particular, *Chapter 3.2 Databanks*, is maintained.

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. 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 freezer management, and 'view only' access to their group's FreezerPro contents stored in the Biobank.

3.3 In addition to the requirements of Principle 7, all researchers are encouraged to use FreezerPro to catalogue materials from 4^0C fridges, -20^0C freezers and liquid nitrogen storage that have a risk rating lower than '*Major*'.

Responsibility: Laboratory Manager or Approved Researcher

a) Ensure the contents of local ultracold freezers are catalogued in FreezerPro and identify material to be sent to the Biobank. Compulsory data for all materials, including materials rated as '*Irreplaceable'* or '*Major'* in 4^0C fridges, -20^0C freezers and liquid nitrogen storage, comprises:

- Chief Investigator details
- Research Group details
- Research grant ID (eg. 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)

b) Prioritise for entry into FreezerPro any materials rated as '*Irreplaceable'* or '*Major'* (as per the risk assessment table provided in Appendix 1).

Responsibility: Biobank Manager

a) Allocate access to FreezerPro via a licence to the Laboratory Manager and/or an Approved Researcher of each research group once that person has completed a FreezerPro training course.

4. Local Ultra-Cold Freezer Management

4.1 All local ultra-cold freezers must be managed in accord with this Policy in order to keep research 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 kept in a secure and alarmed room or building and connected to the University Building Management System or equivalent monitored Building Management System or equivalent independent freezer monitoring system.

4.3 All local ultra-cold freezers must be connected to a backup power supply.

4.4 Freezer facilities must be air-conditioned (temperature controlled) and have appropriate fire detection.

4.5 Each research group must identify staff responsible for the local ultra-cold freezers they use and the contents of those freezers.

4.6 There must be local on-call lists of staff to attend ultra-cold freezers in case of failure.

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

4.8 New ultra-cold freezers must be purchased from the recommended suppliers and brands chosen by Strategic Procurement and the Biobank Manager.

Responsibility: Research Development Manager and Technical Services Manager

a) Ensure all local ultra-cold freezers have regular "local" maintenance which includes:
   i. Defrosting the doors minimum once per month.
   ii. Conducting a full defrost if directed by maintenance technicians in the inspection cycles.
b) Ensure all local ultra-cold freezers 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 ultra-cold freezer is kept is air-conditioned (temperature controlled) and has appropriate fire detection.
d) Ensure all local ultra-cold freezers 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 utilised by University researchers in a third party institution include:

i. Connection to a monitored Building Management System
ii. Connection to a backup power supply
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 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: Research Development Manager and School Manager

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, a risk assessment will be performed and Legal and Risk and the Biobank Manager will be consulted 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.

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 refrigerated research material

7.1 Any loss of refrigerated research material due to failure or critical malfunction of ultra-cold freezers, -20^{0}C freezers, 4^{0}C fridges or liquid nitrogen storage must be reported as soon as possible to Legal and Risk, the Biobank Manager and the relevant 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 research materials.

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

The Biobank Manager is the FreezerPro administrator and is responsible for transfers and storage of ultra-cold research materials in the Biobank facility.

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

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 research materials.

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.

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).

Strategic Procurement 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^{0}C freezers.

RMO File/Document Number	2016/894
Policy Custodian	Provost and Deputy Vice-Chancellor and Vice-President (Research)
Responsible Officer	Biobank Director
Endorsed by (Academic Board or VCE)	VCE on 11 May 2016
Approved by	Vice-Chancellor and President on 18 May 2016
Related Documents and Policies	*Research Data and Primary Materials Policy* *University Records Policy* *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	*OGTR Guidelines for the Transport, Storage and Disposal of GMOs* *Australian New Zealand Standard AS/NZS 2243.3:2010*
Superseded Policies	n/a
Date Effective	18 May 2016
Next Review Date	18 May 2019
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 freezer material

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

Rating	Impact Description	Examples
5 Extreme/Irreplaceable	• 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: • Already extinct • Danger of extinction • Current ethical considerations
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 • Serious impact on the reputation of the affected researcher(s)	Can be replaced by with major impact in loss of research funds and time, e.g.: • Repeat a long-term animal/clinical study to collect and analyse new samples
3 Moderate	• 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	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
2 Minor	• 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	Can be easily replaced and has 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	Can be easily replaced and has no impact in loss of research funds and time, e.g.: • Duplicate of samples