University of Cape Town Clinical Research Centre	Standard Operating Procedures

Title	**Blood Sampling Processing and Transport**
Number	09
Version	2

	Name	Title	Signature	Date
Reviewer	Brenda Wright	Project Manager		**04 Aug 2015**
Authoriser	Delva Shamley	CRC Director		04 Aug 2015
			Effective date	04 Aug 2015
			Review date	04 Aug 2018

1. Purpose/scope

To describe the procedure of processing and transporting blood samples taken from participants for Safety Results, Pharmacokinetic or Pharmacogenomics analysis.

2. Templates/forms

CRC 9.1 Example of Sampling Process Log

3. Glossary/definitions

Transit Laboratory

This laboratory/room is situated near the ward/consulting room where samples are collected and is used to process the samples as necessary, prior to being shipped to the analysis laboratories

4. Responsibilities and procedure

4.1 Safety Bloods

Prior to the start of the trial relevant staff will receive training on the handling and processing of all Safety bloods according to the trial protocol and/or study-specific safety laboratory manual. The Safety laboratory will supply their own kits and requisition forms to be completed and shipped with the samples

4.2 Pharmacokinetics and/or Pharmacogenomics samples

Prior to the start of the trial, relevant staff will receive training on the handling and processing of these samples according to the trial protocol and/or the laboratory manual supplied by the Analytical Laboratory. The staff responsible for the processing of these samples will complete a Sampling Process Log (see example)

4.3 General

4.3.1 Responsible Laboratory staff will check the medical stock and equipment to ensure adequate stock and updated calibrated certificates of all equipment used in the Transit Laboratory.

4.3.2 A member of the trial team (runner) will be appointed by the Principal Investigator to transfer the samples drawn from participants to the Transit Laboratory where the samples will be processed and/or stored.

4.3.3 If required by the protocol/Laboratory manual, ice will be made available to store sample tubes (pre and/or post collection). Additional supplies of ice should always be on hand to re-stock for the next sample.

4.3.4 All samples will be labelled as specified in the protocol and/or laboratory manual. The phlebotomist, the runner and the laboratory assistant will ensure that all samples are labelled correctly prior to blood draw, transferring of samples to laboratory and processing of samples.

4.3.5 Relevant source documents will be completed reflecting the time of sample drawn, time received in laboratory, time in and out of centrifuge and time of storing in freezer. Comments regarding difficult sampling and/or haemolysis after centrifugation must be entered on source documents.

5. Document history:

Version No.	Date	Reviewer	Details of changes
1	08/2015	B Wright	Included processing of Safety Bloods

Study Number: Laboratory Process Log

Participant Initial:		__ __ __			Participant Number:			E6903_____	
Centrifuge Speed:		1 500g = 3 973 RPM		Centrifuge Temperature:		4°C	Time of centrifugation: 10 minutes		Freezer temperature: -20°C (samples to be frozen within 30 minutes of plasma preparation)
Date	Visit No:	PK Time Point:	Time received in Lab	Time into centrifuge	Time out of Centrifuge	Comment & Initial	Time into Freezer	Date shipped	Comment & Initial
___/___/____	2	Pre-dose	___:___	___:___	___:___		___:___	___/___/____	
		1 hr post	___:___	___:___	___:___		___:___		
		2 hr post	___:___	___:___	___:___		___:___		
		4hr post	___:___	___:___	___:___		___:___		
		8hr post	___:___	___:___	___:___		___:___		
___/___/____	3	Pre-dose	___:___	___:___	___:___		___:___	___/___/____	
		1 hr post	___:___	___:___	___:___		___:___		
		2 hr post	___:___	___:___	___:___		___:___		
		4hr post	___:___	___:___	___:___		___:___		
		8hr post	___:___	___:___	___:___		___:___		
___/___/____	4	2hr post	___:___	___:___	___:___		___:___	___/___/____	
___/___/____	8	Pre-dose	___:___	___:___	___:___		___:___	___/___/____	
		1hr post	___:___	___:___	___:___		___:___		
		2hr post	___:___	___:___	___:___		___:___		
		4hr post	___:___	___:___	___:___		___:___		

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Training Log for Data Recording		
Name:	**Initial:**	**Date:**

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