Work Instruction	**Administration, processing, storing and shipping of blood samples for clinical trials when central bloods are required**
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CONTENTS:

1.0	**Purpose, Scope & Objectives**
	The purpose of this work instruction is to ensure that the correct procedures are followed for every trial that requires patient blood samples to be taken, processed, stored and shipped to a central lab. The processes involved are predominantly carried out by the HCA's, however on occasions the research nurse may need to cover.
2.0	**Personnel & Responsibilities**
	HCA's Research Nurses
3.0	**Background**
	Bloods for clinical trials are often processed 'centrally' meaning that one lab processes all samples for the trial. This ensures consistency in analysis and reporting. These samples must be taken, processed, stored and shipped according to stringent instructions, contained in the lab manual, to ensure that the

	samples are viable on arrival in the central lab.
4.0	**Definitions**
	HCA = Health Care Assistant SD = Source Data SIV – Site Initiation Visit
5.0	**Health & Safety**
6.0	**Equipment & Documentation**
7.0	**Procedure**
	Administration Kits will be sent at around the time of the SIV to the department. These need to be stored in the lab room and the relevant team need to be made aware they have arrived. Kits need to be checked monthly for expiry and if required re-ordered (re-ordering process will be found in the lab manual). **NB – At time of SIV, check with monitor regarding on-line ordering system and log in requirements** The HCA's have a day a month protected time to review lab supplies and do a stock take. **Process** - If central bloods are required at the patient visit this will be indicated on the SD/visit checklist. - All blood kits that are required for central analysis are stored in the lab room cupboard. All are labelled according to trial name. - Select the correct kit for the correct patient visit - At time of prepping book courier/dry ice as required. - Enter details of courier booking onto Outlook calendar - When samples are processed the requisition form (stored in the kit box) needs to be completed. White copy is sent with the sample to the central lab, pink/yellow copy is stored in patient SD folder. Each trial will have a lab manual which describes the processes required for each sample, these manuals are stored with the kits in the lab room. The department has a -80 freezer on level 6 in combined labs where samples can be stored if required. **NB All samples processed need to be recorded in the sample tracker logbook, stored in the lab room.**
8.0	**References**
9.0	**List of Appendices**
	N/A
10.0	**Document Control**
	All Work Instructions are stored on the shared research drive: G/Research Common/Training & Education/How To work instructions/ Printed copies are not controlled and therefore may not be the current version of the document.

11.0	**Training Record & Competency Assessment**
	Records of the training and competency assessment for this work instruction shall be retained by the nominated educator for the staff group involved. All staff members have a responsibility to retain their own training records for continuing personal & professional development.
12.0	**Monitoring Compliance and Effectiveness**
	Any failure to send the correct samples to central labs will trigger a root cause analysis. If the team Leader or SMT notice any recurring themes these will be place on the risks and issues register as an issue. If central labs report hemolyzed, clotted or failed samples a root cause will be performed to identify what went wrong e.g. timing of samples taken/sent, courier failure etc
13.0	**Revision History**
	Issue 1 – First issue
14.0	**Managerial Approval**

Name	**Signature**	**Title**	**Date**
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