Roles and Responsibilities for a Single-site Research Project

Principal Investigator (PI)	• Is appropriately clinically qualified and experienced to conduct the clinical trial at the site • Responsibilities include: ◦ clinical conduct of the research project at the site ◦ medical care and supervision of participants at the site ◦ submission of the ethics application to the reviewing HREC's research office ◦ ongoing communication with the reviewing HREC's research office ◦ dissemination of information from the HREC to the sponsor and project/trial coordinator ◦ creation of the site specific assessment (SSA) form ◦ submission of the research governance/SSA application to the site research governance officer (RGO) ◦ ongoing communication with the site RGO • Is thoroughly familiar with the research protocol and the investigational product(s) • Is compliant with Good Clinical Practice (GCP) (if applicable to the research project) and regulatory requirements • May delegate some duties to appropriately qualified and experienced staff, but remains responsible
Associate Investigator (AI)	• Is appropriately clinically qualified and experienced to undertake duties in the research project • Is thoroughly familiar with the research protocol and the investigational product(s) • Is compliant with Good Clinical Practice (GCP) (if applicable to the research project) and regulatory requirements • Performs research project duties as required, but does not have authority for the site or research project
Sponsor	• Carries the medico-legal responsibility associated with the conduct of a research project (e.g. agreements, insurance, indemnity) • Usually initiates, organises and supports management of a research project • May be an institution, investigator, collaborative group or commercial company • Must be an Australian entity • Is responsible for safety monitoring and reporting to the reviewing HREC in Victoria • Is responsible for post-approval reporting to the reviewing HREC in Victoria

Detailed information is available at http://ichgcp.net.

Monitoring and Reporting on a Single-site Research Project

Report	PI Responsibility	Sponsor Responsibility
Safety report	• Notify sponsor of safety event occurrence • Communicate with site RGO • Sign report	• Submit **Safety report** to reviewing HREC's research office • Communicate with PI/trial coordinator
Annual safety report form (interventional clinical trial only)	• Communicate with sponsor • Communicate with site RGO • Sign report	• Submit **Annual safety report form** to reviewing HREC's research office • Communicate with PI/trial coordinator
Amendment request form	• Communicate with sponsor • Communicate with site RGO – research governance/SSA amendment may be required • Sign form	• Submit **Amendment request form** to reviewing HREC's research office • Communicate with PI/trial coordinator
Progress report – project form (HREC)	• On request, notify sponsor of site information • Communicate with site RGO • Sign report	• Submit **Progress report – project form** to reviewing HREC's research office • Communicate with PI/trial coordinator
Project final report/Site closure report	• On request, notify sponsor of site information • Communicate with site RGO • Sign report	• Submit **Project final report/Site closure report** to reviewing HREC's research office • Communicate with PI/trial coordinator
Protocol deviation or violation report	• Notify sponsor of protocol deviation or violation occurrence • Communicate with site RGO • Sign report	• Submit **Protocol deviation or violation report** to reviewing HREC's research office • Communicate with PI/trial coordinator
Progress report – site form (RGO)	• Submit **Progress report – site form** to site RGO	N/A
Site audit report for research	• On request, submit **Site audit report for research** to site RGO	N/A
Complaint report	• Submit **Complaint report** to site RGO and (if advised) to reviewing HREC • Communicate with sponsor	• Record the complaint

Monitoring and reporting information (Victoria) is available at: www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting.