North Bristol NHS Trust

Standard Operating Procedure

Management of Research & Innovation Fridges, Freezers & Dry Ice

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CONTROLLER:	Contracts & Quality Management Officer

Document Version History

VERSION NUMBER	EFFECTIVE DATE	SUMMARY OF CHANGES SINCE THE PREVIOUS VERSION
1.0	04-12-17	N/A
2.0	19-03-20	Updates to dry ice disbursement, purchasing, access, and logging of samples, storage & transportation of Dry Ice and Appendix C. Addition of second back up -80°C freezer.

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT CHECKING IT IS THE LATEST VERSION

Current versions of all Research & Innovation SOPs and accompanying documents are available online. If you are reading this document in printed form, please check that the version number and date match the most recent version on the Research & Innovation website: www.nbt.nhs.uk/research

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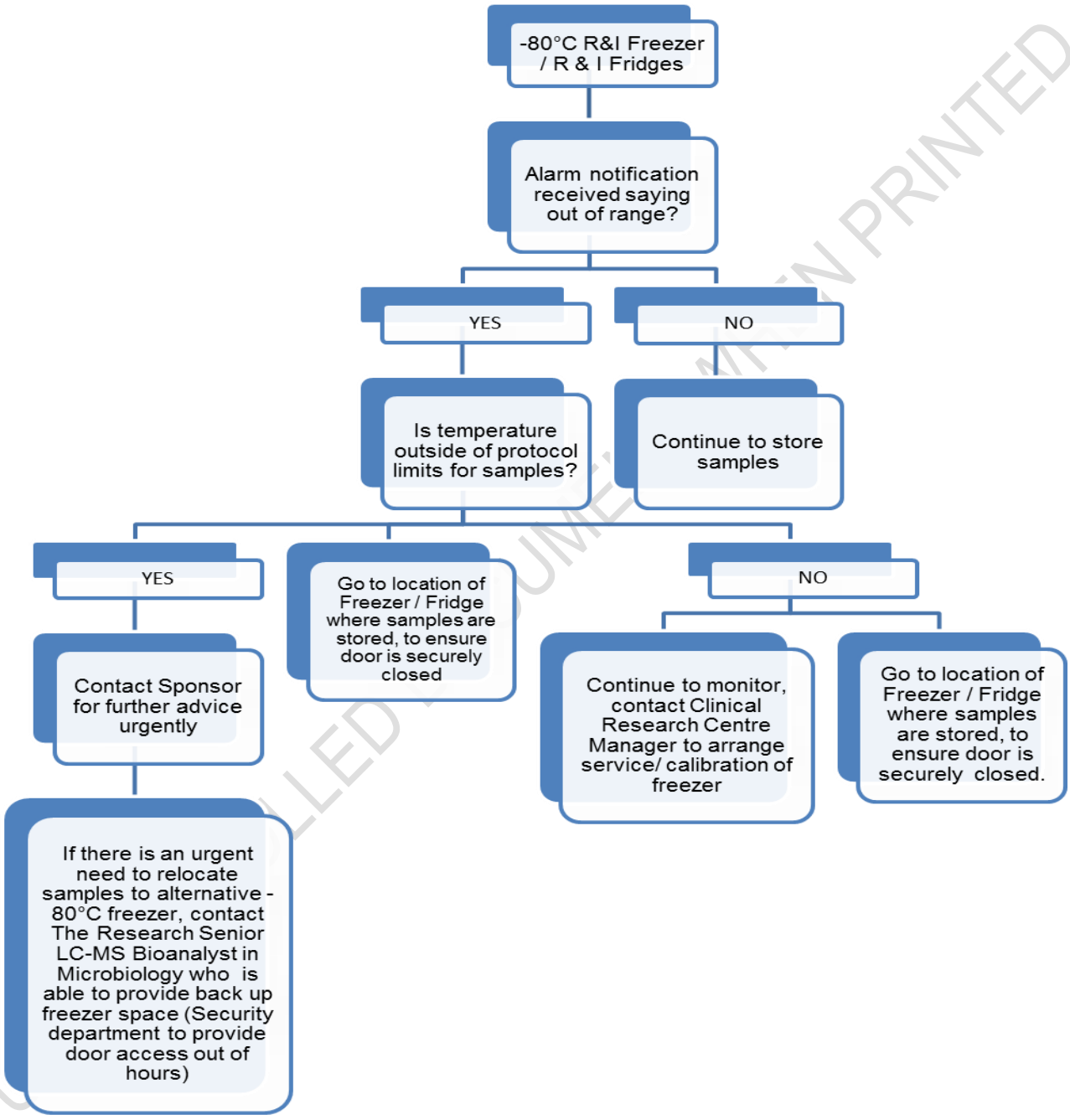
i. SOP Flowchart



