Work Instruction	**Site Initiation Visit (SIV) preparation and attendance**
Version	Work Instruction 010 v1.0
Date	28 August 2019
Review Date	2 years
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1.0	**Purpose, Scope & Objectives**
	The purpose of this work instruction is to ensure that site initiation visits (SIV) are organised at the most appropriate time for study opening and that the process runs smoothly for all involved. This instruction will also outline the staff who need to be in attendance at the SIV
2.0	**Personnel & Responsibilities**
	Senior Research Administrator Relevant Clinical Staff for Oncology Clinical Trials (PI, Sub-I's, research nurses, HCA's) Data Manager Sponsor representatives (Clinical Research Associates / Study Monitors etc) Supporting Services, where applicable (e.g. Pharmacy / Histopathology / Pathology / Radiology) R&D staff
3.0	**Background**
	At the point at which the study is ready to open, Sponsor companies perform a SIV. This visit/teleconference/webinar is designed to let all personnel involved in the

	delivery of the clinical trial understand the requirements of the protocol and the practical aspects of delivery. This is an opportunity for staff to discuss patient pathways, ask questions and raise any concerns they may have. It is a valuable opportunity for the team to get together and think about the practicalities of delivering the trial at site. Poorly attended SIVs can lead to staff having a limited understanding of the protocol and trial design which in turn can lead to delays in recruitment. Therefore, it is imperative that SIV's are well attended.
4.0	**Definitions**
	SIV = Site Initiation Visit PI = Principal Investigator Sub I = Sub-Investigator HCA = Health Care Assistant
5.0	**Health & Safety**
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6.0	**Equipment & Documentation**
7.0	**Procedure**
	SIV's are commonly organised once the budget and contract and all regulatory approvals are in place. **Identify a suitable date for all the individuals required to attend** 1. Request suitable dates from the PI, as this person's availability is paramount 2. Confirm Sponsor availability based on the dates the PI has supplied 3. Look at the availability of the wider research team, this can be done by checking the off duty 4. Check availability of pharmacy 5. Book a room to host the SIV (see appendix A for room booking details) 6. Once date has been set, invite all relevant personnel, including any relevant supporting services. This can be done using an Outlook calendar invite and should include date, time, location and any other relevant information. 7. Put SIV date and details into shared calendar 8. Request agenda from Sponsor company, attach this to the calendar invite once available. 9. Request SIV slides from Sponsor company before SIV date, this is to ensure that any presentations are compatible with local IT. 10. Re-send calendar updates as appropriate and as the SIV date approaches. **On the day of the SIV** 1. Print off the Study Initiation worksheet, saved in G/Research Common/MPE and trial set up/study initiation questionnaire. (This document must be fully completed by the B6 nurse attending the SIV) 2. Take 'Study Set Up' folder to the SIV (This folder contains all relevant documents pertaining to the study and is stored in the middle office filing cabinet in the feasibility drawer) 3. Where possible, set up room up in advance (e.g. computer is turned on and slides ready to go). This is to ensure a swift start. NB. On occasions the Sponsor may wish to spend additional time at site in order to review the site files. Please check if additional time is needed by the Sponsor in order to facilitate this as the monitors room may need to be booked out.
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 SIV attendance 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**
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