Management of Research & Development Fridges, Freezers & Dry Ice

Division: Strategy & Transformation

Specific staff groups to whom this policy directly applies	Likely frequency of use	Other staff who may need be familiar with policy
Research staff and support staff involved in the storage, handling, monitoring, relocation, destruction, or audit of research samples, IMPs, or dry ice within temperature-controlled storage managed by R&D.	Regular	Staff involved in Research outside of the division of Strategy & Transformation.

Main Author(s):	Angelo Micciche – Research Infrastructure Manager
Consultation:	Research & Development Senior Team
Approval Authority (Committee/ Group/ Lead Clinician):	Trust Research Group
Executive Lead (Trust-Wide only):	Tim Whittlestone
Date of Approval:	27th May 2026
Next Review Due:	27th May 2029
Version:	RD QMS SOP 018. Version 3.0
KEYWORDS:	Samples, IMP, Dry Ice, Research, Fridge, Freezer, Human tissue, calibration, destruction
Summary of changes since the previous version	SOP on new Trust template Updated Department reference, location of files stored in Teams Added responsibility to team leaders for staff to be created in T Scan system temperature monitoring system Removed temp sensor that was changed in Appendix A. Added destruction / disposal of Samples Expanded relevant policies and guidance. Added cleaning & Decontamination. Added location of calibration certificates Changed title of SOP to include Dry Ice

1. Purpose	This SOP describes the requirements for the use, monitoring, and management of Research & Development fridges, freezers, and dry ice, including actions to be taken in the event of equipment failure or temperature excursions. It also outlines arrangements for the secure logging, relocation, cleaning, audit, and authorised destruction of research samples
2. Key Messages	• Research samples and IMPs must be stored within protocol-defined temperature ranges at all times. • All sample movements must be fully traceable using approved logs. • Temperature monitoring is mandatory for all R&D-managed fridges and freezers. • Temperature excursions must be escalated promptly in line with sponsor and R&D requirements. • Dry ice must only be handled by trained staff using appropriate PPE. **Abbreviations:** IMP: Investigational Medicinal Product R&D: Research and Development Office HTA- Human Tissue Authority T_scan- Remote temperature monitoring system R&D Fridges and Freezers- Fridges and Freezers that are managed by the Research and Development office at North Bristol NHS Trust, include the -80°C R&D Freezer SOP: Standard Operating Procedure -80°C R&D Freezer: The -80°C freezer referenced in Section 8.6 of this SOP
3. Relevant Policies & Guidance	• Safety Data Sheets for Dry Ice & Manufacturers Guidelines for Dry Ice (Carbon Dioxide, Solid)

	• https://bcga.co.uk/publications/tis7-guidelines-for-the-safe-transportation-storage-use-and-disposal-of-solid-carbon-dioxide-dry-ice-revision-3-2021/ • Human Tissue Act 2004 - Governs storage and use of human tissue. Research samples containing human tissue must have appropriate HTA licensing or exemptions. • Awareness of HTA Code of Practice & Standards – Research Sector Codes of Practice | Human Tissue Authority • GDPR - Personal data associated with samples must be anonymized or pseudonymized where possible. • UK Policy Framework for Health & Social Care Research - Provides governance for managing research samples. • Good Clinical practice guidelines (ICH E6 (R3)) - Adherence to GCP ensures ethical and scientific quality standards for sample handling. • Maintenance of Research Equipment SOP (RD/QMS/SOP/004) • Calibration Certificates
4. Operational Areas Included	All environments involved in temperature-controlled research sample storage
5. Operational Areas Excluded	None
6. Who should read this	Research Staff involved in research using storage of Samples or IMP in Research Fridges or Freezers and staff involved in any call out for fridge / freezer failure outside of hours
7. Roles responsible for carrying out this procedure	**Research Staff** Ensure samples/IMPs are labelled, logged, and stored correctly. Comply with study-specific storage requirements. Respond to temperature alerts where designated.

	Research Team Leaders / PIs Ensure appropriate staff are set up on T-Scan for relevant studies. Ensure protocol-defined temperature ranges are communicated and adhered to. **Clinical Research Centre Manager** Oversight of equipment servicing, calibration, audits, and defrosting.