1. PURPOSE AND SCOPE

This SOP outlines the requirements for the use and monitoring of R&I fridges and freezers, and the actions to be undertaken in the case of R&I fridge and/or freezer failure.

It is necessary to ensure that samples and Investigational Medicinal Products (IMPs) are held in optimum conditions, within the ranges required by the individual research study protocols.

2. DEFINITIONS/ABBREVIATIONS

IMP	Investigational Medicinal Product
NBT	North Bristol NHS Trust
R&I	NBT Research & Innovation Office
R&I fridges and freezers	Fridges and freezers that are managed by the Research & Innovation office at North Bristol NHS Trust, including the -80°C R&I Freezer
SOP	Standard Operating Procedure
-80°C R&I Freezer	The -80°C freezer referenced in clause 5.5 of this SOP

3. WHO SHOULD USE THIS SOP

This SOP applies to all staff who use R&I fridges and freezers, and those staff who are on the call out list in the case of R&I fridge and/or freezer failure.

4. WHEN SHOULD THIS SOP BE USED

This SOP is applicable each working day when R&I fridges and freezers are in use and when an R&I fridge and/or freezer alarm activates.

5. PROCEDURE

5.1. Equipment Use

(a) All R&I 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&I 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&I Freezer, in the key safe outside of Research & Innovation Office (3rd Floor, Learning & Research Building).

(c) If an IMP is being held in an R&I fridge/freezer /cabinet, no other substances can be held in there.

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(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 must have a sample identifier, this must be appropriately labelled with the contact details of the local research staff and R&I study number on the outer bag or on a paper insert within.

(g) All samples stored in the -80°C R&I Freezer should be logged in advance of using it. The samples log is held on the K drive at the following location: K drive/ Research workforce folder/-80 R&I freezer log.

The following information must be completed on the samples log:

- Date samples went in the freezer
- Study team
- Contact details
- Shelf number you have placed them on
- Study name
- Study R&I number
- Sample identifier i.e. patient 001-06
- Number of samples
- Time sample was placed in freezer
- Date/time 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.

(h) It is imperative the sample identifier recorded on the actual samples/ substances matches the electronic log on the K drive (K drive/ Research workforce folder/-80 R&I freezer log) and that it is fully completed. Please see **Appendix C** for reference.

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

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

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(k) Procedures for the safe handling of Dry Ice must be observed. See **Appendix A** for further information on hazards, packing, handling, transportation and disposal and disbursement of Dry Ice.

(l) No samples are to be stored or removed from the -80°C R&I Freezer without the online samples log on the K drive being completed.

(m) Where any IMPs are stored in R&I fridges and freezers within the Clinical Research Centre or other remote location, 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).

5.2. Temperature Monitoring

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

Staff planning to store samples in any R&I 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 Matron in R&I who will be able to arrange this for you, or provide instructions on how to set this up.

The temperature range for samples / IMPs stored must be correctly set once you have access to the T-scan temperature monitoring system. Please contact R&I for further assistance.

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

5.3. 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 also 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, 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.

