5 – MATRIX OF SHARED RESPONSIBILITIES

Clinical Trials

Scientific/academic merit of the research			
Sponsor	**Coordinating PI**	**HREC**	**Research Governance**
Ensure that human research meets the relevant scholarly or scientific standards: Ensure that the importance and relevance of the research question and validity of the proposed setting and methodology has been assessed. Implement a system to manage quality throughout the design, conduct, recording, evaluation, reporting and archiving of the trial. Ensure that proportionate arrangements are in place for trial monitoring and audit	Lead the team of researchers undertaking the design, conduct and reporting of the trial	Assess whether scientific or academic merit of the trial has been evaluated (through scientific peer review), as robust, formal and independent of the researcher and sponsor. Assess whether the trial design or methodology poses any ethical concerns	Implement quality systems for the conduct of the trial at the site Monitor compliance with internal policies and procedures and manage any issues identified

Suitability of the Co-ordinating Principal Investigator (CPI) and Key Members of the Trial Management Group			
Sponsor	**Coordinating PI**	**HREC**	**Research Governance**
Select an appropriately qualified CPI Utilise qualified individuals (e.g., biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial		Assess whether the Coordinating Principal Investigator (CPI) and if applicable, key members of the CPI's team (e.g. protocol co-authors) have sufficient expertise to undertake all research activities, including GCP training.	
Suitability of the Principal Investigator (PIs) and their Team			
Sponsor	**PI**	**HREC**	**Research Governance**
Select investigators that are qualified by education, training and experience		Be informed of the number and type of investigational sites and the PI at each site through HREC review	Assess whether the local PI and their trial team have the necessary training and experience to undertake the trial as described in the protocol

FUNDING TO MANAGE AND COMPLETE THE TRIAL			
Sponsor	**Coordinating PI**	**HREC**	**Research Governance**
Provide or arrange for the financing of a trial and ensure adequate resources are available	If delegated by the sponsor, oversee the preparation/ management of the budget for the conduct of the trial	Assess how the trial is, or will be, funded in order to assess whether the sponsor is likely to have adequate funds and resources to complete the trial.	
RESOURCES TO CONDUCT THE TRIAL AT THE SITE			
Sponsor	**PI**	**HREC**	**Research Governance**
Select investigators with adequate resources			Assess whether there are adequate facilities and staffing available to conduct the proposed trial at the trial site based on target recruitment agreed with the sponsor. Assess how the trial will be funded at the site in order to assess whether the site is to be provided with adequate funds and resources to complete the trial

CONFLICTS OF INTEREST			
Sponsor	**Coordinating PI and PIs**	**HREC**	**Research Governance**
Establish processes to identify and manage actual and potential conflicts of interest	Declare any conflicts of interest	Assess the measures that have been put in place to manage conflicts of interest involving researchers and whether issues raised pose any ethical concerns	Provide mechanisms to identify, declare and manage conflicts of interest relating to site staff
		Ensure its members disclose to it any actual or potential conflict of interest	Assess whether conflicts of interest raise any business implications for the institution