

<b>Work Instruction</b>	<b>Process to screen a patient</b>
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<b>1.0</b>	<b>Purpose, Scope &amp; Objectives</b>
	To describe the administrative process when a patient is screened for trial participation
<b>2.0</b>	<b>Personnel &amp; Responsibilities</b>
	All staff
<b>3.0</b>	<b>Background</b>
	Once a patient is referred to Oncology Clinical Trials both the PI and clinical research team will need to check the patient is eligible according to the inclusion and exclusion criteria outlined in the trial protocol. It is very important that this is done accurately as failure to screen properly could lead to a patient being entered into a trial that they are not eligible, this could be unsafe for the patient and may lead to a protocol violation. Additionally it is important that eligibility is checked in a timely manner so that patients can have sufficient time to consider their potential participation.
<b>4.0</b>	<b>Definitions</b>
	PI = Principle Investigator SCR = Somerset Cancer Register

<b>5.0</b>	<b>Health &amp; Safety</b>
	As per Trust policies and guidance:
<b>6.0</b>	<b>Equipment &amp; Documentation</b>
<b>7.0</b>	<b>Procedure</b>
	<p>Process to screen patient</p> <p>Print inclusion/exclusion from protocol  Print all documents required as source for screening e.g.  Histology  Scans  Past treatments e.g. Chemo, radiotherapy  Clinic annotations if relevant</p> <p>Attach patient sticker or write pt details on inclusion/ exclusion  Check inclusion/exclusion and tick each point checked, sign and date (this is an initial check to ensure no obvious exclusions and not all criteria will be able to be met until end of screening )</p> <p>If ineligible move details from screening to screen fail on tracker and complete trial screening log and Edge form</p> <p>If eligible ensure appointment is booked for patient and put on relevant team tracker. Update appointment onto the on-line diary in Outlook</p> <p>If appointment is in time period that has already been prepped give front sheet and documents to prepper</p> <p>Update SCR</p> <p>NB If the whole screening process has not been completed update tracker comments and highlight in red what has been done.</p>
<b>8.0</b>	<b>References</b>
	N/A
<b>9.0</b>	<b>List of Appendices</b>
<b>10.0</b>	<b>Document Control</b>
	<p>All Work Instructions are stored on the shared research drive: G/Research Common/Training &amp; Education/How To work instructions</p> <p>Printed copies are not controlled and therefore may not be the current version of the document.</p>
<b>11.0</b>	<b>Training Record &amp; Competency Assessment</b>
	<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 &amp; professional development.</p>
<b>12.0</b>	<b>Monitoring Compliance and Effectiveness</b>
	The SMT will monitor their own teams' compliance with this process, bringing up

	concerns with team members as they occur and escalating to the team leader if there is non-adherence.
<b>13.0</b>	<b>Revision History</b>
	Issue 1 – First issue
<b>14.0</b>	<b>Managerial Approval</b>

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