

Work Instruction	Prepping of paperwork for patient visit
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1.0	Purpose, Scope & Objectives
	<p>The purpose of this work instruction is to ensure consistent prepping of paperwork for patient trial visits.</p> <p>The Health Care Assistants (HCA's) are responsible for getting the paperwork ready in anticipation of the patient visit. The ability to do this job correctly is reliant on the SD/visit checklists sheets being accurately constructed by the research nurses and the patient visit schedule being correctly put in the team calendar by the administration team.</p> <p style="text-align: center;">The success of the prepping is a whole team responsibility as everyone has a part to play.</p>
2.0	Personnel & Responsibilities
	<p>HCA's Research Nurses Administrators Data managers</p>
3.0	Background

	<p>Clinical Trial Protocols require patients to be seen and data to be collected at very specific time points. The full requirements of each visit are laid out within the schedule of activities contained in the protocol, with further instructions given throughout the protocol and appendices. Following site selection, the nurses will review the protocol, SoA and any relevant appendices and construct a SD/Visit checklist for each potential patient visit. These are stored in G/Research Common/Trials Folder/Open/'Trial Name'/Work folder.</p> <p>Getting the patient visit prepped accurately is integral to the smooth running of the research shift and should be done in advance of the patient's scheduled visit date.</p> <p>If done accurately the HCA's can get everything ready for the patient visit, the nurses can see the patient and collect ALL the data required for the visit then the data managers can upload ALL the data in a timely fashion with less data omissions/errors. This will ultimately result in less data queries for the whole team and by default increase capacity.</p>
4.0	Definitions
	<p>HCA = Health Care Assistant SD = Source Data SoA = Schedule of Activities</p>
5.0	Health & Safety
6.0	Equipment & Documentation
7.0	Procedure
	<ul style="list-style-type: none"> - Each HCA has designated, protected prepping time each day. This will be decided by each HCA at a time most convenient to the service and entered into the Outlook calendar. This will be read out at the morning meeting each day. The HCA's will complete prepping at separate times throughout the day. This time is protected time and the whole team are made aware not to interrupt/disturb the HCA's or involve the HCA's in other tasks during this time. (To be done well/accurately, this job requires concentration) - Review Team diary in Outlook to see which patients need prepping for the following week during the protected prepping time. - It is also important that the Outlook calendar is re-reviewed daily (am and pm) to identify any new patients. If new patients have been added to the calendar at short notice, the administration team and research nurses will also make every effort to inform the HCA's as soon as possible. - Once a patient has been identified that needs prepping, find the patients SD folder. (These are stored alphabetically by trial name in the main research office) - For new patients please refer to WI 001 as to how to make up a new SD folder. - Confirm that the patient's scheduled visit on Outlook calendar corresponds with the next anticipated visit as per the protocol/ SD folder. (Occasionally the visit recorded in the Outlook calendar is

	<p>incorrect, therefore it is important to double check what is anticipated is correct, although administrators and nurses should make every effort to ensure the correct visit is recorded in the calendar)</p> <ul style="list-style-type: none"> - Print off the correct SD sheet for the anticipated visit (These are stored in the G drive/Research Common/Trials Folder/Open/'Trial name'/Work folder). - Complete the required headers on each SD/visit checklist page (both sides). - Once all paperwork has been gathered for the visit, use the tick box in the left-hand column to confirm that everything has been included for the anticipated visit. The required paperwork is stored either in the blue folders underneath the TV or within the relevant trial folder stored on the G drive. <p>NB If central bloods are required this will be indicated on the SD/visit checklist document. Please refer to WI 018 for how to process, store and ship blood samples for clinical trials</p> <ul style="list-style-type: none"> - Place completed SD folder on prepping shelf in main office according to the correct day. - Once patient is fully prepped, enter as 'prepped' on Outlook calendar.
8.0	References
9.0	List of Appendices
	N/A
10.0	Document Control
	<p>All Work Instructions are stored on the shared research drive: G/Research Common/Training & Education/How To work instructions/</p> <p>Printed copies are not controlled and therefore may not be the current version of the document.</p>
11.0	Training Record & Competency Assessment
	<p>Records of the training and competency assessment for this work instruction shall be retained by the nominated educator for the staff group involved.</p> <p>All staff members have a responsibility to retain their own training records for continuing personal & professional development.</p>
12.0	Monitoring Compliance and Effectiveness
	Any errors in the prepping process will be highlighted to the Team leader and a root cause analysis completed.
13.0	Revision History
	Issue 1 – First issue
14.0	Managerial Approval

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