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| Roles and Responsibilities in a Research Project |
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# Multi-site Research Project

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

# Single-site Research Project

| Role | Responsibilities |
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| **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
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| **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
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Detailed information is available at <http://ichgcp.net>.

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