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**Contracts Checklist**

**This checklist is to support research teams submitting a project for a Site Specific Assessment (SSA) and submission is mandatory.**

**Applies to;**

1. Medicines Australia Clinical Trial Research Agreement (CTRA) or Medical Technology Association of Australia Clinical Investigation Research Agreement (CIRA)
2. Victorian Research Translation Centres Research Collaboration Agreement (Non-Commercial)
3. Standard Medicines Australia Form of Indemnity for Clinical Trials or Medical Technology Association of Australia Standard Indemnity Form for Clinical Investigations
4. Certificate of Insurance
5. Clinical Trial Notification (CTN) Therapeutic Goods Administration (TGA) Acknowledgement

**Please submit the Agreement, Indemnity +/- Insurance to the Office for Research at** [ResearchContracts@phcn.vic.gov.au](mailto:ResearchContracts@phcn.vic.gov.au) **for review as soon as possible before Sponsor signature and SSA submission. Any Non-Standard Agreement will require Legal counsel review.**

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

**CTRA/CIRAs**

Please complete the Checklist on pages 2 – 4.

**Please note that the Agreement for CRG, Phase IV or post-market studies does not include Schedules for Indemnity, Insurance or Guidelines for Compensation Therefore, in these Agreements:**

**Schedule 3 = Schedule 6 for commercially sponsored trials**

**Schedule 4 = Schedule 7 for commercially sponsored trials**

**Collaboration Agreement (Non-Commercial)**

Please complete the Checklist on pages 4.

**Standard Form of Indemnity – not required for CRG/Collaborative studies**

If the application includes a Standard Form of Indemnity please complete the separate Standard Form of Indemnity Checklist on page 5.

**HREC Review Only Indemnity – not required by Peninsula Health as only single site HREC review is conducted.**

**Certificate of Insurance – not required for CRG/Collaborative studies**

If the application includes a Certificate of Insurance please complete the items in the Schedule 4 section of the CTRA/CIRA Checklist.

**CTN TGA Acknowledgement – not required when a TGA approved drug product is used in the project.**

If the application includes a CTN Acknowledgement please complete the Checklist on page 5.

**Abbreviations used in checklists**

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| NaCTA (previously SEBS) | National Clinical Trial Agreement Panel (Review body for Schedules 7 and 4) |
| SEBS (now NaCTA) | Southern Eastern Border States (Review body for Schedules 7 and 4) |

**CTRA/CIRA Checklist**

|  |  |
| --- | --- |
| **Document title** | |
| Includes theProtocol Number/Study Acronym/Short title\_ERM Project ID Document type (eg. CTRA)\_FE date. | Yes |
| **Front page and body of the Agreement** | |
| The Institution details are as follows;   |  |  | | --- | --- | | **Name of Institution:** | Peninsula Health | | Address: | 2 Hastings Road, Frankston, VIC 3199, Australia | | ABN: | 52 892 860 159 | | Yes |
| The document footer lists as the Site: Peninsula Health (Frankston Hospital and/or Rosebud Hospital) as appropriate for this Study. | Yes |
| The full legal name of the Sponsor/Local Sponsor or CRG, their ABN, registered address and contact name and phone number is listed.  Fax number can be listed as N/A. | Yes |
| The Sponsor/CRO acting as the Local Sponsor is an Australian legal entity.  Where a CRO is acting as the Local Sponsor the Sponsor (Organisation) is not listed as a party to the Agreement. | Yes  Yes  N/A |
| The Study Name and Protocol number are correct. | Yes |
| The Date of Agreement is inserted as “Date of the last party to sign”. | Yes |
| No changes are made to the body of the Agreement.  Changes are not allowed. All changes are to be detailed in Schedule 7 (CTRA) or Schedule 4 (CRG). | Yes |
| **Schedule 1** | |
| The Study Name is correct. | Yes |
| The Study Site “Peninsula Health (Frankston Hospital and/or Rosebud Hospital)” as appropriate for this Study are listed. | Yes |
| Target Number of Participants: Are the same numbers as stated for this site in the site governance application. | Yes |
| Recruitment Period: Dates are correct and Start date does not pre-date expected activation date. | Yes |
| The Principal Investigator’s name and address (as for Peninsula Health Study Site) are correct. | Yes |
| The name of the HREC “The Peninsula Health Human Research Ethics Committee” or if reviewed by an external HREC, the name of the external HREC is correct. | Yes |
| Equipment: the make and model number of equipment to be provided for the study is listed.  For CRG Agreements mode of management at the end of study is selected.  Please note that only capital equipment not laboratory kits or consumables is to be listed. | Yes  N/A  Yes  N/A |
| Investigational product(s) is listed correctly.  If no IP “There is no IP being used in this study” is inserted. | Yes  Yes  N/A |
| **Schedule 2** | |
| The currency is in Australian dollars (excl. GST). | Yes |
| The amounts of payment have been reviewed and accepted. | Yes |
| Requirements to complete case report forms (CRFs) within a specified period have been reviewed and accepted. | Yes  N/A |
| The following text has been included;  “Payments will be made to the Institution per the details on the Institutional invoice within 30 days of receipt of a valid invoice.”  *Please note longer terms will be considered if justified.*  “HREC/RGO review fees are payable on receipt of a Recipient Created Tax Invoice and is required on submission of the application. | Yes  Yes |
| Instructions for invoice submission to Sponsor are included.  If a third party is making payments on behalf of the Sponsor instructions are: invoices are made out to the Sponsor +/- and sent “care of” the payor (who will pay the invoice). | Yes  Yes  N/A |
| If a third party is making payments on behalf of the Sponsor there is a statement included that makes this clear.  Please note the Sponsor must maintain legal obligation for payment even if received by the Institution from a third party payor unless there is an approved Special Condition in Schedule 7 that states the third party payor (not Sponsor) is fully responsible for making payments for the Study to Institution. | Yes  N/A |
| **Schedule 3 – not required for CRG studies** | |
| See Standard Form of Indemnity Checklist on page 5 | |
| **Schedule 4 – not required for CRG studies** | |
| A current insurance certificate is provided.  (ie. An expiry date of a minimum of 3 months in the future or Sponsor has confirmed renewal prior to the expiry date).  Insertion in the CTRA is not required but is accepted. | Yes |
| Includes as a named insured/additionally insured the full, legal name of the Australian entity acting as Sponsor as it appears on the Agreement. | Yes |
| States the cover is for Clinical Trials and or Public and Products Liability. | Yes |
| Provides insurance coverage for a minimum of AUD 10 million for any one occurrence and in the annual aggregate. | Yes |
| Contains an excess/deductible, or self-insured retention amount not greater than AUD 25,000 for each and every claim or series of claims (in the aggregate) arising out of one original cause. Nil is acceptable. | Yes |
| **Schedule 5** | |
| A link to the Guidelines for Compensation on the Medicines Australia or Medical Technology Association of Australia website is provided. | Yes |
| **Schedule 6 (or Schedule 3\*)** | |
| The Protocol Title, version and date are correct. | Yes |
| **Schedule 7 (or Schedule 4\*)** | |
| Only NaCTA/SEBS or Peninsula Health Legal Counsel approved wording is included.  Any wording not approved by NaCTA/SEBS will either require review by Peninsula Health Legal Counsel or submission, review and approval by NaCTA which will greatly extend approval timelines. | Yes  N/A |