8. Procedure:

8.1 Equipment Use

(a) All R&D fridge and freezer units should be inspected and any faults found reported immediately in accordance with the SOP on Maintenance of Research Equipment (RI/QMS/SOP/004).

(b) All R&D fridge and freezer units should be kept locked, and keys stored in the designated key safe either in the Clinical Research Centre reception; or in the case of the -80°C R&D Freezer, in the key safe outside of Research & Development Office (3rd Floor, Learning & Research Building).

(c) If an IMP is being held in an R&D fridge/freezer /cabinet, no biological substances can be held in the same fridge / freezer.

(d) All reagent, biological, tissue samples or any substance requiring refrigeration or freezing should be placed in an appropriate container to prevent the possibility of spills, odour leakage or spoilage.

(e) Bottles, tubes and containers with a cap or top must be stored in an upright position unless stored securely within sealed bags/containers.

(f) All samples/substances stored and removed must have a sample identifier attached to the individual sample (may be study specific labelling). All Samples must be appropriately labelled, and the sample identifier matches the details entered on the sample log. The sample identifier must be recorded to correlate back to the patient to confirm consent.

(g) If the individually labeled samples are also stored within a larger bag / sample storage container, the contact details of the local research team and R&D study number must be on that bag / sample container as well as on the log sheet.

(h) All samples stored / removed to/ from the -80°C R&D Freezer should be logged in advance of using it. The samples log is held on the Microsoft Teams at the following location R&S-R&I-Department team, Fridges, Freezers, Samples and drug logs channel. The Samples log sheet is called: R&D -80 Freezer samples stored.xlsx

The following information must be completed on the samples log:

- Date samples went in the freezer
- Research team
- Contact details
- Contact Number
- Freezer Shelf number you have placed them on
- Study name
- Study R&D number
- Temp Range in protocol for samples
- Sample identifier i.e. patient 001-06
- Number of samples
- Time & Date sample was placed in freezer
- Time & Date sample was removed from the freezer

When completing the form please be sure to use the correct tab to reflect the shelf used to store your samples.

(i) It is imperative the sample identifier recorded on the actual samples/ substances matches the electronic log on R&D -80 Freezer samples stored.xlsx and that it is fully completed. Please see **Appendix B** for reference.

(j) Staff accessing the -80°C R&D Freezer should always use appropriate Personal Protective Equipment, such as gloves which are provided in the freezer storeroom.

(k) Maintenance and annual service of R&D fridges and freezers should be performed by authorised personnel and certification provided. This is the responsibility of the Clinical Research Centre Manager.

(l) Procedures for the safe handling of Dry Ice must be observed. See section 9 for further information on hazards, packing, handling, transportation and disposal and disbursement of Dry Ice.

(m)No samples are to be stored or removed from the -80°C R&D Freezer without the online samples log on the Microsoft Teams being completed. The file is : R&D -80 Freezer samples stored.xlsx

(n) Where any IMPs are stored in R&D fridges and freezers within the Clinical Research Centre or other remote locations, a designated member of staff from the relevant research team is to be set up on the T-scan temperature monitoring system (see section 5.2 below for further details). It is the responsibility of the Research Team leader to ensure relevant and appropriate staff are set up on the temperature monitoring system (T-Scan) for those studies that have samples stored in Fridges and freezers.

8.2 Temperature Monitoring

Temperature monitoring for the -80°C R&D Freezer and other R&D fridges and freezers is provided by T-scan remote monitoring) (www.tscanweb.com/auth/login.)

Staff planning to store samples in any R&D fridges or freezers must be set up on the T-scan temperature monitoring alert system prior to samples being logged and stored.
Please contact the Research Infrastructure Manager or Research Matrons in R&D or the Clinical Research Centre Manager who will be able to arrange this for you.

The temperature range for samples / IMPs stored must be correctly set once you have access to the T-scan temperature monitoring system. This should be in line with other samples stored in the same fridge / freezer. Please contact R&D for further assistance.

Please refer to **Appendix A** for a list of remotely monitored fridges, freezers and cabinets, their locations, and sensor identification numbers.

