Dorset County Hospital NHS Foundation Trust

RESSOP003 - LABORATORY WORK & DRY ICE HANDLING IN CLINICAL RESEARCH

SOP Title	RESSOP003 - Laboratory Work & Dry Ice Handling for Research Staff		
SOP Number	RESSOP003	**Policy Version Number**	1
Applicable to	All research staff required to work in the Pathology department on clinical trial related activity		
Aim of the Policy	The purpose of this Standard Operating Procedure (SOP) is to ensure the health, safety and welfare of staff when undertaking clinical trial related activities within the Pathology laboratories at Dorset County Hospital and the Weymouth Research Hub		
Next Review Due Date	06/03/2026		
Author/ Reviewer	Josie Goodsell Research Project Manager Anthony Homer Research Governance & Quality Lead		
Policy Sponsor	Sarah Doyle Head of Research		
Responsible Executive	N/A- Local SOP		
Expert Group	Research Quality Group		
Date Approved	06/03/2025		
Ratified by	Sarah Doyle- Head of research		
Date Ratified	22/04/2025		
Primary Specialty	Research		
Secondary Specialty	N/A		

Document Version Management			
Version	Date	Reviewer	Description of Change(s)
1.1 (DCH RES 016)	03/2025	Anthony Homer/	Update and renumbering of policy number

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		Amy Thomson	

Content

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Sample Processing

BD-SOP 2309 – Centrifuge Safe Use

WI-18 – Use of the Centrifuge

BS-HAEM SOP 8843 – Blood Film Preparation

MICRO-Policy 0023 – Personal Protective Equipment

Sample Storage

HIST/GEN/-SOP 0098 – Temperature Monitoring System

Sample Shipping

PAN-PATH-POLICY 0059 – Referral of Biological Substances to Other Laboratories

WI-03 – Despatch of Tissue Samples to Research Centres

WI-26 – Courier despatch of dry Ice and ambient blood samples

Handling of Dry Ice

BS-CONT DOC 1620 – Disposal of Frozen Co2 Pellets (Dry Ice)

MICRO-Policy 0023 – Personal Protective Equipment

Sample Destruction

D-PAN-P-POL8 – Waste Management in Pathology

HIST/GEN-SOP 0043 – Sharps Disposal

Adverse Incidents i.e. spillage

MICRO-SOP 0246 – Leaking Specimens and Spillage Safety Protocol

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1. Introduction

1.1

Research staff required to work in the Blood Sciences department on clinical trial related activities have individual responsibilities under Health and Safety legislation to ensure the health, safety and welfare of themselves and others who may be affected by their activities

1.2

County Hospital Foundation Trust management staff has a duty of care to their staff and to others who may be affected by the activities of the department.

2. Aims and Objectives of this SOP

2.1

The primary objective of this policy is to outline the proper procedures for the handling and processing of specimens in the laboratory for research studies.

2.2

To ensure the safe handling, storage, and disposal of dry ice.

3. Scope

3.1

All Research staff engaged with clinical trials where samples such as blood and urine are collected from participants to be processed in a laboratory setting.

4. Definitions

Definition	Description
EN511	European standard regulating the manufacture and sale of thermal, cold-weather, and water-resistant safety gloves
EN166	European standard covering the requirements for protective eyewear.

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UN1845	Numeric identifier for dry ice assigned by the United Nations (UN) and the UN Committee of Experts on the Transport of Dangerous Goods
UN3373 Cat B	Numeric identifier for biological samples, category B assigned by the United Nations (UN) and the UN Committee of Experts on the Transport of Dangerous Goods
ADR Treaty	International Carriage of Dangerous Goods by Road
GCP	Good Clinical Practice

5. Equality Impact and Compliance Assessment

- Equality has been considered, see Appendix 1.

6. Data Protection Impact Assessment

- Data protection and confidentiality has been considered, see Appendix 2.

