

Work Instruction	Creating a Source Data / Visit Checklist
Version	Work Instruction 020 v1.0
Date	01/10/19
Review Date	2 years
Author	Julie Cunningham
Authorised by	Julie Pascoe

CONTENTS:

- 1.0 Purpose, Scope & Objective
- 2.0 Personnel & Responsibility
- 3.0 Background
- 4.0 Definitions
- 5.0 Health & Safety
- 6.0 Equipment & Documentation
- 7.0 Procedure
- 8.0 References
- 9.0 List of Appendices
- 10.0 Document control
- 11.0 Training record & competency
- 12.0 Monitoring compliance & effectiveness
- 13.0 Revision History
- 14.0 Managerial Approval

1.0	Purpose, Scope & Objectives
	The purpose of this work instruction is to ensure that prior to opening a trial for patient recruitment a trial specific source data / visit checklist is created for every trial.
2.0	Personnel & Responsibilities
	Research Nurses
3.0	Background
	Being ready to approach the first patient for a new trial takes a lot of preparation, frequently team members will have completed on-line as well as face to face training and attended site initiation visits in order to fully understand the requirements of the protocol. Despite this training, the translation of a trial protocol into confidently approaching, screening and recruiting a patient into a new trial can be complicated. Additionally, there are a number of staff members (Nurses, HCA's, administrators, data managers etc) involved in ensuring that every aspect of the protocol is followed, and everything is done correctly. In order to improve oversight and make sure everything is done in the right

	<p>order the research nurses create their own SD checklists/visit templates to try and make sure nothing is forgotten.</p> <p>These SD checklists/visit templates need to be created and ready for use prior to green light so that the team can confidently approach their first patient as soon as possible.</p> <p>If created well, the patient visit will run smoothly and all data required will be collected, this in turn will enable the data managers to enter data contemporaneously and minimise data queries.</p>												
4.0	Definitions												
	<p>HCA = Health Care Assistant SD = Source Data SoA = Schedule of Activities GANTT = Generalized Activity Normalization Time Table</p>												
5.0	Health & Safety												
6.0	Equipment & Documentation												
7.0	Procedure												
	<p>The following templates are stored in the G Drive/Research Common/Standard Letterheads forms and labels/What is Source Data/Templates and Logos / Source Data Current:</p> <ul style="list-style-type: none"> • Source Data template consent to screening • Source Data template Baseline • Source Data template consent to full study • Source Data template Randomisation • Source Data template Treatment visit • Source Data template Unscheduled visit <p>Not all templates will be required for every study, and it is up to the nurse creating them to use their best judgement as to which templates are required for the trial they are being created for.</p> <p>On creating the templates for the new study the nurse needs to ensure the trial name is inserted at the top of each page and that the footer is completed with the following information:</p> <table border="1" data-bbox="327 1541 1305 1693"> <tr> <td>Work sheet version:</td> <td>(start with V1.0 and work up as changes are made)</td> <td>Created by:</td> <td>Name of person creating the checklist</td> </tr> <tr> <td>Work sheet date:</td> <td>Date the sheet was created</td> <td>Checked by:</td> <td>Name of the person double checking the checklist</td> </tr> <tr> <td>Protocol Version:</td> <td></td> <td>Protocol date</td> <td></td> </tr> </table> <p>Using the SoA / GANTT chart contained in the trial protocol (and all relevant foot notes) as well as further explanations contained within the main protocol the nurse designing the SD/Visit checklist can edit the templates accordingly to create a document that ensures all scheduled patient activities are completed according to protocol.</p> <p>Whilst creating the document the nurse needs to think about how the whole team can work together to deliver the protocol effectively and ensure that all data is collected. With this in mind, the templates have</p>	Work sheet version:	(start with V1.0 and work up as changes are made)	Created by:	Name of person creating the checklist	Work sheet date:	Date the sheet was created	Checked by:	Name of the person double checking the checklist	Protocol Version:		Protocol date	
Work sheet version:	(start with V1.0 and work up as changes are made)	Created by:	Name of person creating the checklist										
Work sheet date:	Date the sheet was created	Checked by:	Name of the person double checking the checklist										
Protocol Version:		Protocol date											

	<p>been designed with a 'prepping' column on the left-hand side, if the HCA's need to prep anything for the visit (e.g. paperwork, questionnaires, samples etc) the nurse needs to put a tick-box in the relevant section as this will alert the HCA that they need to do something in anticipation of the visit. The second column is to be completed by the nurse/HCA seeing the patient and the third column is to be initialled by the nurse seeing the patient. Therefore, when creating the new template the nurse needs to think about the whole patient pathway.</p> <p>The sections in red should be completed so that the person seeing the patient knows when the next scheduled visit or scan is due, this is done to ensure that we have maximum time to book future appointments and scans and so that the patient has good prior notice of future appointments.</p> <p>The post visit checklist is completed after the patient has been seen and is designed to act as a prompt for all the administrative tasks that need to be performed for the patient following the visit. This section can be completed by anyone in the team.</p> <p>Once created the nurse responsible needs to request a colleague who is also familiar with the protocol to review.</p> <p>SD/ Visit checklists are to be created for every visit the patient is going to attend.</p>
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
	<p>SD/ visit checklists are created by a registered research nurse and double checked by another registered research nurse who is also familiar with the protocol.</p> <p>They are continually open for review and improvement as they are being used and if changes are required to any SD/visit checklists these changes are to be made contemporaneously.</p>

13.0	Revision History
	Issue 1 – First issue
14.0	Managerial Approval

Name	Signature	Title	Date
Author			
Julie Cunningham			
Reviewers			
Julie Pascoe			
Ben Hyams			