RESEARCH EDUCATION: ORHPP PI/ INVESTIGATOR TRAINING TOPICS

S/N	TOPICS	SUB-TOPICS	DURATION (includes Q&A)	TARGET AUDIENCE
1A	i) Overview of the Office of Human Research Protection Programme (OHRPP)	• Overview of Research Ethics Governance • Overview of OHRPP Organisational Structure • Overview of NHG DSRB Biomedical Domain (A – E) & NHG DSRB Population Health (Domain F)	1hr	• Principal Investigators • Clinical Research Coordinators • Study/ Trial Administrators & Research Team
	ii) Overview of the NHG Domain Specific Review Board (DSRB)	**NHG DSRB Biomedical Domains (Domain A – E)** • Role of DSRB • Introduction to the various Domains • Submitting an Application • DSRB Review Process (Overview of Domains A- E Application, Review Process & Approval Process) • Post Approval & Study Closure (i.e. Continuing Review, Monitoring, UPRISTO etc.)		
2A	i) Overview of the Office of Human Research Protection Programme (OHRPP)	• Overview of Research Ethics Governance • Overview of OHRPP Organisational Structure • Overview of NHG DSRB Population Health (Domain F)	1hr	• Principal Investigators • Clinical Research Coordinators • Study/ Trial Administrators & Research Team
	ii) Overview of the NHG Domain Specific Review Board (DSRB)	**NHG DSRB Population Health (Domain F)** • Role of DSRB • Introduction to the various Domains • Submitting an Application • DSRB Review Process (Overview of Domain F Application, Review Process & Approval Process) • Post Approval & Study Closure (i.e. Continuing Review, Monitoring, UPRISTO etc.)		
3A	NHG DSRB Biomedical Domains A- E: Common Errors In Answering the NHG DSRB ROAM Application Form		1hr	• Principal Investigators

				• Clinical Research Coordinators • Study / Trial Administrators & Research Team
3B	NHG DSRB Population Health Domain F: Common Errors In Answering the NHG DSRB ROAM Application Form		1hr	• Principal Investigators • Clinical Research Coordinators • Study / Trial Administrators & Research Team
4	Research Quality Management (RQM) Study Review Findings	• Role of RQM • Objectives of RQM Study Review Findings • Presentation on the analysis of collated study review findings • Sharing of case studies of major findings from study review findings	1hr	• Principal Investigators • Clinical Research Coordinators • Study / Trial Administrators & Research Team
5	Responsible Conduct of Research (RCR)	• Definition of RCR • Components of RCR • Sharing of RCR Case Studies		
6A	i) Study Start-Up Training	i) Preparing & Maintaining Your Investigator File • Essential Documents. • Starting Your Study. • During the Study. • After Study Completion. • Good Documentation Practice. • NHG RQM study review findings on study documentation. • Documentation templates and resources.	1hr	• Principal Investigators • Clinical Research Coordinators • Study/Trial Administrators & Research Team
7A	i) Study Start-Up Training	ii) Documentation in Clinical Trials • Overview on the essential documents that must be maintained before, during and after a clinical trial. • Principles of good documentation practice. • Information to be recorded on source documents.	1hr	• Principal Investigators • Clinical Research Coordinators

		• NHG RQM study review findings on study documentation. • Documentation templates and resources.		• Study/Trial Administrators & Research Team
8	Research Policy(ies) and SOP Updates (DSRB & PCR SOPs) *NB: Timing dependent on number of SOPs to be updated.*		30min-45min (approx., see NB)	• Principal Investigators • Clinical Research Coordinators • Study/Trial Administrators & Research Team
9	Customised OHRPP PI Trainings	After being in consultation with the department's representative, RE will customise the training based on the list of the selected sub-topics for the department, so as to target the specific needs required and/or clarify issues encountered.	1hr-1.5hrs	• Principal Investigators • Clinical Research Coordinators • Study/Trial Administrators & Research Team

The above information is accurate at time of print and subjected to changes without prior notice.

For enquiries please write in to research_education@nhg.com.sg with the "Enquiries about OHRPP PI Training" as the subject header.