7. Stakeholders and Consultation

- Research Project Manager representatives at Dorset County Hospital.
- Research Quality Group at Dorset County Hospital.
- Research SOP Working Group
- Research Quality Group

8. Roles and Responsibilities

The policy applies to all staff of the research department, and those who have an active role in the study. The following 'key staff' also have responsibilities listed here:

- Research staff- should ensure they receive, understand, and document all necessary training to fulfil the requirements of this SOP.
- Delegated staff- The delegation will be updated with staff and their roles which will define who is responsible for laboratory specimens.

It is recommended that Research staff are immunised against Hepatitis B. To obtain the full benefits of immunisation there is a need to have three injections of Hepatitis B

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vaccine over four to six months followed by a 5 year booster. These vaccinations can be obtained through occupational health with the organisation.

9. Training and Implementation

There are three specific areas of training identified as part of this SOP, namely laboratory safety training, clinical trial specific training needs analysis conducted and planned implementation and handling of dry ice training.
Research personnel must have up to date training in GCP and appropriate training as required by the research study.

a. **Blood Sciences Laboratory Specific Training**
   Research staff should ensure they are familiar with all relevant aspects of working within the Blood Sciences laboratory environment. This training is provided in the form of an induction by a member of the Blood Sciences team. In addition, Research staff can be accompanied by a colleague with experience in working in the laboratory.

b. **Clinical Trial Specific Training**
   During the 'set-up' phase of a new clinical trial, induction training is provided to all staff associated with delivering the study. This training ensures familiarisation with the Protocol, Investigators Brochure, Laboratory Manual and any other study specific documents and software.

c. **Handling of Dry Ice Training**
   Research staff are responsible for ensuring they have undertaken the relevant training and have provided evidence to their line manager of having read and understood this SOP prior to using dry ice. Training is available via CRN Wessex

- New users must read and understand this SOP before carrying out this procedure
- Existing users must read and understand the revisions section
- All users must have undergone recent GCP training
- Data security Awareness mandatory training Equality and Diversity
- Health Safety and Welfare
- PAS training and Refresher training

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- Safeguarding Adults
- NIHR Fundamentals of Research Course
- Study Specific Training as per individual sponsor/ study team

10. Risk Management

- Risk Management for this SOP is conducted via three key processes;
    - The SOP approval process involves governance and risk subject matter experts identifying generalized risks and mitigations to be written into the draft SOP prior to approval.
    - The delivery of this SOP will be monitored both by the review periods identified and the datix incident reporting system to implement corrective and preventative actions through this SOP.
    - The study feasibility process (RESSOP009) identifies risks related to individual study delivery and their compliance with this SOP.

11. Approval

- This SOP has been approved in accordance with the Policy and Procedure for the Development and Management of Policies and Clinical Guidance (Ref 1126)

12. Monitoring and Reviewing Arrangements

- Monitoring:

  To be reviewed every three years, unless agreed otherwise, in accordance with the following link: Home

- Reviewing Arrangements**:**

  This SOP will be reviewed at least every three years, in accordance with the Policy and Procedure for the Development and Management of Policies and Clinical Guidance (Ref 1126).

13. Dissemination

- This approved SOP will be uploaded to the Trust Policies and Clinical Guidance database and published and accessible via the Trust intranet, StaffNet.

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14. Policy Content

All samples processed in the laboratory should be handled, stored, packaged, and dispatched in accordance with the individual requirements of the study as defined in the Protocol and Laboratory Manual. Adherence to GCP guidelines in the handling of **r**esearch specimens is essential.

14.1 Sample Processing

Research samples must be processed by appropriately trained and delegated Research Staff, in accordance with the clinical trial Protocol, Laboratory Manual, or laboratory specific instructions/SOPs, which will detail specific sample volume, consumables/kits, timelines and conditions for collection, processing, storage and shipping. This may involve use of a centrifuge (BD-SOP 2309 – Centrifuge Safe Use, Maintenance and Cleaning) and the creation of blood films (BS-HAEM SOP 8843 – Blood Film Preparation).

