PROCEDURE

Metro South Health Research Biorepositories – Emergency Preparedness and Work Health and Safety

PR2017/108
Version No. 3.0

PURPOSE

Metro South Health (MSH) is committed to enhancing research biorepository capacity within the health service. MSH research biorepositories are required to have in place a robust emergency preparedness plan to minimise loss of biospecimens or data due to unforeseen operational disruptions caused by natural or man-made disasters.

Additionally, MSH is responsible for the safety of research biorepository personnel and protection of the quality and integrity of the collection. The purpose of this procedure is to outline the recommended elements of emergency preparedness and work health and safety for research biorepositories, based on international best practices.

OUTCOME

Whilst research biorepositories must be operated in accordance with the MSH Research Biorepository Governance Framework, principles may be adapted so that they are appropriate to the mission and goals of each research biorepository.

This procedure applies to all MSH or Queensland Health (QH) employees whose usual reporting line is through a MSH facility or service (including visiting medical officers, visiting health professionals, students and researchers) who operate or access, or who propose to establish or access, a research biorepository that includes biospecimens collected, processed or stored within MSH facilities.

Failure to comply with this procedure may amount to research misconduct on the part of the responsible individual. This procedure must be read in conjunction with other MSH Research Management and Research Biorepository procedures.

KEY PRINCIPLES

The following key principles guide MSH research biorepositories in their emergency preparedness and compliance with work health and safety requirements. The way in which individual MSH research biorepositories put these principles into operation may be scaled in relation to the research biorepository's size of operations.

MSH research biorepositories must ensure biospecimen derivatives and data that they house are stored securely, including measures to protect them in the case of foreseeable operational disruptions caused by natural or man-made disasters.

- Biospecimens are essential for translational cancer research. Collections of stored and well annotated biospecimens and their derivatives represent considerable investment of time and resources and in many cases, they are irreplaceable.

- As Custodians of biospecimens and associated information, research biorepositories have a responsibility to maximise their ability to maintain appropriate storage of the biospecimens and data that they house. Therefore, it is important to have in place an emergency response plan and systems to enable continuous storage of biospecimens and data during a disaster.
- Custodians must ensure sufficient space is available to accommodate the material planned for initial, future and backup storage and provide for the safe movement of people, equipment and biospecimens, as needed or as required by law and/or other regulatory agencies.
- All MSH research biorepositories must comply with all work health and safety requirements contained within this procedure and the MSH Human Resources Policy Framework.
- All personnel encountering biospecimens or involved in the operations of the research biorepository must be trained in safety procedures to minimise injuries to them and protect the material and information held in the research biorepository.
- All researchers accessing MSH biospecimens must be aware that samples have not been screened for potential pathogens and therefore may result in severe illness or even death if not handled properly. Following dispatch, the responsibility for the correct handling of the samples lies solely in the hands of the end user (the approved researcher) and is not the responsibility of the issuing research biorepository. Any illness resulting from the mishandling of these samples is not the responsibility or liability of the research biorepository, MSH, Queensland Health or any associated sponsors.

LEGISLATION OR OTHER AUTHORITY

Legislation

- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- *Human Rights Act 2019 (Qld)*
- *Public Health Act 2005 (Qld)*
- *Therapeutic Goods Act 1989 (Cth)*
- *Transplantation and Anatomy Act 1979 (Qld)*

To the extent an act or decision under this document may engage human rights under the *Human Rights Act 2019*, regard will be had to that Act in undertaking the act or making the decision. For further information on the *Human Rights Act 2019* see: https://www.qhrc.qld.gov.au/

Regulation

- Transplantation and Anatomy Regulation 2004 (Qld)

Statements, papers and guidelines

- International Society for Biological and Environmental Repositories (ISBER): Best Practices: Recommendations for Repositories Fourth Edition
- Organisation for Economic Co-operation and Development (OECD): Best Practice Guidelines for Biological Resource Centres
- World Health Organisation (WHO): Common Minimum Technical Standards and Protocols for Biological Resource Centres Dedicated to Cancer Research

MSH policies, procedures, manuals and frameworks

- Metro South Health Research Management Policy (PL2017/55)
- Risk Management Policy (PL2018/62)
- Risk Management Procedure (PR2018/97)

RESPONSIBILITIES

Executive Management

Ensure collaborative, harmonised, clear and detailed publicly available policies, procedures and Standard Operating Procedures (SOPs) are in place for the establishment and operation of all MSH research biorepositories.

