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)  • 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)  • 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>.

Authorised by the Coordinating Office for Clinical Trial Research

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