Work Instruction	**Planning for a monitoring visit**
Version	Work Instruction 024 v1.0
Date	08th November 2019
Review Date	2 years
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CONTENTS:

1.0	**Purpose, Scope & Objectives**
	This instruction describes the preparation and planning required in order to facilitate a monitoring visit with a Sponsor company.
2.0	**Personnel & Responsibilities**
	All Oncology Clinical Trial Staff
3.0	**Background**
	The purposes of trial monitoring visits are to verify that: (a) The rights and well-being of human subjects are protected. (b) The reported trial data are accurate, complete, and verifiable from source documents. (c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s). The monitor or CRA are appointed by the Sponsor, should be appropriately trained and familiar with all aspects of trial delivery. The Sponsor will decide on frequency and extent of monitoring required for the study and the site conducting the study will facilitate these visits as required.

4.0	**Definitions**
	ICH GCP – International Conference for Harmonisation Good Clinical Practice CRA – Clinical Research Associate
5.0	**Health & Safety**
6.0	**Equipment & Documentation**
7.0	**Procedure**
	- Each Sponsor appoints a CRA/Monitor, who is responsible for liaising with the site. - The CRA/Monitor will perform the initial site initiation visit (SIV) and then establish regular contact with the site to arrange the required monitoring visits. (Commercial studies are likely to monitor more frequently than non-commercial studies and for low risk studies, monitoring visits can be done remotely). Additionally, the CRA/Monitor may be in contact in between visits by phone or webinar to discuss trial progress, data queries or concerns. - Prior to the monitoring visit the CRA/monitor will send you a confirmation letter informing you of the date and time they expect to arrive and the length of time they will spend on site. They will also list the documents they would like you to have available for the visit. This will likely include: all site files, delegation and training logs, patient source data folders & hospital notes. (It is good practice to order the patient notes the week before the visit and place on the monitoring shelf in the notes cupboard – please follow WI 002 to trace notes correctly) - Book the monitoring room and update the team calendar so that the whole team are aware the monitoring visit is anticipated. - On the day of the visit ensure the CRA/monitor is greeted, shown where the monitoring room and facilities are, and all hospitality is extended - The CRA/monitors will go through their work and come back to you if they have any queries on the day of the visit, however it is good manners to check in on the CRA/monitor every so often to check is all going as anticipated. - Following the visit, the CRA/monitor will contact the site with a follow up letter. This will detail what happened at the visit and may have further instructions or request for the site to complete. These letters usually follow within 3-5 days of the visit. - Monitor follow up letters are everyone's responsibility and all actions must be completed by the most appropriate person in the team. - Monitoring letters are filed in the site file correspondence section.
8.0	**References**
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 CRA/monitor will be checking compliance with monitoring, queries and follow up from visits and if they have any concerns this will be raised by the Sponsor with the site.
13.0	**Revision History**
	Issue 1 – First issue
14.0	**Managerial Approval**

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