Metro South Research

Support Custodians in the establishment and operation of a research biorepository through the provision of guidance and support when interpreting principles and provisions contained within the MSH Research Biorepository Governance Framework.

MSH Research Biorepository Strategic Oversight Committee

Review and approve all Research Protocols and SOPs and provide clarification and assistance in emergency preparedness and work health and safety requirements for each research biorepository.

Custodian/Principal Investigator – responsible officer

Ensure the research biorepository's emergency preparedness and work health and safety requirements are in compliance with the MSH Research Biorepository Governance Framework and appropriate for the type of biospecimens collected.

Research biorepository manager

Implement appropriate emergency preparedness and work health and safety requirements methodologies on behalf of the research biorepository and report any matters which require action to the Custodian.

Laboratory technician/technologist assistant/clinical personnel

Research biorepository personnel must possess sufficient educational background, experience and training to assure that assigned tasks are performed in accordance with the MSH Research Biorepository Governance Framework and applicable SOPs.

SUPPORTING DOCUMENTS

Attachment 1 - Application

Attachment 2 - Work Health and Safety Checklist

DEFINITIONS

See the MSH Research Biorepositories Glossary

PROCEDURE - EMERGENCY PREPAREDNESS AND WORK HEALTH AND SAFETY

STEP 1: Risk assessment

Assess likelihood of various types of disasters based on the geographic location of the research biorepository in accordance with the MSH Risk Management Policy (PL2013/06), Integrated Risk Management Framework and Risk Assessment Tool.

STEP 2: Mitigate risks

Establish necessary systems to mitigate identified risks, for example:

- Back-up power system(s) to minimise biospecimen or data loss due to loss of commercial power. Regularly test the back-up power generation system for reliable function.
- Consider dividing the collection between two geographically separate locations so that a disaster affecting one of the storage locations would leave the other set of biospecimens intact.

STEP 3: Develop emergency response plans

Establish an emergency response plan for responding to a variety of relevant risks and emergency situations (eg fire, freezer/fridge malfunction or plumbing leak). The emergency response plans must include contact information for all appropriate personnel and professional service providers (eg facilities personnel and power supply providers).

STEP 4: Test and review

Test the emergency response plan by simulating how it would be used during a disaster and repeat regularly (eg annually). Review the general emergency response plan at least annually to verify that it remains current.

STEP 5: Training and education

At the time of hiring new personnel, train all applicable personnel on the general and specific emergency response plan(s) and SOPs. Provide regular updates to all applicable personnel and review regularly (eg annually).

STEP 5: Work health and safety

Ensure the research biorepository complies with all work health and safety requirements contained within this procedure and the MSH Human Resources Policy Framework. A safety management plan and fire prevention plan must be developed for each collection. Research biorepositories must develop written SOPs as part of a research biorepository's internal governance to ensure safety precautions based on national, regional and local regulations.

STEP 6: Self-audit, review and compliance

Utilise Attachment 2 - Work Health and Safety Checklist to aid in self-auditing, review and compliance.

PROCEDURE DETAILS

Procedure Number
PR2017/108

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MSH Research Biorepositories – Emergency Preparedness and Work Health and Safety Procedure

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PL2017/53
MSH Research Biorepositories Policy

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05 July 2021

Date of Next Review
05 July 2024 (within the next 3 years)

ATTACHMENT 1 - Application

1.0 Emergency preparedness

1.1 Emergency response planning

Emergencies can cover a wide range of natural and man-made disasters, all of which may have varying effects on the facility and on the ability of the research biorepository to carry out its essential functions. The type and duration of disasters may depend on the geographic location at which the research biorepository is located. MSH research biorepositories must have a written disaster recovery/incident response and business continuity plan for responding to a wide variety of emergency situations. This plan must be tested periodically (ie at least annually) to ensure that all personnel are trained and that the plan meets the anticipated needs. Copies of these plans must be distributed to all appropriate staff.

