National Institute for Health Research

Processing, Storage and Shipment of Samples in the King's Clinical Research Facility

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Authorised by	Professor Peter Goadsby, CRF Director
Related documents	CRF-LAB-SOP-1: Use of the Centrifuges for the Processing of Clinical Trial Samples in the King's CRF CRF-LAB-SOP-2: Procedure for Dealing with Biological Sample Spillage in the King's CRF CRF-LAB-FRM-2: Study Sample Log CRF-LAB-FRM-4: Fridge/Freezer Transfer Document CRF-LAB-FRM-5: Sample Packing and Shipment Form CRF-LAB-FRM-6: Receipt of Samples Form CRF-LAB-FRM-8: -20° Freezer Sample Log CRF-LAB-FRM-10: -80° Freezer Sample Log CRF-HS-COP-1: King's CRF Health and Safety Code of Practice KCH Waste Management Policy
Keywords	Samples, fridge, freezer, protocol, sample log
Supporting references	See Section 6.0

Change History		
Date	Change details, since approval	Approved by
23rd December 2013	1. Amended text in SOP title from "Clinical Research Facilities" to "King's Clinical Research Facility" 2. Amended name of Director to reflect new Director 3. Amended logos to update to current CRF letterhead template 4. Amended document number from CRF SOP009 to	E Giemza

	CRF-LAB-SOP-3 to comply with QPulse document numbering system 5. Amended numbers of documents referred to throughout the text to reflect revised QPulse/CRF numbers 6. Removed reference to CRF SOP010 on Use of Freezers in the CRF as this SOP is still in draft 7. Amended section 5.4.7 to state that freezer maps should be created and a copy placed on door of freezer and removes text stating that a freezer map template was available on the CRF shared "t" drive	
January 2016	1. Update to the related documents, including new CRF forms 2. Updated Section 5.0 to reflect current CRF practice and procedures 3. Addition of a section (Section 5.5) on the shipment of samples from the CRF 4. Minor administrative amendments to the text	E.Giemza
February 2018	1. Section 5.4: update to the procedures for logging samples stored in the CRF freezers 2. Minor amendments to the text for clarity	E.Giemza

Review History		
Date	Review details	Approved by
23rd December 2013	Review of v1.0 conducted by Lara Edwards, CRF QA Manager, superseded by v2.0 (effective date 03rd January 2014)	E Giemza
January 2016	Review of v2.0 conducted by Georgia Bullock, CRF QA Manager, as per the review date. Changes made as per 'Change History' and re-issued as v3.0.	E. Giemza
February 2018	Review of v3.0 conducted by Georgia Bullock, CRF QA Manager, as per the review date. Changes made as per 'Change History' and re-issued as v4.0.	E. Giemza

1.0 Background

1.1 The King's Clinical Research Facility (CRF) provides facilities to support researchers who require blood samples to be processed and stored, in preparation for safe transfer to a relevant laboratory for further analysis. This process may be undertaken by a core CRF staff member or by a user of the CRF.

1.2 The CRF must ensure that anyone using the sample processing areas within the CRF has been appropriately trained in the use of the relevant equipment and is competent at completing sample processing procedures.

1.3 Once samples are processed according to the study protocol, CRF Standard Operating Procedures (SOPs), Good Clinical Practice and relevant King's College Hospital (KCH) policies, they must be pseudonymised in compliance with the study protocol requirements, and must also meet data protection and ethical requirements for ensuring anonymity to the study subjects, where necessary. All study samples must be easily identified and located once stored.

2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe the processes for the safe processing, storage and shipment of samples within the CRF.

3.0 Scope

3.1 This SOP applies to all samples collected from study subjects, which are to be processed and/or stored by CRF staff in the sample processing areas. This SOP also applies to users of the CRF using the sample processing areas to process and/or store samples.

3.2 The CRF encompasses the Clinical Trials Facility (CTF), the Experimental Medicine Facility (EMF) and the Cell Therapy Unit (CTU). CRF SOPs will apply to the CTF and EMF only and staff working in those areas should work to all relevant CRF SOPs. The CTU will continue to control and use its own policies and SOPs to ensure compliance with Good Manufacturing Practice (GMP).

4.0 Responsibilities

4.1 All CRF staff and users of the CRF processing samples should ensure that they have received adequate training before commencing any sample processing. They are also bound to adhere to the procedures described in this SOP and be

familiar with the relevant related CRF SOPs and Forms, and relevant KCH policies.

4.2 It is the responsibility of each study's Principal Investigator (PI) to ensure that samples are processed, stored and shipped according to the study protocol and/or the study laboratory manual.

5.0 Procedure

5.1 **Processing of samples**

5.1.1 Gloves, aprons and eye protection (safety goggles) must be used at all times when processing body fluids. Gloves should be removed to complete other tasks in the sample processing areas (eg: using the telephone) and protective clothing should be removed before exiting the sample processing areas.

5.1.2 Sample tubes must be correctly labelled according to the sample processing instructions in the study protocol and/or study laboratory manual. Label details should be cross-referenced with the study subject and study-specific documentation to minimise errors.

5.1.3 Study-specific sample processing instructions should be followed as detailed in the study protocol and/or study laboratory manual.

5.1.4 Samples which have been spun down should be removed from the centrifuge and placed in a suitable storage rack (or on ice if required by the study protocol/laboratory manual).

5.1.5 An appropriate pipette (as detailed in the sample processing instructions and/or study laboratory manual) should be used to transfer the appropriate blood component (plasma/serum) from the sample into the relevant pre-labelled storage tube.