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5.4. **Relocation of samples**

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

(a) The first is located in the same freezer room as the R&I -80°C R&I 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 in to 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 in to 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 NBT samples have been relocated into this back up freezer as well as R&I 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 The Research Senior LC-MS Bio analyst (Mark Bayliss) or principle 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 NBT 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 The Research Senior LC-MS Bioanalyst (Mark Bayliss) or Security department

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

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5.5 **Access to -80°C R&I Freezer**

The key for the -80°C R&I Freezer is stored in a key safe on the wall located outside the Research & Innovation 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&I. There is a signing out sheet with the key that must be completed.

The -80°C R&I Freezer is located within the Learning & Research Building, within the phase 2 University of Bristol Freezer store room 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 & Innovation -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 Matron and Research Infrastructure Manager have access to this area.

5.6 **Purchasing of new Fridges and Freezers**

Any purchase of new equipment such as a fridge or freezer cannot be purchases independently.

Any purchase must include the cost of purchasing and installing the T-scan monitoring probe and, where needed, the remote supporting module.

5.7 **Defrosting of -80°C, -20°C Freezers**

Freezers will be defrosted annually by R&I staff. Samples will be relocated to an alternative suitable freezer in advance of defrosting.

5.8 **Audit**

The -80°C R&I Freezer will be audited annually by R&I staff.

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6 DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the Trust intranet shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP. The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

7 RELATED SOPS AND DOCUMENTS

- The following documents are available on the R&I website: www.nbt.nhs.uk/research

RI/QMS/SOP/004	Maintenance of Research Equipment

- Awareness of HTA Code of Practice & Standards
  www.hta.gov.uk/sites/default/files/Code%20E.pdf

- Safety Data Sheet & Manufacturers Guidelines for Dry Ice
  www.boconline.co.uk/en/images/tg-9390-carbon-dioxide-solid-v1.3. tcm410-39610.pdf
  www.boconline.co.uk/en/images/bcga-guidelines-dry-ice_tcm410-39415.pdf

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Appendix A

Guidelines for 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.

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
- 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)

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Storage of Dry Ice

The following steps should be performed to ensure safety:

- Only experienced and trained people should use, store and handle dry ice
- Dry ice properties should be known and understood
- Dry ice should be stored in a well-ventilated room away from direct sunlight or heat sources. It should be stored in a Styrofoam box
- Dry ice must NOT be stored in an gas tight container, as within large containers, gas atmospheres will build up
- Do not expose dry ice to high ambient temperatures unnecessarily as this increases the sublimation rate and thereby the risk of a carbon dioxide –rich atmosphere.
- DO NOT use or store dry ice in confined areas, walk-in fridges, freezer or rooms without ventilation.
- Disbursement should only be performed using the cage outside the clinical research centre.
- Keep the container lid closed when not in use
- Avoid leaning into the container for longer than necessary
- Ensure adequate low level ventilation wherever dry ice is stored.

We now have a lockable cage outside of the CRC for the disbursement of dry ice. The cage can be found down the slope to the right hand side of the building and the key will be kept in the top drawer of the safe on reception.

- When placing dry ice in the cage please can you write the team name on the box. Once the dry ice has disbursed you are responsible for disposing the packaging

Packing of Dry Ice

- Ensure that samples are appropriately labelled and packaged prior to placing on dry ice
- Ensure dry ice is packaged in containers that allow the release of CO_2 gas
- DO NOT place dry ice into an airtight container, as this can produce sufficient gas build up to cause an explosion
- Take care when lifting, opening and closing packages containing dry ice
- Ensure that packaging provided is strong and well designed.
- Ensure that packaging has appropriate safety markings on the side of the dry ice e.g:
    - Carbon Dioxide Solid
    - Class 9 label
    - UN number (UN1845)
    - Delivery address
    - Sender
    - Orientation label to demonstrate which way up the box should be handled
    - Net weight

Do not remove or deface packaging or labels.

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Transportation of Dry Ice

- Dry ice is classified as a 'dangerous good'. Where possible, official couriers who have had dry ice awareness training should be used to ship and transfer samples
- In extreme circumstances it may be necessary to transport samples without a courier. If this is the case, please discuss this with your Line Manager or a member of the R&I Senior Team prior to doing so
- If transport is authorised, the following precautions should be taken in addition to the above:
    - Use the minimal amount of dry ice necessary for sample stabilityCarry a spillage kit incorporating: goggles, gloves and plastic container to collect spilt dry ice
    - It is preferable to transport dry ice in vehicles where the driver's cab is isolated from the load compartment. If this is not possible, the load should be well insulated and adequate ventilation must be maintained throughout transportation.
    - Always carry the carbon dioxide safety data sheet with you where transporting in a vehicle.
    - Unload the product as soon as possible at the end of the journey and move it to a suitable storage location.

First aid for dry Ice burns

- Move the dry ice casualty to a well-ventilated room away from the dry ice, if possible
- Seek medical assistance
- Spray with water for at least 15 minutes
- Cover affected area with a dry sterile dressing
- Avoid potential impact of affected areas
- Ensure that clothing is loosened to provide unrestricted circulation
- Do not remove clothing from site of cold burn
- Observe for shock
- DO NOT administer food or drink until reviewed by a medical team

Further First Aid information is outlined within the safety data sheet available online at:
https://www.boconline.co.uk/en/images/tg-9390-carbon-dioxide-solid-v1.3._tcm410-39610.pdf

Disposal of dry Ice

Leave the unused portion of dry ice to sublimate in The cage installed outside the Clinical Research Centre (The cage can be found down the slope to the right hand side of the building and the key will be kept in the top drawer of the safe on reception)

- When placing dry ice in the cage please can you write the team name on the box. Once the dry ice has disbursed you are responsible for disposing the packaging
- NEVER dispose of dry ice in a sink, toilet or other drain

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- NEVER dispose of dry ice in a rubbish bin
- NEVER leave dry ice in corridors, offices or any other enclosed spaces.

It is the responsibility of the relevant research team to ensure the dry ice is disposed of in a safe manner and all necessary precautions have been taken.

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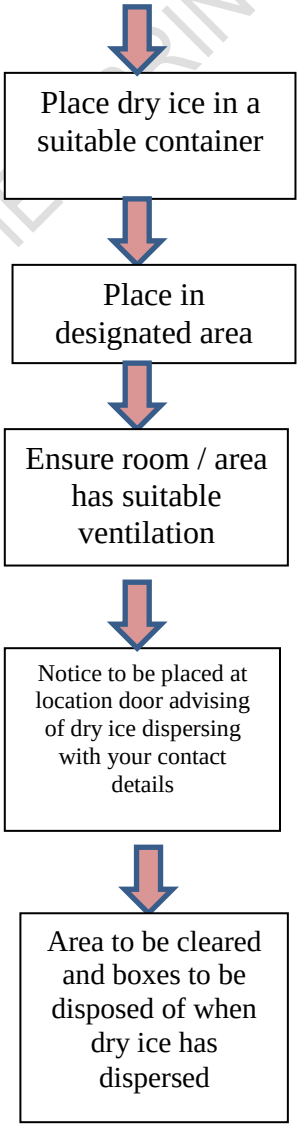
Disposal of dry Ice - Flow Diagram



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Appendix B

List of Temperature sensor ID's for T Scan remote Temperature monitoring system

Sensor ID	Location	Description
336124	Brain Centre	Freezer (-20c)
337298	Brain Centre	Freezer (-70c)
337300	Brain Centre	Freezer (-80c)
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 2, phase 2 freezer room (room space label 3-075)	- 80 R & I Freezer

