**Checklist for the Medicines Australia Clinical Trial Research Agreement (CTRA) or Medical Technology Association of Australia Clinical Investigation Research Agreement (CIRA)**

**Checklist for the Standard Medicines Australia Form of Indemnity for Clinical Trials or Medical Technology Association of Australia Form of Indemnity for Clinical Investigations**

**Before negotiating the agreement with a commercial sponsor or Collaborative Research Group (CRG), please consult and refer the Sponsor or CRG to the** [**Legal and Regulatory**](https://www.alfredhealth.org.au/research/ethics-research-governance/essential-elements-for-research-applications/legal-and-regulatory-requirements) **section on the Alfred Health website.**

**This will assist in identifying the correct agreement template to be used and any Alfred Health requirements.**

**Project Number:**

**Project Title:**

**Name of Principal Investigator:**

**Name of Alfred Submission Coordinator:**

Is the agreement on a standard Medicines Australia /Medical Technology Association of Australia template?

Yes  Skip **A**. and go to **B**.

No  Go to **A**.

**A. Non-Standard CTRA/CIRAs**

Please forward the agreement to Alfred Health Legal Counsel and liaise directly with

Jacky Mandelbaum ([J.mandelbaum@alfred.org.au](mailto:J.mandelbaum@alfred.org.au)).

Once the agreement has been finalised, please forward the agreement along with confirmation from Alfred Health Legal Counsel that the document provided has been reviewed and approved by Alfred Health Legal Counsel.

Has approval from Alfred Health Legal Counsel been provided with the agreement?

Yes

**B. Standard CTRA/CIRAs**

Please select which template has been used:

Medicines Australia Standard Form (for Commercially Sponsored Pharmaceutical Studies)

Medicines Australia CTRA: Contract Research Organisations (CROs) acting as the Local Sponsor

Medicines Australia Collaborative or Co-operative Research Group (CRG) Studies

Medicines Australia Phase IV Clinical Trials (Medicines)

Medicines Australia Phase IV Clinical Trials (Medicines) Contract Research Organisation (CROs) acting as the Local Sponsor

MTAA Standard Clinical Investigation Research Agreement (CIRA)

MTAA CIRA: Standard Clinical Investigation Research Agreement Post Market

MTAA CIRA: Contract Research Organisation (CRO) acting as the Local Sponsor

MTAA CIRA: Post Market Clinical Trial (Medical Devices) – Contract Research Organisation (CRO) acting as Local Sponsor

Please complete the Agreement Checklist

\*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

**Standard Form of Indemnity**

Does the application include a Standard Medicines Australia Form of Indemnity for Clinical Trials or a Standard Medical Technology Association of Australia Form of Indemnity for Clinical Investigations?

Yes  No

**If Yes,** please complete the Standard Form of Indemnity Checklist as well.

**HREC Review Only Indemnity**

Does the application include a Medicines Australia or Medical Technology Association of Australia HREC Review Only Indemnity?

Yes  No

**If Yes,** please complete the HREC Review Only Indemnity Checklist as well.

**Abbreviations used in checklists**

|  |  |
| --- | --- |
| ARTG | Australian Register of Therapeutic Goods |
| CTN | Clinical Trials Notification |
| HREC | Human Research Ethics Committee |
| SEBS | Southern Eastern Border States (Review body for Schedules 7 and 4) |

