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PROJECT SCOPE SUMMARY & TERMS OF REFERENCE

Project Title	Clinical Trials		
Project Reference		Other Reference	
Project Sponsor		Project Manager	Sue Ellis
Advisory Group			
Project Start Date	January 2008	Project End Date	February 2009
PROJECT DEFINITION			
Purpose / Background	<p>The NZ Cancer Control Strategy Action Plan 2005-2010 has identified participation in clinical trials as one of the necessary actions for achieving the goals and objectives set out in the Cancer Control Strategy (Outcomes 49 and 58).</p> <p>The purpose of this project is to undertake a situational analysis of clinical trial activities across the region to identify areas for improvement and opportunities to inform and support advancement of clinical trial research.</p>		
Relationship to NZ Cancer Control Strategy Action Plan	Outcome / Results	Specific Action	
	<u>NZ Cancer Control Strategy: Action Plan 2005-2010, Goal 3, Objective 1:</u> Provide optimal treatment for those with cancer. <u>Objective 2:</u> Develop defined standards for diagnosis, treatment and care for those with cancer.	<u>Outcome/Results 49:</u> “There is increased participation in clinical trials”. <i>All cancer treatment providers have an identified policy of supporting clinical trials and ensuring suitable patients are given the opportunities to enrol.</i> <u>Outcome/Results 58:</u>	

	<p>Objective 4: Improve the quality of care delivered to adolescents with cancer and their family/whanau.</p> <p>Goal 6, Objective 1: Extend and enhance research across the continuum of cancer control.</p>	<p><i>Ensure maximum accrual into age-specific clinical trials.</i></p>
Vision / Objectives	<p>Vision: The central region clinical trial units will have the research capacity and capability to support and contribute to achieving cancer control outcomes across the region.</p> <p>Project Objective: To ensure policies, processes, resources (including sustainable funding) and structures are in place to support ongoing clinical trials research.</p>	
Key Stakeholders	Internal	External
	Regional DHB Funders and Providers (including primary, secondary, tertiary, Iwi and Pacific providers and PHOs)	Ministry of Health
	RCTS Clinical Trials Team	Cancer Control Council
	CCN Care Coordinators Forum	Mallaghan Institute
	Clinical Research Unit, Wellington Blood & Cancer Centre	NZGG referral and clinical guidelines group
	NGOs	
	Non- Māori, Māori and Pacific consumers	
	Paediatric Oncology Unit	
	Adolescent and Young Adult Coordinators	
Project Linkages	<ul style="list-style-type: none"> • Clinical Trial Units annual and strategic planning • Regional cancer network activity, including Tumour Stream projects and Addressing Inequalities programme • Cancer Control Council - research strategy development • Ministry of Health Cancer control programme 	
Critical Success Factors / Key Performance Indicators / Benefits	<p>Benefits In keeping with the New Zealand Cancer Control Strategy Action Plan (2005-2010), there will be a regional approach to support clinical trial research activities.</p> <p>Key Performance Indicators</p> <ul style="list-style-type: none"> • Undertake a situational analysis of clinical trials across the region to determine staffing numbers, funding issues, types of 	

	<p>trials, governance structures and shows recent audits.</p> <ul style="list-style-type: none"> • Review data collection (including domicile breakdown, ethnicity, number on cancer registration compared with number on clinical trials) • Undertake a literature review of clinical trial research access issues. • Work with key stakeholders to develop an action plan to implement recommendations from the project. 								
Key Deliverables	<ol style="list-style-type: none"> 1. A report with recommendations. 2. An action plan to implement recommendations. 								
Scope Inclusions / Exclusions	<p>Exclusions:</p> <p>Funding of ongoing implementation projects that may fall out from this initial project.</p>								
Key Inequalities focus areas	<p>Support for Māori and Pacific patients to access clinical trials, that takes account of culturally appropriate methodology, ethnicity, geographic and socioeconomic perspectives, such as indirect costs (<u>He Korowai Oranga: Māori Health Strategy (2002), Objective 2.1: Iwi and Māori communities and government health agencies working together in effective relationships to achieve Māori health objectives</u>).</p> <p>Support for those patients who live outside where clinical trials are being undertaken and cannot afford the cost for travel and accommodation.</p>								
Key workforce focus areas	<p>The situational analysis will include the following key workforce areas:</p> <ul style="list-style-type: none"> • Clinical trial unit resource support • Service delivery capacity • Research capability, including Maori research capability. 								
Key Assumptions	<ul style="list-style-type: none"> • Service providers and stakeholders will work collaboratively with CCN to achieve the project deliverables. • Sufficient resources, including workforce availability and funding, to progress the project. 								
Key Constraints	<p>The role of the CCN is to facilitate this project, DHBs and clinical trial units will be responsible for prioritisation and implementation of recommendations from this project.</p>								
Key Risks	<table border="1"> <thead> <tr> <th>Risks</th> <th>Mitigating Strategies</th> </tr> </thead> <tbody> <tr> <td>Clinical trial research not seen/supported as core business by DHBs.</td> <td>Support Clinical Trial Units to work with DHBs to ensure clinical trials get necessary support.</td> </tr> <tr> <td>Lack of stakeholder buy-in due to competing agendas.</td> <td>Critical to involve/engage with key stakeholders. Strong relationship management with key stakeholders. Active stakeholder participation in the project planning process.</td> </tr> <tr> <td>Project milestones delayed.</td> <td>Ensure realistic project planning. Regular reporting of project</td> </tr> </tbody> </table>	Risks	Mitigating Strategies	Clinical trial research not seen/supported as core business by DHBs.	Support Clinical Trial Units to work with DHBs to ensure clinical trials get necessary support.	Lack of stakeholder buy-in due to competing agendas.	Critical to involve/engage with key stakeholders. Strong relationship management with key stakeholders. Active stakeholder participation in the project planning process.	Project milestones delayed.	Ensure realistic project planning. Regular reporting of project
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		variance and highlighting of risks as early as possible.	
PROJECT APPROACH			
Project Approach	A situational analysis will be undertaken to determine current issues for the region's clinical trial units and a plan developed to support future service development.		
Project Milestones	<ul style="list-style-type: none"> • Agreement of Project Scope. • Agreement on data to be collected. • Hold discussions with relevant clinical trial staff. • Collate and analyse information gathered. • Provide drafts of analysis and feedback provided. • Write report. • Work with stakeholders to develop a plan aimed at addressing identified issues. 	Date	<p>December 2008</p> <p>16 January 2009</p> <p>19 – 23rd January</p> <p>30 January</p> <p>13 February</p> <p>Complete by 20 February</p> <p>28 February.</p>
Project Cost	CCN will cover project costs related to project management, including Project Manager salary and overheads.		
Document Control	Sue Ellis, Version 4	Date	19 December 2008
Associated Documents		Date	
		Date	
Approved by		Date	