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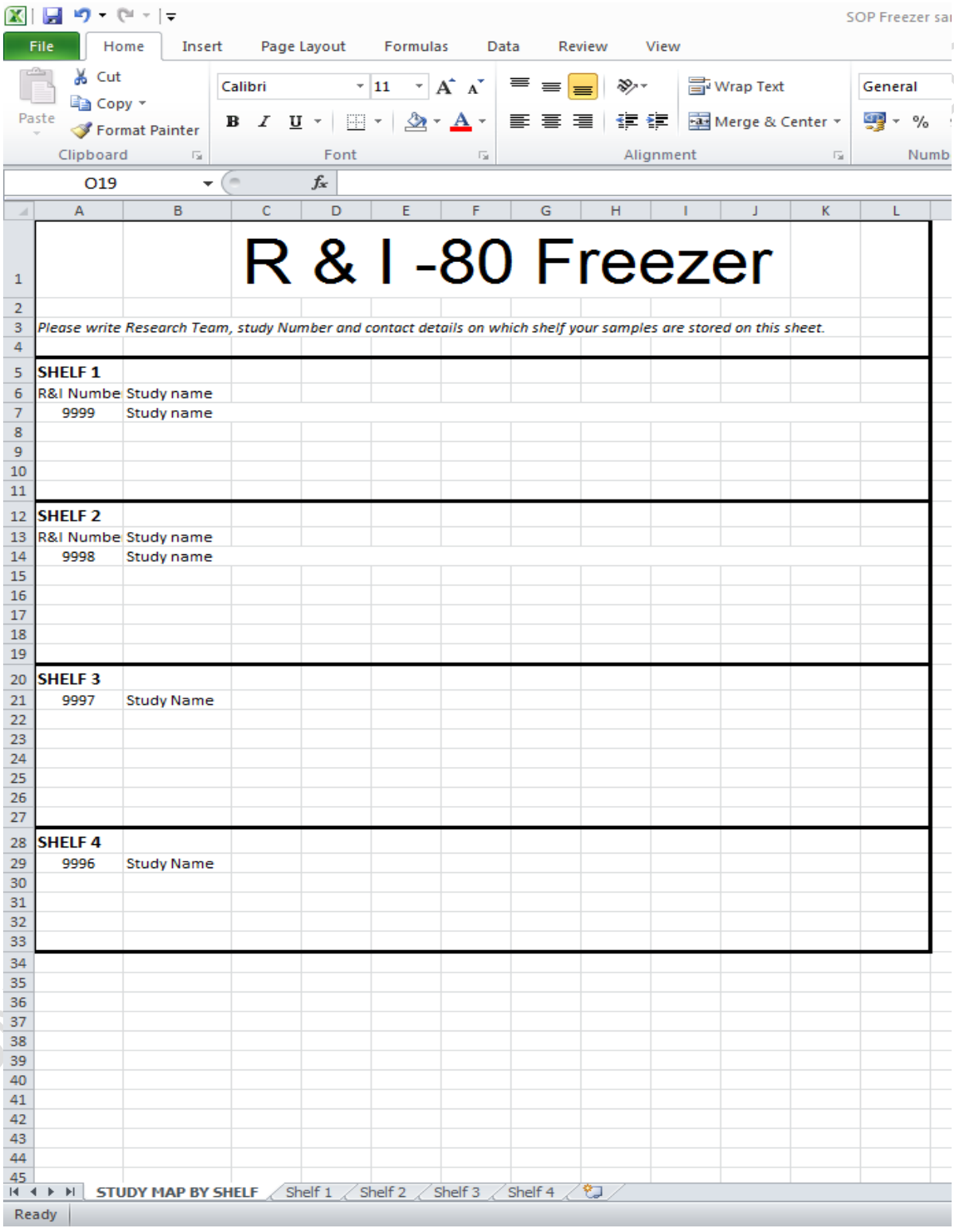
Appendix C