8.3 Temperature Out of Range Actions

If there are samples in the faulty fridge/freezer, a temperature reading must be taken immediately using supplied temperature sensors in place. (Please note that this step is only required where there is no automated logging system in place. If the T-scan remote temperature monitoring system is in place, then this step is not necessary as temperatures are continuously monitored and recorded.)

Refer to the study specific SOP for sample storage and the study protocol for further guidance. You must also contact the study sponsor to inform them of the situation.

If the samples are outside of temperature range for the sample as detailed above, further escalation to the sponsor for guidance is required.

If you are unable to contact the sponsor or gain guidance from the study specific SOP and protocol, please follow the guidance in this SOP for relocation of samples in the interim.

All temperature excursions affecting research samples must be documented and retained within the study file for audit and sponsor review.

8.4 Relocation of samples

R&D has arranged for two -80°C freezer backups to be made available. In the case of R&D freezer failure, either of these back up freezers can be used.

(a) The first is located in the same freezer room as the R&D -80°C R&D Freezer and is located almost directly behind this freezer in the middle aisle. The -80°C freezer back up has a University of Bristol (UoB) sign on the front saying “-80 Freezer back up”.

Please relocate the samples into this freezer in case of failure, ensuring you use appropriate Personal Protective Equipment such as gloves which are provided in the freezer room.

Once samples have been relocated into this UoB back up -80°C freezer, please email Emma Foose on emma.foose@bristol.ac.uk and Paul Savage P.B.Savage@bristol.ac.uk

advising that R & D Research Samples have been relocated into this back up freezer as well as R&D Research@nbt.nhs.uk to inform of the breakdown and relocation.

(b) The second back up freezer is located in Microbiology Laboratory 2 in the Pathology building, opposite the Learning & Research building. It is located in room space label SMD 203-2-032. Please attempt to contact Principal Scientist & Antimicrobial Reference Laboratory Manager (Alan Noel) in Infection sciences for assistance in the first instance.

This back up freezer is located in a restricted area (Antimicrobial Reference Laboratory) and you will need to contact Trust security to escort you through due to door access controls within Pathology building outside of normal working hours.

There is a door code to Laboratory 2 where the freezer is located which can be obtained from Security department

Anyone accessing -80°C freezers should always use appropriate Personal Protective Equipment such as gloves which are provided in the freezer storeroom.

Following relocation, sample logs must be updated immediately and retained for audit. Sponsor notification must be undertaken where required by the protocol.

8.5 Destruction of Samples

Authorisation:
Samples that may need to be destroyed must be verified by checking the sample destruction date, or sample storage time as detailed in the study protocol.

Once this has been verified, you must obtain approval for destruction of specific samples listed from the sponsor of the study in writing.

Documentation:

Once approval has been granted, this communication must be stored / archived with the study documentation.

Method:

- Biohazardous material: disposal via appropriate biohazard waste stream in accordance with Trust policy.
- Non-biohazardous material: disposal via appropriate waste stream in accordance with Trust policy

Compliance:
Ensure destruction of samples complies with Trust policies and HTA guidelines.

8.6 Access to -80°C R&D Freezer

The key for the -80°C R&D Freezer is stored in a key safe on the wall located outside the Research & Development Office (space room label 3-003), next to the door intercom, 3rd Floor,

Learning & Research building. You can obtain the key safe code by contacting R&D. There is a signing out sheet with the key that must be completed.

The -80°C R&D Freezer is located within the Learning & Research Building, within the phase 2 University of Bristol Freezer storeroom on Level 3. The access door to this area is on Level 3, beyond the kitchen area. The freezer storeroom has space label 3-075 on the outside of the room. The freezer itself is clearly labelled “Research & Development -80°C Freezer”.

If you wish to have samples stored in the freezer you must have your ID door access granted into this area first. The Research Matrons, Research Infrastructure Manager & Clinical Research Centre Manager have access to this area.

8.7 Purchasing of new Fridges and Freezers

Any purchase of new equipment such as a fridge or freezer for research purposes cannot be purchased independently. Requests for equipment of this nature must be submitted to Research Senior Team.

Any request for purchase must include the cost of purchasing and installing the T-scan monitoring probe and, where needed, the remote supporting module including installation. Assistance may be sought from the Clinical Research Manager to obtain quotes with external supplier.

