Work Instruction	**Creating a site file for non-commercial studies**
Version	Work Instruction 012 v1.0
Date	22 August 2019
Review Date	2 years
Author	Charley Evans
Authorised by	Kay Facey

CONTENTS:

1.0	**Purpose, Scope & Objectives**
	The purpose of this 'How To' sheet is to ensure that all study related documents are stored correctly and in accordance with ICH GCP regulations.
2.0	**Personnel & Responsibilities**
	All staff
3.0	**Background**
	On occasions non-commercial trial sponsors do not supply a site file to store the trial related documents. This may be due to budgeting on behalf of the Sponsor. On these occasions the Trust is expected to create their own site file so that all trial related documents are kept in one place. This is a requirement of ICH GCP regulations
4.0	**Definitions**
	ICH GCP = International Conference Harmonisation Good Clinical Practice
5.0	**Health & Safety**

6.0	**Equipment & Documentation**
	A4 lever arch file 2 packs of trial dividers A4 poly-pocket
7.0	**Procedure**
	1. Print off 'Trial Master File / Investigator site file table of contents with description' from the Trust's intranet - staffnet/departments/research and development/documents/TMF & ISF_table of contents. 2. Complete details on page 1 of the 'Trial Master File / Investigator site file table of contents with description', this information will be written in the protocol. 3. Use the 'Trial Master File / Investigator site file table of contents with description' as a guide to building the file. 4. Label file dividers according to the section numbers listed on the 'Trial Master File / Investigator site file table of contents with description' (1-17) 5. Open the G drive to locate the documents required for sections 1 – 17 (G/Research common/trial folders/'Open' or 'Setup'). Select the trial name and use the folders to access the required documents. 6. Print off the documents listed within each section (one section at a time) 7. File within the relevant section. 8. Place the 'Trial Master File / Investigator site file table of contents with description' at the front of the site file, as this is section 0. 9. Create a front cover and side cover for the A4 file, where possible please use the trial logo and full study title (typed, not hand-written) 10. Laminate the covers and attach neatly to the A4 file.
8.0	**References**
	ICH GCP – International Conference for Harmonisation: Good Clinical Practice Guidelines E6 R2 (Nov 2016)
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**
	All site files created will be audited annually
13.0	**Revision History**
	Issue 1 – First issue
14.0	**Managerial Approval**

Name	Signature	Title	Date
Author			
Charley Evans			
Reviewers			
Kay Facey / Julie Pascoe			
Ben Hyams			