**Agreement Checklist**

|  |  |
| --- | --- |
| **Clause or Schedule** | **Please check** |
| Is the name of the Institution “Alfred Health ABN 27 318 956 319 a body corporate established under the *Health Services Act 1988* (Vic) of Commercial Road, Melbourne 3004”?  Just “Alfred Health” is also acceptable if the ABN and address are correct. | Yes |
| Is the Sponsor or CRG the same Sponsor or CRG listed in the CTN? | Yes  N/A |
| Has the full legal name of the Sponsor or CRG been listed, and their ABN and address provided? | Yes |
| The sponsor of a trial must be an Australian legal entity. Where a CRO is acting as the local sponsor, is the international organisation stated in a table on page 1 as the Organisation?  The organisation should not be a party to the agreement. A third party beneficiary clause has been approved by SEBS. | Yes  N/A |
| Are the study title and protocol number correct? | Yes |
| The Date of Agreement should be entered when the last Party signs or a reference made to clause 13.1 (sponsor/post-market) or 14.1 (CRG) which stipulates this definition. Has this been left blank or the cross-reference been made? | Yes |
| Have changes been made to the body of the agreement?  Changes are not allowed. All changes are to be detailed in Schedule 7 or Schedule 4. | No |
| Schedule 1: Are the Study Name and local Study Site details correct? | Yes |
| Schedule 1, Target Number of Participants: Are the numbers the same as stated for the site in the ethics or site governance application? | Yes |
| Schedule 1, Recruitment Period: Are the dates correct? | Yes |
| Schedule 1: Is the name of the HREC “The Alfred Hospital Ethics Committee” or if reviewed by an external HREC, the name of the external HREC? | Yes |
| Schedule 1, Equipment: Has equipment to be provided for the study been listed?  If equipment is listed:  Is the medical equipment provided by the Sponsor TGA-approved?  If TGA-approved, is the equipment being sourced from the local Australian Sponsor as defined on the ARTG?  If No to either question, please include the equipment on the CTN.  Equipment may need to be reviewed by the Research Product Introduction Group. | Yes  N/A  Yes  No  N/A  Yes  No  N/A |
| **Clause or Schedule** |  |
| Schedule 2: Are you happy with the terms and conditions of payment? | Yes |
| Schedule 2: Are the amounts specified exclusive of GST?  If they are inclusive of GST, you will in effect receive 10 per cent less. Are you satisfied with the amounts specified?  Please ensure the amounts cover the costs outlined in the resource centre declarations. | Yes  Yes |
| Schedule 2: Is the currency in Australian dollars?  If not, are you satisfied with the converted amounts specified? | Yes  No  Yes  N/A |
| Schedule 2: Will you receive a Start-Up fee if you haven’t signed a Pre-Nup/Site Start-Up Agreement? | Yes  N/A |
| Schedule 2: Are you able to comply with any requirements to complete case report forms (CRFs) within a specified period? | Yes  N/A |
| Schedule 2: Are you able to meet any deadlines by which you are required to enrol the required number of participants? | Yes  N/A |
| Schedule 2: Are you satisfied with the definition of a “screen failure” and the capped number of screen failures? | Yes  N/A |
| Schedule 2: Will you be reimbursed for the work associated with the preparation of any future amendment applications, SAE reporting, annual progress reports, meetings etc? | Yes  No |
| Schedule 2: Have any “bonus” payments been offered which could be considered as an inducement to enrol additional patients? | Yes  No |
| Schedule 2: Has archiving been included in the payments? | Yes  No |
| Schedule 2: Is a third party making payments on behalf of the local sponsor?  If so, if they fail to pay, are you required to chase payments with this third party? This is not allowed. The local sponsor is ultimately responsible for payment. | Yes  No  Yes  N/A |
| Schedule 2: Are there any terms which you are unsure about?  If so, please forward to the Ethics Office. | Yes  No |
| Schedule 2: Have the account details been completed?  If Monash University is to administer the payments the account details need to be those of Monash University. | Yes |
| Schedule 3: Has an unsigned indemnity been inserted? | Yes |
| Schedule 4: Has a current insurance certificate complying with the minimal requirements been inserted? Please check the expiry date. | Yes |
| Schedule 5: Have the Guidelines for Compensation been attached or a link to them on the Medicines Australia or Medical Technology Association of Australia website provided? | Yes |

|  |  |
| --- | --- |
| **Clause or Schedule** | **Please check** |
| Schedule 6 (or Schedule 3\*): Are all of the details correct? | Yes |
| Schedule 7 (or Schedule 4\*): Has only the SEBS-approved wording been included?  Any wording not approved by SEBS will either require review by Alfred Legal Counsel which may incur a fee depending on the amount of work involved, or submission, review and approval by SEBS.  If the third party beneficiary clause has been included, it must have been approved by SEBS for the particular sponsor. | Yes  N/A |
| Has the Sponsor asked you to sign any other Agreements?  If so, please forward to the Ethics Office for review before signing. | Yes  No |

**Standard Form of Indemnity Checklist**

|  |  |
| --- | --- |
| **Clause or Schedule** | **Please check** |
| Has the Institution been defined as “the Indemnified Party” in the “To” clause? | Yes |
| Is the name of the Institution “Alfred Health ABN 27 318 956 319 a body corporate established under the *Health Services Act 1988* (Vic) of Commercial Road, Melbourne 3004”? | Yes |
| Has the Sponsor been defined as “the Sponsor” in the “From” clause? | Yes |
| Has the full legal name of the Sponsor been listed, and their ABN provided? | Yes |
| Are the study title and protocol number correct in the “Re” clause? | Yes |
| Paragraph Number 1: Has the correct participant group (patients of the Indemnified Party or non-patient volunteers) been selected as “the Participants”? | Yes |
| Paragraph Number 1: Has the correct name of the Principal Investigator been inserted for “the Investigator”? | Yes |
| Has the indemnity been defined as “Schedule 3” or “Exhibit X”?  If so, this should be deleted as the signed indemnity should be separate to the CTRA/CIRA. | Yes  No |

**HREC Review Only Indemnity**

|  |  |
| --- | --- |
| **Clause or Schedule** | **Please check** |
| Has the Institution of the Reviewing HREC been defined as “the Indemnified Party” in the “To” clause? | Yes |
| If the Alfred Hospital Ethics Committee is the reviewing HREC is the name of the Institution “Alfred Health ABN 27 318 956 319 a body corporate established under the *Health Services Act 1988* (Vic) of Commercial Road, Melbourne 3004”? | Yes |
| Has the Sponsor been defined as “the Sponsor” in the “From” clause? | Yes |
| Has the full legal name of the Sponsor been listed, and their ABN provided? | Yes |
| Are the study title and protocol number correct in the “Re” clause? | Yes |
| Paragraph Number 1: Has the correct participant group (patients of the Indemnified Party or non-patient volunteers) been selected as “the Participants”? | Yes |
| Paragraph Number 1: Has the legal name/s of the institution/s for which the Reviewing HREC has oversight been listed? | Yes |
| Paragraph Number 1: Has the correct name/s of the Principal Investigator/s been inserted for “the Investigator”? | Yes |
| Has the indemnity been defined as “Schedule 3” or “Exhibit X”?  If so, this should be deleted as the signed indemnity should be separate to the CTRA/CIRA. | Yes  No |

**Declaration:**

This checklist is complete and accurate.

………………………………..………

Principal Investigator

………………………………..………

Signature of Submission Co-ordinator