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**Single-site Higher Risk Research Checklist**

**This checklist is to support research teams submitting a project through the Higher Risk Pathway and submission is mandatory.**

**Prior to submission through ERM, project protocols must be submitted to the Office for Research so that the review pathway appropriate to the project can be determined.**

**If this has not been done COMPLETE THIS TASK BEFORE PROCEEDING**

|  |  |
| --- | --- |
| **Person Submitting** |  |
| Name |  |
| Email |  |
| Telephone |  |
| Department |  |
| **Project Details** |  |
| ERM Project ID Number |  |
| Full Project Title |  |

|  |  |  |
| --- | --- | --- |
| **Required (Project dependent)** | **Yes** | **N/A** |
| If the project is aClinical Trial it is registered on [Home | ClinicalTrials.gov](https://clinicaltrials.gov/) |  |  |
| All submitted documents have a Version Number and Date in the footer. |  |  |
| **Human Research Ethics Application (HREA)** | | |
| All investigators listed on the protocol are included in the Application Form. |  |  |
| The Principal Investigator is a senior staff member of Peninsula Health unless otherwise authorised by the Office for Research. |  |  |
| Investigator(s), Head of Department +/- Head of Supporting Department(s **signatures collected** **electronically through ERM.** |  |  |
| **Victorian Specific Module (VSM)** | | |
| VSM is completed and uploaded. |  |  |
| **Fees and Charges** | | |
| Ethics/Governance Payment Form (RCTI) completed. |  |  |
| **Protocol** | | |
| A Peninsula Health Protocol Template been used. |  |  |
| For Clinical Trials a protocol compliant with the SPIRIT Statement has been used. |  |  |
| **Qualifications and Training** | | |
| Investigator(s) CV is updated within the last three years. |  |  |
| For clinical trials, GCP Certificates are included for all Investigators and dated within the last three years. |  |  |
| **Site Specific Assessment (SSA) Form** | | |
| 1.2: Study type selected is correct. |  |  |
| 3.1/3.2: Start and Finish dates align with dates in the Protocol. |  |  |
| 3.3: Any Peninsula Health department providing support is listed. |  |  |
| Investigator(s), Head of department +/- Head of Supporting department **signatures collected electronically through ERM.** |  |  |
| **Participant Information and Consent Form (PICF)** | | |
| Participant Information and Consent Form(s) (PICFs) are compliant with NHMRC Approved Templates. |  |  |
| Peninsula Health Logo has been included. |  |  |
| Peninsula Health Complaints contact is listed as Manager Office for Research Telephone 9784 2679, Email researchethics@phcn.vic.gov.au |  |  |
| **Data Collection Tools** | | |
| Data Collection Tools (*questionnaires, surveys, focus group questions / themes, telephone questionnaires)* are validated and compliant with required wording. |  |  |
| **Recruitment and Advertising** | | |
| It any participants are to be recruited, the invitation to participate has been included. |  |  |
| Materials, (*letter or email invitations, posters, brochures or leaflets, content for media (including radio, print and digital / social media)* are compliant with required quidelines. |  |  |
| **Legal and Regulatory Documents** | | |
| Contracts Checklist is completed and uploaded. |  |  |