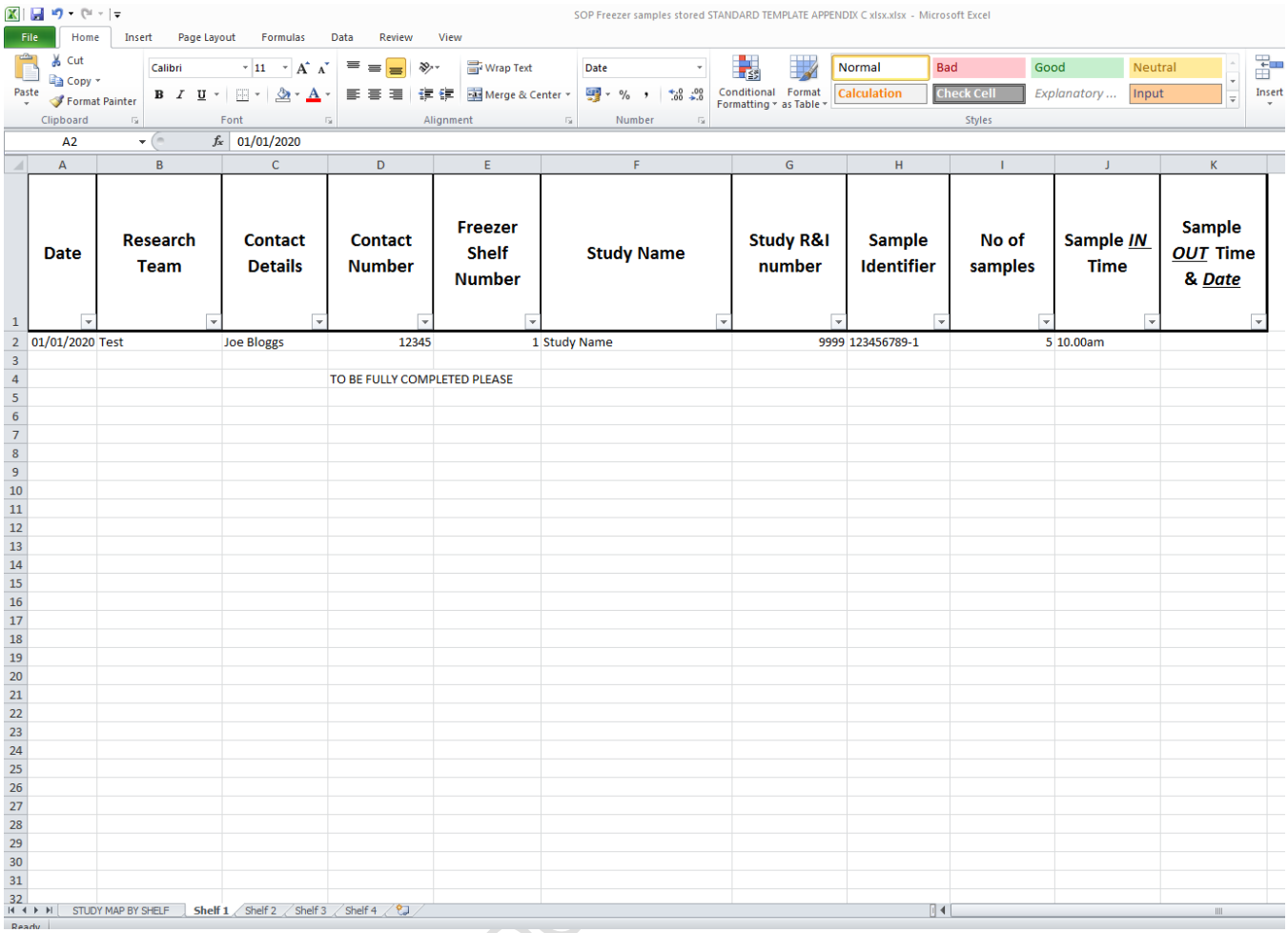
Samples / Substances Log Sheet



R & I -80 Freezer

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

SHELF 1		
R&I Numbe	Study name	
9999	Study name	
SHELF 2		
R&I Numbe	Study name	
9998	Study name	
SHELF 3		
9997	Study Name	
SHELF 4		
9996	Study Name	



	A	B	C	D	E	F	G	H	I	J	K
1	**Date**	**Research Team**	**Contact Details**	**Contact Number**	**Freezer Shelf Number**	**Study Name**	**Study R&I number**	**Sample Identifier**	**No of samples**	**Sample *IN* Time**	**Sample *OUT* Time & *Date***
2	01/01/2020	Test	Joe Bloggs	12345	1	Study Name	9999	123456789-1	5	10.00am	
3											
4				TO BE FULLY COMPLETED PLEASE							

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