1.2 On call

Key individuals should be identified who will serve as being “on call” or who will be able to respond to an emergency at the research biorepository. Leave schedules must be monitored to ensure that coverage of essential responsibilities is in place should key individuals be unavailable. Emergency contact numbers must be posted in prominent locations in the research biorepository and must be carried by staff members at all times who are ‘on call’. The contact information must be reviewed on a regular basis to ensure that the information contained therein is current.

MSH research biorepositories must have a check list of activities for “on call” staff to follow during an emergency. “On call” staff must be familiar with the location and operation of certain key equipment and controls (ie circuit boards) that may need to be checked during an emergency. Telephone numbers for professional assistance must be clearly posted in the research biorepository and accompanying administrative areas (eg engineering or facilities personnel, power companies, fuel supply companies and transportation services).

1.3 Security systems

Notification of security and environmental monitoring systems must be verified on a routine basis. Where possible, emergencies should be simulated to ensure proper follow-through for the established emergency plan. If not located in a MSH hospital, the Custodian, research biorepository manager or appropriate staff member must communicate with local power providers before an emergency occurs to request that the research biorepository be placed on a list of “high priority” users for power restoration following an emergency. If the research biorepository inventory systems are housed on a server located away from the research biorepository, some consideration should be given to storing electronic inventory records on site. Otherwise, in an emergency, needed records may not be accessible.

1.4 Evacuation

In the event of an impending need for evacuation, research biorepositories that utilise liquid nitrogen (LN_2) bulk tank(s) should arrange to have them filled.

1.5 Splitting stored biospecimens

Depending on the “value” and the ability to replace certain samples, some research biorepositories may decide to divide collections and store them in different environmental storage containers or even at different geographic locations so that a disaster affecting one component of the collection would not eliminate the entire collection.

Whenever possible, MSH recommends splitting stored biospecimens into two sets of aliquots, each set stored in a different location. This strategy will avoid unnecessary loss in case of adverse events in one location. Custodians must consider the following logistical issues when splitting stored biospecimens:

- increase in number of freezers per MSH research biorepository
- access to differing and appropriate freezer storage locations (ie differing electrical circuits)
- sophisticated databases which provide automated sample positioning (based on business rules) and/or a duplication of data input needed per collection
- transfer or retrieval of samples daily (may have considerable impact on resources and access to dry ice stores is critical for transfer.

For multicentre research projects it is recommended that each collection centre retain a set of aliquots at the place of collection, with the other set transported to another location which is common for all participant centres.

1.6 Back-up storage capacity

Adequate backup capacity for low temperature units must be maintained in anticipation of possible equipment failure. If space and funds allow, backup storage must be made available within MSH. Where this is not possible, research biorepository personnel must identify backup space in a nearby facility to allow for transfer of biospecimens in case of an emergency. Extra capacity equipment must be equal to the capacity of the largest single storage unit and should be maintained in reserve at operating temperature. The total amount of backup storage required for large research biorepositories should be determined empirically, but will typically be 1.5% to 3% of the total freezer capacity for LN_2 storage and will be 10% for mechanical freezer storage. Backup space should be available in the research biorepository itself, if possible.

1.7 Malfunctioning units

MSH research biorepositories must have a written SOP for transferring samples from a failed or malfunctioning unit (one that has exceeded or is on the verge of exceeding its acceptable operating temperature range or become over-filled) and for the return of the samples to their original location once it is considered safe to do so. The SOP must include the freezer or refrigerator name or number as well as the location within the freezer where the samples have been relocated. Proper processes must be followed for sample retrieval to ensure that proper conditions are maintained to protect the sample, and that documentation is completed to record any change in inventory.

2.0 Work health and safety considerations

2.1 MSH Human Resources Policy Framework

All MSH research biorepositories must comply with the MSH Human Resources Policy Framework.

2.2 Protection of persons

The first, basic requirement of a research biorepository is global safety. This includes protection of persons and of the environment against biological and chemical hazards, as well as protection of the data and information associated with the biospecimen collected. The management of these risks should be based on a general implementation of a precautionary principle similar to those used in accredited National Association of Testing Authorities (NATA) Australia and International Organisation of

Standardisation (ISO) laboratories and clinical settings, and should be embodied in a general safety management plan.

