Document Title: Centrifugation

Document Number: SOP096

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers, and Research Pathology
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Directorate:	Research and Development
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For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Version Number	Modification:
2.0	**Updated for CRF**

Key Points of this Document

1 Purpose and Contents

a. Due to all the potential hazards, it is essential that all members of staff using centrifuges in a safe manner. This document outlines good working practices when using any centrifuge as well as specific instructions on how to use each model.

2 Roles & Responsibilities

a. Initial training will be provided during Laboratory induction. Afterwards practical training in this procedure will be carried out by a competent member of the Research and Development department. Following a period of supervision, (depending on the individual needs of the trainee) there will be a competency-based assessment. Online refresher training should be completed every two years afterwards.

b. All centrifuges are and are serviced annually. If a fault should arise in the interim contact the maintenance company. Centrifuges must also be serviced and calibrated if they have moved location.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

4 Procedure

4.1 General centrifuge use

a. Wear appropriate personal protective equipment, gloves and protective eyewear. When handling any human samples gloves should always be worn. When working in the point of care room eye protection must be worn when aliquoting samples that have been centrifuged. Occasionally samples can be difficult to be removed after centrifugation. In

these incidences take the bucket to the biological hood and then remove sample. In the point of care room wear eye protection if samples are difficult to remove from bucket

b. Sealed buckets should be used when centrifuging blood or other body fluids**.** An appropriate diameter centrifuge tube holder should be chosen to prevent the centrifuge tube from excessive lateral movement.

c. Centrifuge buckets must always be matched for size and weight and used as opposite pairs. Samples within the buckets must always be used as matched and balanced opposite pairs (matched tube size, number and volume).

d. Sealed buckets must be placed into all of the available spaces on the rotor arm during centrifugation (even if empty). Placement of all buckets is important as this provides structural support for the rotor head during centrifugation.

e. Use the study specific protocol to set speed (rpm/ g), acceleration/ deceleration, time and temperature. When starting the centrifuge wait until centrifuge reaches designated speed. If there are any unusual noises occur stop the centrifuge immediately and wait a minimum of 10 mins before opening.

f. Any spillages in or around the centrifuge must be cleared up immediately with Tristel following Sections 4.2, 4.3 and 4.4 of this document.

g. At the end of session, leave lid in open position and switch off the centrifuge.

4.2 Spillages

a. Clean any spillages that occur immediately:

b. Wearing adequate PPE - gloves, lab coat, goggles/ visor.

c. Small spills: Tristel fuse solution can be used. Leave for one minute for the Tristel solution to neutralise the spillage.

d. Larger spills: use the bleach granules contained in the biohazard spillage kit to absorb the liquid.

e. Clear up with paper towels. Dispose of any used paper towel into the clinical waste. Remove gloves and wash hands.

f. Then perform a deep clean of the centrifuge.

4.3 Breakages

a. N.B. Where there has been skin contact with a spillage or sharps injury, Occupational Health Department must be notified. Follow occupational exposure to body fluids (Needle-stick) procedure (DN180).

b. If abnormal sounds are made while the centrifuge is spinning, then stop the machine immediately. Wait 10min before opening if you are worried the centrifuge is making unusual sounds, this is to allow aerosols to settle. Wait 30 min if you hear load noises from the centrifuge.

c. Remove the sealed centrifuge bucket from the centrifuge and take it to the safety cabinet to be opened. Use a biohazard spillage kit if a blood tube has broken inside the bucket. If bleach is used to decontaminate bucket, then it must be rinsed with water to avoid corrosion.

d. Remove any broken glass or plastic with forceps and place it into a sharps bin.

e. Use a damp paper towel to remove any small pieces. Avoid putting hands inside the centrifuge chamber, if necessary, remove the rota

f. Dispose of any contaminated material in clinical waste.

g. Put back all the buckets empty. Restart the centrifuge and listen for an abnormal sound while the centrifuge is running. If there still unusual sounds stop the centrifuge and continue to look for broken pieces. Do not introduce any samples to the centrifuge until there are no abnormal sounds. If necessary, discuss with R&D manager if an engineer is required.

4.4 Centrifuge cleaning

a. Ensure any spillages are immediately cleaned up.

b. Minimum weekly clean wipe out centrifuge buckets using 70% ethanol spray/ Clinell wipes.

