Work Instruction	**Making up a new Source Data (SD) folder for a new trial patient**
Version	Work Instruction 001 v1.1
Date	12 Aug 2019
Review Date	2 years
Author	Irene Harvey
Authorised by	Julie Pascoe

CONTENTS:

1.0	**Purpose, Scope & Objectives**
	To ensure consistency of administration of patient held records within the oncology clinical trials team
2.0	**Personnel & Responsibilities**
	All Oncology Clinical Trial Staff
3.0	**Background**
	Each patient recruited to a research trial is given a red plastic notes folder which contains information relevant to their study participation, these are referred to as Source Data folders (SD) locally. They are stored in the trials office alphabetically per trial name.
4.0	**Definitions**
	SD = Source Data
5.0	**Health & Safety**
	As per Trust policies and guidance: - Information Governance Policy V5 (January 2019)

6.0	**Equipment & Documentation**
	Red plastic folder and A4 poly pockets are stored in the oncology clinical trials store room which is accessible by key code. The required blank paperwork is stored alphabetically in blue A4 filing system in the trials room, electronic versions are also stored in the oncology clinical trials drive under G/Research Common/Training & Education/How To work instructions/ These folders contain patient identifiable information therefore need to be stored in a lockable room and need to consider both ICH GCP guidelines and UHPNT information governance policy.
7.0	**Procedure**
	Order of documentation within the SD folder 1. Patient case note front sheet Copy of consent(s) behind front sheet 2. Clinical Trial Evaluation sheet 3. Concomitant Medications sheet 4. Adverse Event Sheet 5. Medical History Sheet 6. Tumour Evaluation Forms / Tumour Tracker, facing outward at back with imaging in between in date order 7. Relevant Case Report Forms and Source Data checklists, with most recent visit nearest the front, all previous visits to be kept in date order thereafter. 8. Copies of any relevant screening/baseline/study familiarisation documentation 9. Eligibility Checklists, if applicable **NB – Make sure the patient case note front sheet is always at the front and on display**
8.0	**References**
	ICH GCP – International Conference for Harmonisation: Good Clinical Practice Guidelines E6 R2 (Nov 2016) UHPNT Information Governance Policy V5 (January 2019)
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**
	A sampling audit of 10 CRF's across 12 open studies to be completed annually. The result of the audit will be shared with the team along with any lessons learnt
13.0	**Revision History**
	Issue 1 – First issue
14.0	**Managerial Approval**

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