Roles and Responsibilities in a Research Project

Multi-site Research Project

Role	Responsibilities
Coordinating Principal Investigator (CPI)	• Is appropriately clinically qualified and experienced to conduct the clinical trial • Responsibilities include: – overall clinical conduct of the research project at all sites approved by the reviewing Human Research Ethics Committee (HREC) – medical care and supervision of participants – 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 site Principal Investigators, sponsor and project/trial coordinator – creation of a site specific assessment (SSA) form for each participating site and transferring it to the site Principal Investigator • 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 • Is the Principal Investigator for their own site • May delegate some duties to appropriately qualified and experienced staff, but remains responsible
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 – provision of site-specific documents* (as required) to CPI for inclusion in ethics application – 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)

Role	Responsibilities
	• 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 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

*Site-specific documents may include: curriculum vitae for site investigators; site-master participant information and consent form (PICF).

Single-site Research Project

Role	Responsibilities
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)

Role	Responsibilities
	• 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 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.

To receive this document in another format, phone 0408 274 054, using the National Relay Service 13 36 77 if required, or email Coordinating Office for Clinical Trial Research <multisite.ethics@safercare.vic.gov.au>.

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