4.4.2 Deep clean

a. A deep clean is required before servicing or if there is centrifuge needs decontamination.

b. Remove buckets and inserts with Tristel fuse solution. If Tristel in not available a bleach solution can be used. A bleach solution can be made following the instructions in the biohazard spillage kit.

c. Buckets and inserts should be placed into a sink and washed with Tristel fuse/ Bleach solution for a couple of minutes, rinse thoroughly with running tap water and leave to dry.

d. Buckets can be left to dry or rubbed with paper towels.

e. Wipe round the inside of the centrifuge chamber with 70% ethanol spray/ clinell wipe. Avoid putting your hand inside of the centrifuge chamber as this can cause injury. Use a pair long forceps holding the paper towel. If necessary, the rota inside the centrifuge can be removed. Some centrifuges only require a button to be pressed to remove the rota. Other centrifuges require 10ml hexagonal key.

f. Micro centrifuges use a paper towel soaked in Tristel fuse to wipe down then use 70% ethanol spray to remove the Tristel. If 70% alcohol is not available, use water to remove Tristel. Alternatively use a clinell wipe to decontaminate the micro centrifuge.

g. If cleaning prior to servicing a certificate of decontamination must be completed. Fill in Form DN418 (Declaration of contamination status), located on the intranet. Attach the completed decontamination certificate to the centrifuge, together with a note stating that the equipment is not to be used (unless in an emergency) until after service/repair is complete.

4.5 Centrifuge Servicing and Locations

a. Details can be found in the Guidance document GD031

5 Health and safety

5.1 COSHH

a. Staff members need read all COSHH forms related to chemicals used to clean centrifuge These include:

1. Tristel duo and Tristel fuse
2. Chemicals in biohazard cleaning kit- Haz -Tab- chlorine releasing disinfectant granules and tablet
3. Clinell wipes
   70% alcohol

6 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g., Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2018)
Key related documents:	Trust Research Policy DN298 Medical Devices Maintenance and Repair Procedure DN180 -Needlestick Sharp and Splash Incidents involving blood or body fluids, Procedure

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	DATE

I certify the contents of this SOP has been reviewed and ratified

DocuSigned by:
Patrick Calvert
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29-Sep-2023

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Signed by Dr Patrick Calvert, Clinical Director of R&D — Date

SOP Release Date: .....

Appendix 1: Centrifuge Risk Assessment

Description of Activity	**Significant Hazards**
• Centrifugation is a which involves the separation particles from a solution according to their size, shape, density, medium viscosity and rotor speed. • Cleaning centrifuge	• Sample leaks causing aerosol, corrosion and contamination. • Buckets not balanced and lids not sealed. • Mechanical and electrical failure • Biohazards processing human samples such as blood or
Frequency: Daily	**Duration:** 10-20 minutes per occasion
Adverse Effects • Aerosol transmission of infectious disease • Very poor balance of tubes may cause the rotor to fail during operation, possibly generating flying debris.	**People at Risk** Research team Clinical Trial Co-ordinator Tissuebank staff
Number of People Affected:	**Operator and Any members of Staff present in Area**

What Precautions exist to control the risk:

- Wear proper protective equipment (gloves, lab gown and goggles).
- Check the rotor, lids and seals are clean and has no damage or corrosion.
- Report any damage to the person in charge of centrifuge.
- Check tubes for cracks and deformities before each use. Wipe exterior of tubes with disinfectant prior to loading.
- Make sure the buckets are well balanced, tubes to be balanced across from each other in rotor and lids are sealed. All spaces on the rotor arm should have a sealed bucket even if empty.
- Open buckets in biological safety cabinet when handling high risk biohazard samples. Decontaminate buckets with Tristel after each use.
- Stop the centrifuge immediately if an unusual condition (noise or vibrations) begin.
- To know the location of eyewash stations and safety showers.
- In case of centrifuge breakage and there is skin contact with spillage or sharps injury; Occupational health (M-F 9am-5pm) or ALERT team (bleep 432/521) **MUST** be notified.
- Complete a Decontamination certificate after cleaning a centrifuge that is going to be serviced.

Risk Rate:

Likelihood 1	**Severity 2**	**RRN 2**	**H S M L N**
Are these arrangements satisfactory: Yes			