Laboratories should not perform any work on clinical trial samples that are not specified in the Protocol. If additional work is requested by the Sponsor or their representative all relevant documentation must be amended prior to the initiation of any additional work.

14.2 Sample Storage

At the outset of each study, it should be established if there is a requirement for samples to be stored (as defined by the Protocol, Laboratory Manual, or clinical trial specific instructions/ SOPs), and if required whether there is sufficient capacity for the duration of the clinical trial. Trial-specific procedures detailing specific storage conditions and the actions to be taken following failure of storage units (including information about who should be notified, how and where samples may be transferred to) must be agreed at the outset of each study.

Sample storage areas must be adequate, and sample storage units (secure laboratories, incubators, freezers and fridges) must be monitored for compliance (HIST/GEN-SOP 0098 – The Tutela Temperature monitoring system and

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associated tasks.), and maintained and serviced regularly. Temperature and service/maintenance records must be stored safely and available for inspection. Equipment used to monitor temperature must be subject to periodic calibration.

Samples stored in freezers or fridges should be logged with the date entered and removed.

14.3 Sample Shipping

During study review and set up of the trial, the Research team should ascertain whether samples will be shipped in batches or on the day of collection, and who the courier will be along with locations where the collection and shipment of samples will take place. It should also be established if the packaging material is provided by the Sponsor or courier.
Adequate labelling of the specimens and packing should be done in accordance with the study protocol and/or laboratory manual.
Some specimens may require transportation in dry ice.

14.4 Handling of Dry Ice

- Dry ice is the solid form of carbon dioxide (CO2). This is available for use in the form of pellets, slices or blocks and can be supplied loose or in insulated containers. Dry Ice is considered a hazardous material – MICRO-COSHH 0036

- Staff need to be aware that caution must be exercised when using dry ice in order to order to minimise the risks associated with its use.

- The investigator or delegated person must request dry ice from the appropriate courier company as specified in the study protocol.

- Handling dry ice in a well-ventilated area is essential. In poorly ventilated rooms carbon dioxide gas can sink to low areas and replace oxygenated air. This can be dangerous and could cause suffocation if breathed exclusively.

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- Protective thermally insulated closed wrist gauntlets must be worn meeting safety standard EN511 and enclosed footwear at all times. If touched briefly dry ice is harmless but if prolonged contact with the skin is made, the cells will freeze and cause injury similar to that of a burn. Protective eye wear, preferably enclosed goggles, must be worn which comply with safety standard EN166. (MICRO-POLICY 0023 – Personal Protective Equipment (PPE) Policy and Protocol)

- Allow sufficient ice to cover the sample. The ice pellets should be handled with a scoop, and not poured in and out of the box.

- The dry ice must not be left on a work bench in the laboratory as the extreme cold temperature may cause damage.

- The dry ice may be left on the floor in the sealed container that it was delivered in.

- A designated area for storage of samples (in dry ice) awaiting courier collection is available in the Research Nurses Office. This area must have 2 windows open when a dry ice package is in place and staff leaving dry ice packages in this area must communicate to at least one designated individual that the package is awaiting collection and the timeline for collection.

- A package containing dry ice and/or samples cannot be left overnight. If not collected the samples should be returned to the freezer, dry ice should be disposed of and the sponsor should be notified.

- Ensure secure plans are in place for the timely processing and collection of the dry ice package as dry ice sublimates at 10% or 5-10 pounds every 24 hours.

- Patient specimens transported using dry ice are subject to classification, packaging and labelling requirements under ADR - UN1845 (dry ice) and UN3373 (Biological Sample Category B). These labels are mostly pre-printed on the package material. Disposal of Dry Ice

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14.5 Disposal of Dry Ice

If a dry ice package is no longer required, the disposal of this is the responsibility of the investigator or a delegated person.

The dry ice should be unwrapped and left at room temperature in a well-ventilated area i.e. the pathology sluice (BS-CONT DOC 1620) or in an outside space without public access.

The dry ice may take some time to sublimate: 10% or 5-10 pounds every 24 hours.

Dry ice must not be placed into a sink or any other receptacle. The cold temperature cause damage. It should be left in its original packaging in a well-ventilated area.

14.6 Sample Destruction

In some cases, samples are not shipped but are instead destroyed. This could be within Protocol, for example some studies require a backup sample to be retained at site, which is then destroyed upon confirmation that the primary sample has been received and analysed by the Central Laboratory. Samples should never be destroyed without written confirmation from the Central Laboratory or study Sponsor. Sample destruction may also be required due to a sample deviation or withdrawal of patient consent. Samples are to be disposed of in accordance with the trial protocol and trust policy MICRO-SOP 0819

14.7 Adverse Incidents

In the event of spillage of specimens or hazardous material, a trained member of laboratory personnel should be notified, and the spillage handled by a trained member. MICRO-SOP 0246 – Leaking Specimens and Spillage Safety Protocol

15. Legislation, References, local Policies and Guidelines

Legislation:

None

Guidelines & Principles:

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Policies:

BS-CONT DOC 1620 – Disposal of Frozen Co2 Pellets (Dry Ice) - available to view on QPulse

BS-HAEM SOP 8843 – Blood Film Preparation - available to view on QPulse

BD-SOP 2309 – Centrifuge Safe Use, Maintenance and Cleaning - available to view on QPulse

D-PAN-P-POL8 – Waste Management in Pathology Policy - available to view on QPulse

HIST/GEN-SOP 0043 – Sharps Disposal - available to view on QPulse

HIST/GEN-SOP 0098 – The Tutela Temperature monitoring system and associated tasks. - available to view on QPulse

MICRO-POLICY 0023 – Personal Protective Equipment (PPE) Policy and Protocol. - available to view on QPulse

MICRO-SOP 0246 – Leaking Specimens and Spillage Safety Protocol. - available to view on QPulse

MICRO-SOP 0819 – Micro – Control of Clinical Material – Retention and Disposal of Clinical Samples and Cultures – available to view on QPulse

PAN-PATH-POLICY 0059 – Referral of Biological Substances to Other Laboratories. – available to view on Qpulse

MICRO-COSHH 0036 – Liquid CO2 and Dry Ice – available to view on Qpulse

WI-03 – Despatch of Tissue Samples to Research Centres

WI-18 – Use of the Centrifuge November 2017

WI-26 – Courier despatch of dry ice and ambient blood samples

WI-35 – Handling of Dry Ice

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Appendix 1

EQUALITY IMPACT AND COMPLIANCE ASSESSMENT

1. General	
Title of Document	Laboratory Work & Dry Ice Handling in Clinical Research
Purpose of Document	To outline procedures for the handling and processing of specimens in the laboratory for research studies and the handling of dry ice.
Intended Scope	Encompasses general procedures for the handling of ambient, chilled, fand frozen specimens and the storage and shipping of those as defined by the research protocol and its associated laboratory manual.

2. Consultation	
Which groups/ associations/ bodies or individuals were consulted in the formulation of this document?	Circulated for review and comment by the Research Project Management Team prior to approval with the Quality Group
What was the impact of any feedback on the document?	Feedback was considered and incorporated into the final document as appropriate.
Who was involved in the approval of the final document?	The Research Quality Group
Any other comments to record?	None

3. Equality Impact Assessment/Analysis		
Reference: who it may impact		
Age **Disability** **Ethnicity** **Gender reassignment** **Marriage/ Civil Partnership** **Pregnancy/ Maternity** **Religion and Belief** **Sex** **Sexual Orientation**	**Patients** **Members of the local community** **Voluntary Sector Groups**	**Staff Groups** **Volunteers**

ED&I Considerations: (Access, Communications, Service delivery, Cultural competence).	
Does the document positively or negatively affect certain staff or groups of staff? If so, please state how this is justified.	No
Does the document positively or negatively affect certain patients or groups of patients? Please state how this is justified.	No
What measures are proposed to address any inequity?	Assessed at project level
Can the document be made available in alternative format or in translation?	No due to cost restrictions