Those accessing biospecimens from MSH research biorepositories must also acknowledge work health and safety risks as part of the Material Transfer Agreement for samples issued between biobanks and independent researchers. MSH research biorepository biospecimens have not been screened for potential pathogens and therefore may result in severe illness or even death if not handled properly. Following dispatch, the responsibility for the correct handling of the biospecimen lies solely in the hands of the end user (the approved researcher) and is not the responsibility of the issuing biobank. All personnel must follow SOPs laid down under the appropriate level of containment for the micro-organisms being handled, as defined by the World Health Organisation (WHO) and as interpreted by legislation, regulations, policies and procedures, to avoid contaminating samples, risk of infection and environmental dispersion.

2.3 Fire prevention

A fire prevention system is required by building codes for newly constructed facilities and compliance with codes is usually required if a facility is being converted or renovated. Please see the MSH Human Resources Policy Framework for more information.

2.4 Fire prevention plan

Research biorepositories must have a written fire prevention plan. The plan should include a list of major fire hazards, potential ignition sources, proper handling and storage procedures for hazardous materials, and the type of equipment necessary to control each major hazard.

The plan should address SOPs for regular maintenance on equipment used to prevent or control sources of ignition or fires and name or job title of employees responsible for maintaining the equipment.

2.5 Detection systems

Automatic fire detection systems are used to quickly identify a developing fire and alert occupants and emergency response personnel before extensive damage occurs. Automatic fire detection systems do this by using electronic sensors to detect the smoke, heat, or flames from a fire and provide an early warning. Fire/detection/extinguishing/suppression systems must be tested regularly to maintain proper reliability.

2.6 Sprinkler systems

The most common type of fire suppression is a sprinkler system that sprays water upon activation. The standard system has water in the pipes at all times. Excess heat causes the system to activate, spraying water into the area.

When computer equipment and electrical systems are in place, a “pre-action” sprinkler system can be employed. In such a system, the sprinkler pipes are dry until a fire is detected. This type of system prevents water damage from accidental activation of the sprinkler system. Special consideration should be used if sprinkler systems are deployed in proximity to cold rooms where slip hazards could be an issue.

2.7 Non-water-based fire retardants

Due to the nature of certain equipment and stored materials, water may be an unsuitable tool for fire suppression. In these instances, other chemicals may be employed. The chemicals used in these systems generally smother the fire by cutting off the supply of oxygen. While these systems can be very effective and may be critical for valuable collections adversely affected by exposure to water, they are costly and may present safety hazards. Although the majority of these suppressants do not represent a

health risk to staff upon activation, personnel should receive appropriate safety training. Most facilities provide dry chemical fire extinguishers. The suppressant is somewhat corrosive. If used in proximity of mechanical freezers the dry chemical released can be pulled into the compressor area and damage the unit. There is also risk of biospecimen contamination as it is difficult to fully remove and clean up the powder in these areas. Personnel must use extinguishers that contain a non-corrosive gaseous suppressant in research biorepository areas. Please see the MSH Human Resources Policy Framework for more information.

2.8 Training

All personnel coming in contact with biospecimens or involved in the operations of the research biorepository must be trained in safety procedures to minimise injuries to them and protect the material and information held in the research biorepository. Safety training must be:

- given to staff before they begin their work
- updated as needed
- lead by knowledgeable trainers
- appropriate for the background of each employee and to the risks to which each employee is exposed

Appropriate training in the safe handling of cryogenics (if relevant) must be provided and included in a SOP describing the potential health hazards and required safety precautions.

Written SOPs must be developed as part of a research biorepository's internal governance to ensure safety precautions based on national, regional and local regulations. Research biorepositories established on MSH facilities must comply with work health and safety policies and procedures contained within the MSH Human Resources Policy Framework.

2.9 Biological hazards

Relevant personnel should handle all biospecimens as being biohazardous. The use of LN_2 and dry ice poses specific safety hazards. Appropriate gloves, a face shield and a protective garment should always be used when handling these materials. When dry ice is used, controls to ensure sufficient air and oxygen levels must be ensured. Precautions should be taken to minimise risks to injury and damage from biological, chemical, physical, electrical hazards and fire.