8.8 Defrosting, Cleaning & Decontamination of -80°C, -20°C Freezers

Freezers will be defrosted, cleaned and decontaminated annually by CRC Manager or delegated. Samples will be relocated to an alternative suitable freezer in advance of defrosting, and temperature monitoring system suspended for relevant freezer and temporary freezer added during this period.

8.9 Audit

The -80°C R&D Freezer will be audited annually by CRC Manager / Research Operations or delegated team members.

8.10 Dissemination and Training

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001) & Research Staff Training SOP (RD/QMS/SOP/005)

8.11 Calibration & Maintenance records

Certificates / records of calibration and maintenance must be stored and accessible for inspection or when requested. These are stored in the R&S-R&I-Department team on MS TEAMS, Clinical Research centre only channel, Calibration Certificates

9. Dry Ice

Hazard Description

Dry ice is the solid form of carbon dioxide (CO_2). Dry ice is available for use in the form of pellets, slices or blocks and may be supplied loose or in insulated containers. Please check the appropriate safety data sheet for the type of dry ice you are using, with the link above.

Dry ice is very cold (-78.5˚C). It sublimes (turns directly from a solid to a gas without passing through the liquid phase) to an asphyxiant gas (CO_2) that is heavier than air.

It is important that a little bit of dry ice will sublime to a large volume of gas, and it should therefore be used only in well-ventilated areas.

Dry ice must be handled using appropriately insulated gloves. Contact with bare skin can result in severe cold burns or frostbite within a short period of time.

Use of dry ice in poorly ventilated areas can result in the depletion of the oxygen level resulting in asphyxiation.

Symptoms may include increased respiration, headaches, nausea, vomiting, loss of mobility, loss of consciousness.

Placing dry ice into a tightly sealed container can produce sufficient gas build up to cause an explosion. This must be avoided.

Responsibilities for safe handling of Dry Ice

Staff members who need to use, store, or handle dry ice are responsible for:
Undertaking dry ice training. Training must be undertaken prior to use or handling of dry ice
Dry Ice | Industrial Gas | Gas Equipment & Accessories | BOC Shop

Records of dry ice training must be retained and made available on request.

The safe handling and management of dry ice in accordance with national health and safety policies and guideline, and study protocols

Use of personal protective equipment (PPE)