5.1.6 If a Gilson pipette or similar system is used, the dial should be set to the correct amount of fluid to be pipetted.

5.1.7 Disposable pastettes must be discarded into a clinical waste bin and pipette tips into a sharps bin.

5.1.8 Once done, the lid on the original sample tube should be replaced and the tube discarded into a sharps bin.

5.1.9 A fresh pastette (or pipette tip) must be used for each sample.

5.1.10 All waste material from the pipetting process should be placed in a sharps bin or clinical waste bin as appropriate and in compliance with the KCH Waste Management policy.

5.1.11 In the event of any spillages, follow the procedure in *CRF-LAB-SOP-2: Procedure for Dealing with Biological Sample Spillage in the King's CRF.*

5.2 **Documentation of sample processing and storage**

5.2.1 For each sample processed, a study-specific Sample Log should be completed, to document the processing and storage of samples. If no Sample Log has been provided by the Sponsor or study team, the generic CRF form *CRF-LAB-FRM-2: Study Sample Log* can be used. The Log should be readily available for monitoring and audit purposes.

5.2.2 Additional sample logs must be completed when storing samples in the CRF freezers (see Section 5.4).

5.3 **Separation of plasma/serum from blood samples (in the absence of study-specific instructions)**

5.3.1 In the absence of study-specific instructions, use the following guidance:

5.3.2 Plasma – plasma is obtained from whole blood that has been mixed with an anticoagulant. To separate plasma from whole blood, centrifuge tubes for 10 minutes at 2000g.

5.3.3 Serum – serum is obtained from clotted blood that has not been mixed with an anticoagulant. To separate serum from whole blood, allow the blood to clot for at least 30 minutes, then centrifuge for 15 minutes at 1500g. When pipetting the serum from the blood tube into the cryovial, pipette the serum gently so as not to disturb the blood layer below.

5.3.4 If the blood cells are disturbed during this process, re-centrifuge the sample to ensure complete separation before pipetting.

5.4 **Storage of samples**

5.4.1 Samples must be stored according to the instructions in the study protocol and/or laboratory manual.

5.4.2 All samples must be securely sealed before being placed in a CRF fridge or freezer.

5.4.3 All samples must be clearly labelled with the study name and PI name before being placed in a CRF fridge or freezer.

5.4.4 For samples being frozen at -80°C or below, screw-top tubes (e.g. Nalgene, Sarstedt) must be used and not Eppendorf tubes which are liable to 'pop' their lids.

5.4.5 No cracked or broken vials should be stored in the fridge/freezer.

5.4.6 If no study-specific instructions have been provided, samples should be stored in an appropriate storage box suitable for the storage temperature and size of the tubes. Storage boxes are provided in the CRF freezers. The storage of samples in bags or on trays should be avoided wherever possible.

5.4.7 Samples being stored in the -20°C freezers in the EMF and CTF should be recorded on *CRF-LAB-FRM-8: -20° Freezer Sample Log*. This form should be located on the door of the freezer or close by. The Log should be completed when samples are added to the freezer and also when they are removed.

5.4.8 Samples being stored in a CRF -80°C freezer should be recorded on *CRF-LAB-FRM-10:-80° Freezer Sample Log*. Copies of this form can be found in a folder located within the sample processing area. Instructions on how to complete the form are in the folder. The form should be completed when samples are added to the freezer and also when they are removed.

5.4.9 If samples need to be moved internally (ie: from one fridge/freezer to another within the EMF or CTF), staff must complete *CRF-LAB-FRM-4: Fridge / Freezer Transfer Document.*

5.4.10 Samples should not be stored in the CRF freezers or fridges for longer than **3 months**, unless previously agreed with the CRF Manager.

5.4.11 Any queries regarding the storage of samples in the CRF (including the completion of the freezer logs) should be directed to the CRF QA Manager or CRF Manager.

5.5 **Shipment of samples from the CRF**

5.5.1 When samples are due for transfer to a location outside of the CRF, the nominated study team member, or CRF staff member, should follow the instructions in the study protocol and/or laboratory manual. The Sample Log should be completed to record the shipment date, time and the destination.

5.5.2 For samples being packed and shipped to an external company or organisation, staff should complete *CRF-LAB-FRM-5: Sample Packing and Shipment Form*. In addition, *CRF-LAB-FRM-6: Receipt of Samples Form* should be sent with the samples to be faxed or emailed back to the CRF by the recipient.

5.5.3 If samples are being shipped to the US, a Customs Invoice (available on Q-Pulse as DOC9) should be completed as part of the paperwork.

6.0 Related documents & References

6.1 CRF-LAB-SOP-1: Use of the Centrifuges for the Processing of Clinical Trial Samples in the King's CRF

6.2 CRF-LAB-SOP-2: Procedure for Dealing with Biological Sample Spillage in the King's CRF

6.3 CRF-LAB-FRM-2: Study Sample Log

6.4 CRF-LAB-FRM-4: Fridge/Freezer Transfer Document

6.5 CRF-LAB-FRM-5: Sample Packing and Shipment Form

6.6 CRF-LAB-FRM-6: Receipt of Samples Form

6.7 CRF-LAB-FRM-8: -20° Freezer Sample Log

6.8 CRF-LAB-FRM-10: -80° Freezer Sample Log

6.9 CRF-HS-COP-1: King's CRF Health and Safety Code of Practice

6.10 KCH Waste Management Policy

7.0 List of Appendices

N/A

8.0 Approval and sign off

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