4. Compliance Assessment	
Does the document comply with relevant employment/ equality legislation or Trust standards? Please specify.	Yes

5. Document assessed by:

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Name	Anthony Homer
Post Title/ Position	Research Governance & Quality Lead
Date	22/04/2025

Appendix 2

Data Protection Impact Assessment (DPIA) Screening Questions

These screening questions should be used to inform whether a full DPIA is necessary - if you are uncertain, please talk to information.governance@dchft.nhs.uk. See the last page for information about why we must do this.

Please complete all sections

Title of Project	Laboratory Work and Dry Ice for Research Staff
Brief description	The purpose of this Standard Operating Procedure (SOP) is to ensure the health, safety and welfare of staff when undertaking clinical trial related activities within the Pathology laboratories at Dorset County Hospital and the Weymouth Research Hub
Completed by:	
Name	Anthony Homer
Title	Research Governance and Quality Lead
Department	Research
Email	Anthony.homer@dchft.nhs.uk
Date	22/04/2025

		Yes	No	Unknown
1.	Will the project involve the collection of new, person identifiable information[1], or potentially identifiable information, about individuals (patients and/or staff)?		☑	
2.	Will the project compel individuals to provide information about themselves, or involve the processing of personal data not obtained directly from the individual? *i.e., where they will have little awareness or choice, or it is impossible, or would involve disproportionate effort to inform the individuals that the processing is taking place.*		☑	
3.	Will identifiable information about individuals be shared with other organisations or people who have not previously had routine access to the information?		☑	
4.	Are you using information about individuals for a purpose it is not currently used for? *i.e., using data collected to provide care for an evaluation of service development, or data matching from multiple sources.*		☑	
5.	Where information about individuals is being used, would this be likely to raise privacy concerns or expectations? *i.e., will it include health records, criminal records, or other information that people may consider to be sensitive** and private, and may cause them concern or distress.*		☑	
6.	Will the project require you to contact individuals in ways which they may find intrusive?		☑	

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	i.e., telephoning or emailing them without their prior consent.			
7.	Will the project result in you making decisions in ways which could have a significant impact on individuals? *i.e., will it affect the care a person receives?*		☑	
8.	Does the project involve you using new technology which might be perceived as being privacy intrusive? *i.e., using biometrics, facial recognition, artificial intelligence, or automated decision making.*		☑	
9.	Is a service being transferred to a new supplier (re-contracted) and the end of an existing contract, or is the processing of identifiable/potentially identifiable data being moved to a new organisation?		☑	
10.	Will the project involve systematic monitoring of a publicly accessible area on a large scale? *i.e., use of CCTV.*		☑	
11.	Will the project involve the targeting of children or other vulnerable individuals? *i.e., for marketing purposes, profiling or other automated decision making*		☑	
12.	Will designated staff need approved access to this information, either by team membership or individual log-in? *i.e., shared file access, separate software username and password, information asset*		☑	
13.	What is the lawful basis for using this data? *√ all that apply*			
	A. Article 6(1)(e) - Public Task (direct healthcare)			
	B. Article 9(2)(h) (the processing is necessary for health or social care purposes)			
	C. Consent			☑
	D. Unknown			

- If all answers are **NO** then please file this with your project files to document that you have considered any possible risk to data.
- If any are **YES** or **UNKNOWN** please forward this document for review and next steps to informationgovernance@dchft.nhs.uk

OUTCOME

☑No Risk to data, or No data – file locally

Risk to data – forward to informationgovernance@dchft.nhs.uk

- ☐ Low Risk - approved by IG – file locally
- ☐ High Risk – complete full DPIA template and submit to IG

Name of Information Asset Owner: Anthony Homer

Name of Information Asset Administrator: Amy Thomson

Signed by Project Lead Date: 22/04/2025

Signed by Information Governance Date:
(if appropriate)

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