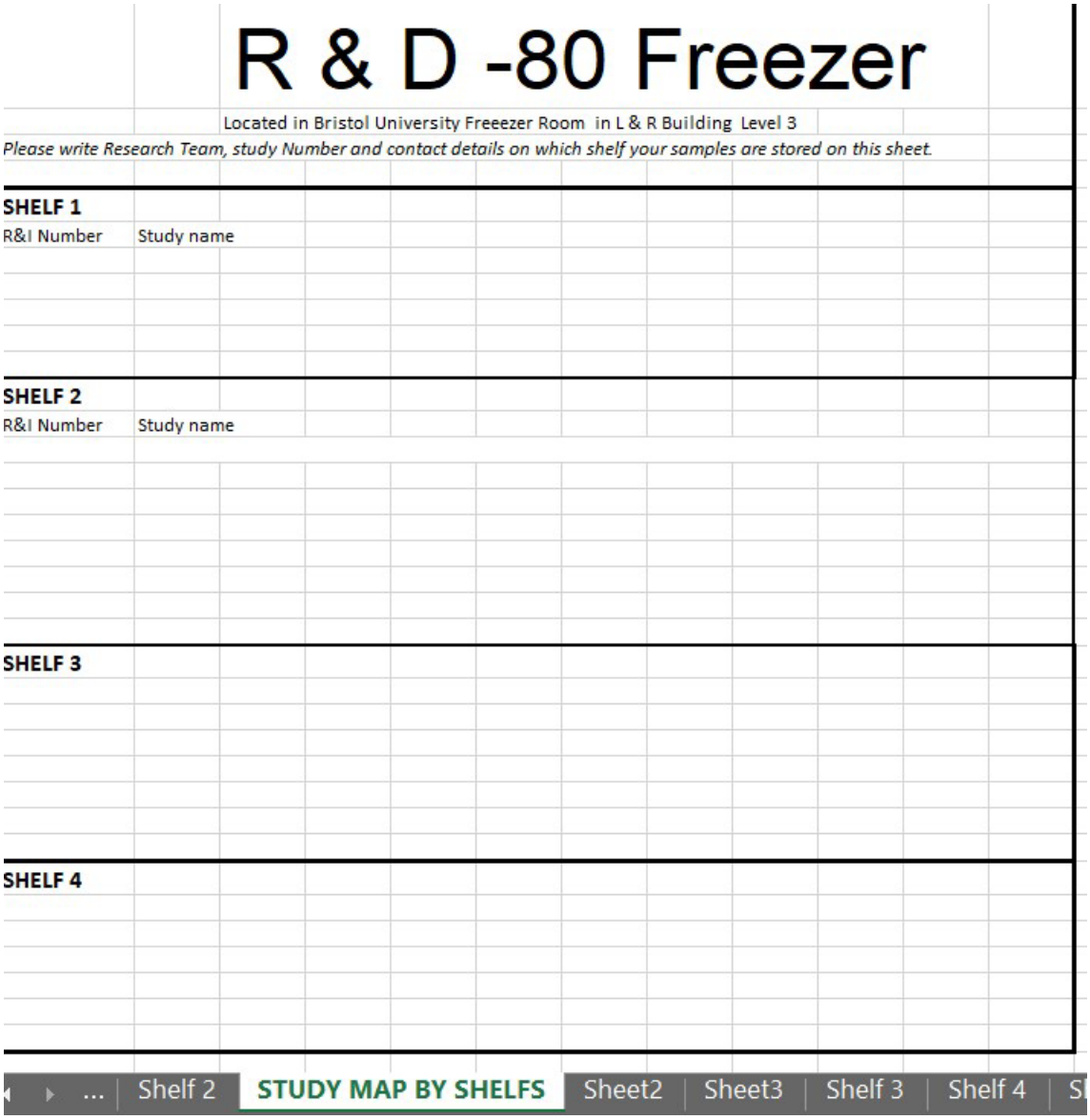
Appendix A

List of Temperature sensor IDs for T Scan remote Temperature monitoring system

Sensor ID	Location	Description
336124	Brain Centre	Freezer (-20c)
337298	Brain Centre	Freezer (-70c)
364346	Brain Centre	Brain Centre Ambient temp
332940	Clinical Research Centre	Clean Utility Ambient temp
332942	Clinical Research Centre	Clean Utility room 3 Ambient temp
336112	Clinical Research Centre	Clean Utility Fridge 2 (+4c)
336114	Clinical Research Centre	Clean Utility Fridge 1 (+4c)
336118	Clinical Research Centre	Clean Utility Fridge 3 (+4c)
336120	Clinical Research Centre	Clean Utility Freezer 1 (-20c)
336122	Clinical Research Centre	Clean Utility Freezer 2 (-20c)
336126	Clinical Research Centre	Clean Utility Freezer 3 (-20c)
336128	Clinical Research Centre	Clean Utility Freezer 4 (-40c)
336130	Clinical Research Centre	Clean Utility drugs cabinet (+20c)
294696	University of Bristol, Learning & Research Building, Level 3, UOB freezer room (room space label 3-075)	- 80 R & I Freezer

Appendix B

Samples / Substances Log sheet



R & D -80 Freezer

Located in Bristol University Freeezer Room in L & R Building Level 3

Please write Research Team, study Number and contact details on which shelf your samples are stored on this sheet.

SHELF 1

R&I Number	Study name

SHELF 2

R&I Number	Study name

SHELF 3

SHELF 4

... | Shelf 2 | STUDY MAP BY SHELFS | Sheet2 | Sheet3 | Shelf 3 | Shelf 4 | S

Date	Research Team	Contact Details	Contact Number	Freezer Shelf Number	Study Name	Study R&I number	Temp range in Protocol for samples	Sample Identifier	No of samples	Sample IN Time & Date	Sample ***OUT*** Time & ***Date***

STUDY MAP BY SHELF | Shelf 1 | Shelf 2 | Shelf 3 | Shelf 4