

Work Instruction	Study Set Up (Feasibility)
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1.0	Purpose, Scope & Objectives
	This work instruction describes the process undertaken by the oncology clinical trials team in order to assess the feasibility of a potential trial.
2.0	Personnel & Responsibilities
	Administration Team Team Leader and Senior Management Team (SMT) Potential Principal Investigators (PI)
3.0	Background
	The Feasibility stage of the study set up process is initiated through R&D following a successful EOI or may come directly from the Sponsor to the Investigators.
4.0	Definitions
	SMT = Senior Management Team EOI = Expression of Interest R&D = Research & Development PI = Principal Investigator
5.0	Health & Safety

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6.0	Equipment & Documentation
7.0	Procedure
	<ol style="list-style-type: none"> 1. On receipt of the feasibility questionnaire email, review and action as advised. 2. If the relevant PI has not been copied in, forward the email on 3. Await response and if no response received by the deadline indicated in the email chase the PI again, copying in team leader. 4. Team leader to speak to investigator to request a decision.
8.0	References
	N/A
9.0	List of Appendices
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>Turnaround time of feasibilities can be monitored via the EOI/Feasibility tracker saved G/research common/MPE & Trial Set up/EOI feasibility tracker.</p> <p>This should be reviewed by the Team Leader monthly to monitor for trends.</p>
13.0	Revision History
	Issue 1 – First issue
14.0	Managerial Approval

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