All biological biospecimens should be considered as potentially infectious. Their collection and processing represents a source of hazard both for the person who is the source of the biospecimens and for the staff involved in these processes. Immunisation of research biorepository's staff is recommended when appropriate vaccines are available. In particular, immunisation against the Hepatitis B Virus (HBV) is mandatory for staff involved in collecting and processing human blood or tissues. In addition, staff should be regularly checked on tuberculosis. Other significant risks are posed by exposure to the Hepatitis C Virus (HCV) and the Human Immunodeficiency Virus (HIV) as well as to the prion that causes Creutzfeld-Jacobs diseases.

2.10 General laboratory safety

In addition to biosafety, research biorepositories must follow strict general safety regulations and Procedures in relation to chemical, physical and electrical safety. All MSH research biorepositories require Material Safety Data Sheet (MSDS) sheets for specific products used within their laboratory.

A MSDS is a document that provides health and safety information about products, substances or chemicals that are classified as hazardous substances or dangerous goods. MSDSs also provide information on the manufacturer or importing supplier. In addition to the MSH Human Resources Policy

Framework, the Queensland Health Intranet Site (QHEPS) and CHEMALERT app also provides relevant information for MSH employees.

The use of liquid gases such as LN_2 for cryopreservation poses a serious source of hazard. Where LN_2 refrigeration is employed, an adequate supply of refrigerant must be maintained. The supply maintained on site should be at least 20% more than the normal re-fill usage to allow for emergency situations.

Handling LN_2 has serious safety implications. Sustained skin contact with LN_2 can cause severe burns. In addition, nitrogen (N_2) displaces oxygen, and the risk is inversely correlated to the size of the room. Oxygen level sensors must always be employed when LN_2 freezers are used in a research biorepository.

When bulk storage and piping systems are used, blockage of relief valves and/or overpressure may lead to simultaneous leakage of LN_2 from a number of relief valves, causing a “white-out” condition in a matter of a few seconds. This leads to a drop of visibility to almost zero and the oxygen level decreases in the area below what is necessary to sustain life.

The setup of LN_2 tank rooms is critical and requires specific emergency equipment to minimise risk to personnel. Oxygen level monitors with digital displays; emergency response kits; alarms; locked doors with visible access into these rooms are essential. Nitrogen is odourless, tasteless and invisible, personnel entering an oxygen deprived room (without Oxygen level sensors and alarms) would not realise to evacuate immediately.

Affected individuals would succumb to the effects. Defined emergency procedures for assisting injured personnel (oxygen deprivation or cold burns) must form part of training for all staff on the same floor as the LN_2 tank room.

It is also important to note that LN_2 expands to 800 times its original volume at room temperature, causing a form of explosion hazard. Plastic and glass containers can easily explode if liquid is trapped when the container is removed from the LN_2 tank. Heavy gloves, a face shield and a protective garment should always be used under these conditions. Safety notices and SOPs must be clearly displayed in the research biorepository area. There are also risks associated with the use of chemical fixatives and solvents used in tissue processing. Electrical safety is an important concern. Deep-freezers must be properly wired to adequate sources of electrical supply, and grounded.

Work in a research biorepository also entails a number of occupational hazards typical of the laboratory environment. These risks must be taken into account before setting up a research biorepository, and their prevention must be integrated in all aspects of the SOPs of the research biorepository.

2.11 Personal protective equipment

Research biorepository personnel must wear personal protective clothing/equipment, as appropriate, when working with biospecimens. In addition to the oxygen deficit risks the use of LN_2 as a refrigerant poses special safety problems because of its low temperature and rate of expansion when placed at ambient conditions. Eye protection is mandatory every time LN_2 is handled to protect against splashes that inevitably occur. Face and eye protection is recommended when handling vials removed from a LN_2 freezer or when dispensing LN_2 from low pressure lines.

Heavy gloves (appropriate for LN_2 use) must be worn to protect hands when handling samples stored within the liquid phase or when transferring LN_2 or other coolants to Dewar flasks. Normal laboratory personal protective equipment (eg closed toed shoes, full cover of legs (no cuffs) and feet and goggles) must be worn when handling coolants. The use of protective equipment, goggles and gloves, in particular, is mandatory when handling cryogenics and the equipment should be placed in an easily accessible and visible location.