

Work Instruction	Delegation Log Management
Version	Work Instruction 022 v1.0
Date	25 th October 2019
Review Date	2 years
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1.0	Purpose, Scope & Objectives
	This instruction describes the process of managing the delegation logs in the oncology clinical trials department
2.0	Personnel & Responsibilities
	All Oncology Clinical Trial Staff
3.0	Background
	<p>Delegation Logs are an important part of good overall study management. ICH GCP requirements state that “the Investigator should maintain a list of appropriately qualified and trained persons to whom the Investigator has delegated significant study related duties” and to document study-specific roles and responsibilities assigned to all staff on the study team by the Investigator.</p> <p>All personnel who have been delegated significant study related duties or tasks, which the Principal Investigator would otherwise do, must be listed on the log. The intention of the log is not to capture every task that an individual may perform, but to list the study personnel and the key study duties/tasks that they have been delegated. This would be any duty/task that could impact significantly on subject safety, protocol compliance, quality and the integrity of the study data.</p>

4.0	Definitions
	ICH GCP – International Conference for Harmonisation Good Clinical Practice PI – Principle Investigator
5.0	Health & Safety
6.0	Equipment & Documentation
	Red & Green team delegation log folders
7.0	Procedure
	<ul style="list-style-type: none"> - List the names of study staff members and record the responsibilities that have been assigned to them using the responsibilities listed on the log. - Each study staff member listed should initial and sign to indicate understanding of the responsibilities assigned. - The site PI should then initial and date each line of the form as each staff member is recorded. - The completed delegation log is then stored in the appropriate delegation log folder in the main research office. There are currently 2 folders per team (red and green) and logs are stored alphabetically. - A file note should be created and placed in the main site file (delegation log section) indicating where the log is being stored. - The Delegation Log spreadsheet stored in the G Drive/OncTrials should then be updated with the new trial and all staff members who have signed the log should enter a 'Y' in their column to indicate that they are on the original log. - Update the log and spreadsheet as needed, following any change in site study personnel. - At the conclusion of the study the log should be removed from the folder and placed in the main site file ready for archiving.
8.0	References
9.0	List of Appendices
	N/A
10.0	Document Control
	<p>All Work Instructions are stored on the shared research drive: G/Research Common/Training & Education/How To work instructions/</p> <p>Printed copies are not controlled and therefore may not be the current version of the document.</p>
11.0	Training Record & Competency Assessment
	<p>Records of the training and competency assessment for this work instruction shall be retained by the nominated educator for the staff group involved.</p> <p>All staff members have a responsibility to retain their own training records for continuing personal & professional development.</p>
12.0	Monitoring Compliance and Effectiveness
	All staff are responsible for ensuring they are on the delegation log of all studies that they work on. They should also ensure that they update the delegation log spreadsheet stored on the G drive/OncTrials.

	The delegation log spreadsheet will be audited annually to ensure compliance.
13.0	Revision History
	Issue 1 – First issue
14.0	Managerial Approval

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