Work Instruction	**Administration of the Consenting process**
Version	Work Instruction 004 v1.0
Date	14 Aug 2019
Review Date	2 years
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CONTENTS:

1.0	**Purpose, Scope & Objectives**
	This instruction describes the administrative processes that are required to demonstrate patient safety and ICH GCP adherence following consent to trial participation. This applies to all clinical trials/research studies the department is participating in.
2.0	**Personnel & Responsibilities**
	All Oncology Clinical Trial Staff
3.0	**Background**
	During the course of receiving consent from a patient to participate in a trial there are various administrative processes that need to be completed in order to ensure the wider MDT are aware that the patient has entered a clinical trial and that ICH GCP is adhered to.
4.0	**Definitions**
	ICH GCP – International Conference for Harmonisation: Good Clinical Practice Guidelines E6 R2 (Nov 2016) PIS – Patient Information Sheet

	GP – General Practitioner
5.0	**Health & Safety**
	As per Trust policies and guidance: - ICH GCP Guidelines E6 R2 (Nov 2016)
6.0	**Equipment & Documentation**
	Patients original consent Relevant Patient Information sheet Relevant GP letter Edge Form Clinical Record Sheet
7.0	**Procedure**
	At or immediately after consent **(to go in a poly-pocket and left on Charley's desk) Nurses / HCA responsibility** - Original Consent - PIS - Completed GP letter - Completed Edge form - Clinical record sheet **Administration following consent** - Copy consent form X2 - Copy PIS x 2 - Copy GP letter x 2 - Original consent and PIS to go in site file - Original GP letter sent to GP with PIS (date letter sent to be added to the clinical record sheet and edge form) - Copy of GP letter to be filed in cream correspondence section in the hospital notes - Clinical record sheet to be filed in blue 'oncology' section of patient notes - Copy of consent and PIS to be filed in red 'consent/living wills' section of patient notes - Copy of Consent to be filed in the red SD folder - Green alert sticker to go on front of notes - White trial sticker to be completed and placed inside front cover of notes - Upload information from edge form to edge system - File the edge form in red/green folder as appropriate
8.0	**References**
	ICH GCP – International Conference for Harmonisation: Good Clinical Practice Guidelines E6 R2 (Nov 2016)
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**
	The Administration team will monitor for compliance and raise any issues with the Team Leader as they occur.
13.0	**Revision History**
	Issue 1 – First issue
14.0	**Managerial Approval**

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