

Work Instruction	Assessment of trial complexity
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1.0	Purpose, Scope & Objectives
	This instruction describes how to use the NCI trial complexity tool for oncology & haematology trials.
2.0	Personnel & Responsibilities
	All Oncology Clinical Trial Staff
3.0	Background
	Trials all vary in complexity and it is important to understand the impact of a trial on team capacity in order to manage the workforce accordingly. The NCI Trial Complexity Elements & Scoring Model (2009) uses a simple scoring method to build a total score of complexity. Having a better understanding of trial complexity for the whole team as well as individual red & green teams will help ensure staff are appropriately allocated.
4.0	Definitions
	NCI – National Cancer Institute WI – Work Instruction SMT – Senior Management Team
5.0	Health & Safety

6.0	Equipment & Documentation
7.0	Procedure
	<ul style="list-style-type: none"> - Using WI 027 Appendix A template enter trial name and protocol version being used to do the assessment. - There are 11 elements of complexity that need to be assessed - Each element is given a score (see WI 027 Appendix B for information on how to score each element) - The total score is then added up (maximum score will be 22) - This is then signed and dated by the nurse completing the assessment.
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
	<p>Trial complexity assessments need to be done for each trial during feasibility to help with workload distribution in the team.</p> <p>Tea leader to ensure all trials have a complexity rating and assess on-going workload with SMT as trials open and close across the team.</p>
13.0	Revision History
	Issue 1 – First issue
14.0	Managerial Approval

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