**Collaboration Agreement (Non-Commercial) Checklist**

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| --- | --- |
| **Document title** | |
| Includes theProtocol Number/Study Acronym/Short title\_ERM Project ID Document type (eg. Research Agreement)\_FE date | Yes |
| **Parties and Project** | |
| Peninsula Health details are listed as: Peninsula Health (ABN 52 892 860 159) of 2 Hastings Road, Frankston, VIC 3199, Australia | Yes |
| The full legal name of the Collaborative Party(ies), their ABN and registered address are correct and consistent throughout the Agreement. | Yes |
| The document footer lists as the Site: Peninsula Health (Frankston Hospital and/or Rosebud Hospital) as appropriate for this Project. | Yes |
| The Project Name and Protocol number are correct. | Yes |
| The Date of Agreement is inserted as “The date of the last Party to sign”. | Yes |
| No changes are made to the body of the Agreement.  Changes are not allowed. All changes are to be detailed in Item 11. | Yes |
| **Schedule** | |
| Item 1: The Project Name is correct. | Yes |
| Item 2 and 3: Commencement and Termination Dates align with the dates in the Protocol.  Commencement date does not pre-date expected start date of the Project at Peninsula Health. | Yes  Yes |
| Item 5: Contacts includes a Peninsula Health staff member. | Yes |
| Item 9: The currency is in Australian dollars (excl. GST). | Yes |
| Item 11: Only wording approved by Peninsula Health Legal Counsel is included. | Yes  N/A |

**Standard Form of Indemnity Checklist**

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| **Document title** | |
| Includes theProtocol Number/Study Acronym/Short title\_ERM Project ID \_Document type (eg. Standard Indemnity)\_Document FE date. | Yes |
| The indemnity has been provided as a separate document to the CTRA/CIRA. | Yes |
| The instructions before the “To” clause have been deleted. | Yes |
| The Institution is defined as “the Indemnified Party” in the “To” clause. | Yes |
| The name and address of the Institution is Peninsula Health, 2 Hastings Road, Frankston, VIC 3199, Australia. | Yes |
| The Sponsor/Local Sponsor is defined as “the Sponsor” in the “From” clause. | Yes |
| The full legal name of the Sponsor/Local Sponsor, registered address and their ABN is listed. | Yes |
| The Protocol title and number are correct in the “Re” clause. | Yes |
| Paragraph Number 1: The correct participant group (patients of the Indemnified Party or non-patient volunteers) is selected and the other deleted as “the Participants”. | Yes |
| Paragraph Number 1: The correct name of the Principal Investigator is inserted for “the Investigator”. | Yes |

**Clinical Trial Notification (CTN) TGA Acknowledgement Checklist – not required when a TGA approved product is used in the project**

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| --- | --- |
| **Document title** | |
| The full legal name of the Sponsor/Local Sponsor and their registered address are the same as appears on the CTRA/CIRA. | Yes |
| The Protocol title and number are correct | Yes |
| The name and address of the Institution is Peninsula Health (Frankston Hospital and/or Rosebud Hospital), 2 Hastings Road, Frankston, VIC 3199, Australia | Yes |