

|  |
| --- |
| Roles and Responsibilities in a Research Project |
|  |
| OFFICIAL |

# 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>.

|  |
| --- |
| 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](mailto:multisite.ethics@safercare.vic.gov.au) <multisite.ethics@safercare.vic.gov.au>.  Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.  © State of Victoria, Australia, Department of Health, March 2024. |