Section 5.
Research and Clincal Trials

5.0 **Research and clinical trials:** Develop an understanding of the research process and different methodologies to facilitate research and clincal trials for cancer treatments, whilst broadening your level of knowledge and skills in contributing to research within the MDT	**Pre and post-registration nurses providing generalist CYP cancer care** (e.g. A&E, PICU, Practice nurses, general wards, radiology departments)		**Unregistered Support Workers in specialist CYP cancer**	**Registrants providing specialist CYP cancer care** (PTC and designated cancer specialist roles in POSCUs)				
Learning outcomes: Practitioners will be able to:	**Pre-reg Children's Field**	**Registered Nurse**	**Health Care Assistant / support worker**	**Nursing Associate**	**Registered**	**Enhanced**	**Advanced**	**Consultant**
5.1 Demonstrates an awareness that clinical trials and research are undertaken within this field and understand own role in relation to practice								
5.2 Describe the principles of cancer clinical trials and research and discuss the role of the nurse in this context								
5.3 Can identify and distinguish between clinical trials, biological research and observational research within cancer treatment								
5.4 Understand the principles of consent to research, including proxy consent and assent as they apply to CYP and vulnerable adults								
5.5 Explain the differences between a treatment guideline and a clinical trial protocol, demonstrating awareness as to why a patient not on trial may be treated against the standard arm of a trial protocol								
5.6 Demonstrates an understanding of factors that may affect accessibility and willingness for patients and carers to participate in research								
5.7 Can discuss an overview of how a clinical trial or research is approved, organised and implemented locally								
Practice competencies: Practitioners will be able to:	**Pre-reg Children's Field**	**Registered Nurse**	**Health Care Assistant / support worker**	**Nursing Associate**	**Registered**	**Enhanced**	**Advanced**	**Consultant**
5.8 Identify members of the local and/or PTC research team and has an understanding of the roles and responsibilities of these team members and can therefore signpost staff and families appropriately								
5.9 Demonstrate an awareness of the research available and upcoming within your clinical environment and why this might vary nationally								
5.10 Locate information about specific clinical trials and demonstrate an awareness of the importance of version control for these documents								
5.11 Understand and participate in the correct level of 'Good Clinical Practice' (GCP) training specific to role								
5.12 Demonstrate an understanding of the strict regulations that research must adhere to and ensures own practice reflects this								
5.13 Identify which patients, in the clinical area, are taking part in research								
5.14 Correctly identify whether a protocol relates to a clinical trial, a standardised guideline, a local guideline, or individualised protocol adhering to GCP principles prior to SACT administration (Note SACT competencies section 6)								

Section 5 continued ▼

5.15 Provide safe and effective care to patients participating in clinical trials in accordance with clinical trial protocols to ensure optimal outcomes and experiences for patients and their carers								
5.16 Understand which patient events are significant for the research team to be informed about and ensure these events are meticulously documented								
5.17 Apply the same high standards of observation and record keeping for CYP following standard or individualised guidelines, as for those taking part in clinical trials								

5.0 **Research and clinical trials:** Develop an understanding of the research process and different methodologies to facilitate research and clinical trials for cancer treatments, whilst broadening your level of knowledge and skills in contributing to research within the MDT	**Practitioner Level** (See Key)	**Level of Achievement Required** (Benner Taxonomy)	**Self Assessment**	**Level Achieved** (Assessed)			**Evidence of Achievement**
Learning outcomes: Practitioners will be able to:				**L**	**Date**		
EXAMPLE 5.8 Identify members of the local and/or PTC research team and has an understanding of the roles and responsibilities of these team members and can therefore signpost staff and families appropriately	✓	Competent	Advanced Beginner	C	28.05.22	J Doe	• Case discussion with supervisor - family shared worry and lack of understanding • Reord of discussion with family in Case Notes • Contacted Research Nurse and let Nurse caring for pt. know.
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5.2 Describe the principles of cancer clinical trials and research and discuss the role of the nurse in this context							
5.3 Can identify and distinguish between clinical trials, biological research and observational research within cancer treatment							
5.4 Understand the principles of consent to research, including proxy consent and assent as they apply to CYP and vulnerable adults							
5.5 Explain the differences between a treatment guideline and a clinical trial protocol, demonstrating awareness as to why a patient not on trial may be treated against the standard arm of a trial protocol							
5.6 Demonstrates an understanding of factors that may affect accessibility and willingness for patients and carers to participate in research							
5.7 Can discuss an overview of how a clinical trial or research is approved, organised and implemented locally							

Section 5b continued ▼

Practice competencies: Practitioners will be able to:													
5.8 Identify members of the local and/or PTC research team and has an understanding of the roles and responsibilities of these team members and can therefore signpost staff and families appropriately													
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Section 5b continued ▼

Action plan to achieve required competency level:		
Reviewed by	Comments:	
Signature and Role:		Date:
Signature and Role:		Date:
Signature and Role:		Date: