Work Instruction	**Management of Amendments**
Version	Work Instruction 011 v1.0
Date	28 August 2019
Review Date	2 years
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CONTENTS:

1.0	**Purpose, Scope & Objectives**
	This work instruction will describe the process undertaken when a trial protocol has an amendment. It covers all trials operating within the department and aims to ensure that amendments are processed quickly.
2.0	**Personnel & Responsibilities**
	All staff
3.0	**Background**
	Amendments are changes made to a research project after approval from a review body has been given. They are categorised as either substantial or non-substantial and it is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial. If the amendment is substantial, the Trust have 35 days to raise any objections with the Sponsor. After the 35 days the amendment can be implemented (providing all relevant approvals are in place). Protocol amendments need to be processed quickly by the site in order to ensure continued safe recruitment to the trial.
4.0	**Definitions**

5.0	**Health & Safety**
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6.0	**Equipment & Documentation**
7.0	**Procedure**
	The Sponsor sends the amendment package to the site. Whoever receives this should ensure that both R&D, PI and Senior Research administrator are all informed. - Add amendment details to red or green team amendment spreadsheet (G/Research common/red team or green team/amendment spreadsheet) and update the details accordingly throughout the amendment - Create an amendment file within the relevant trials folder (G/Research common/Trials folder/'Open' or 'in follow up'/Select relevant trial name/ amendments folder) and label the file according to the amendment number (e.g. SA01) - Put all relevant documents from the amendment pack/email in this new folder. You may want to create further folders to separate documents e.g. Regulatory documents / tracked changes documents / documents in word format etc. - Localise the Word documents where applicable and save in pdf format (Do not send Trust header to the Sponsor for security/governance reasons) - Send the pdf versions to the Sponsor for approval - Await R&D email acknowledgement and Sponsor's email confirmation before implementing the changes/new documents - Upon receiving confirmation that the amendment can be implemented, inform the relevant personnel (e.g. nurses, Pharmacy, Data Managers) via email. Where possible, provide a summary of changes - Print all of the amendment documents and file in the site file, including any updated patient facing documents. Supersede previous versions where applicable and ensure that there are no paper copies in circulation - Update the 'Current Documents' folder and 'Work Folder' accordingly (in the Trials folder on the G Drive). Bearing in mind the 35 day implementation date, it is important that all departments work together to ensure any training requirements are met and all documents are localised and approved by the Sponsor within the available time frame. Collaborative working across departments, good on-going communication and regular updates to all concerned are important if amendments are to be implemented smoothly and protocol violations avoided.
8.0	**References**
	N/A
9.0	**List of Appendices**
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**
	Team Leader and Senior Research Administrator to monitor timeframes for the implementation of amendments and highlight any concerns on the risks and issues register
13.0	**Revision History**
	Issue 1 – First issue
14.0	**Managerial Approval**

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