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| Research Governance and Site Specific Assessment |
| Process and Practice - Appendices |
| OFFICIAL |

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# Appendix 1: Ethics and research governance/SSA

CPI *or* sponsor/CRO creates HREA\*

Sponsor/CRO transfers
HREA to CPI

CPI allocates **HREA role** to sponsor/CRO

CPI is responsible
for HREA

CPI creates SSA
as sub-form

CPI allocates
SSA role to PI

PI is responsible for SSA

PI can view HREA and its supporting documents

Complete HREA

Complete SSA

Upload ethics documents

Upload site documents

Digital signature

Digital signature

HREA must be submitted **before** SSA

HREA submission

SSA submission

Research office (for reviewing HREC) processes ethics review and **approval**

RGO processes research governance/SSA review and **authorisation**

\* For a NMA project with ethical review outside Victoria or Queensland, a **MDF** is created instead of a HREA. The process is the same, except signature is not required on the MDF and it does not go through an *approval* process.

# Appendix 2: Post-approval and post-authorisation

CPI *or* sponsor/CRO creates post-approval sub-form
(e.g. Amendment)
from HREA

Complete sub-form

***Post-approval (ethics)***

Upload documents

Digital signature

Sub-form submission

Research office
(for reviewing HREC) processes sub-form review and **approval** or **acknowledgment**

PI creates post-authorisation sub-form (e.g. *Site Governance Amendment Request*) from SSA

Complete sub-form

Digital signature

Upload documents

Sub-form submission

RGO processes
post-authorisation sub-form review and **authorisation**or **acknowledgment**

CPI *or* sponsor/CRO shares sub-form with PI

***Post-authorisation
(research governance/SSA)***

# Appendix 3: ERM delegation for multi-site project

Use this checklist at commencement of a research project to record the parties responsible for ERM tasks.
The CPI and site PI may delegate some responsibilities to a member of the research team (e.g. trial coordinator).

| **Stage** | **Task** | **Sponsor/CRO** | **CPI** | **Site PI** |
| --- | --- | --- | --- | --- |
| Preparation | Has ERM account |[ ] [ ] [ ]
|  | Has access to [Applicant User Guide to ERM](https://www.clinicaltrialsandresearch.vic.gov.au/ethical-review-manager) |[ ] [ ] [ ]
|  | Has attended/viewed [ERM training](https://www.clinicaltrialsandresearch.vic.gov.au/ethical-review-manager) |[ ] [ ] [ ]
|  | Will be ERM project owner (has full access permissions) |[ ] [ ]   |
| Ethics review in VIC or QLD | Create HREA |[ ] [ ]   |
|  | Create VSM (sub-form of HREA) |[ ] [ ]   |
|  | Complete HREA |[ ] [ ]   |
|  | Complete VSM |[ ] [ ]   |
|  | Upload supporting documents (including VSM) to HREA |[ ] [ ]   |
|  | Record project is NMA *if applicable* |[ ] [ ]   |
|  | Request HREA signature(s) *if applicable* |[ ] [ ]   |
|  | Sign HREA |  | 🗹 |[ ]
|  | Submit HREA |  | 🗹 |  |
|  | Submit VSM |  | 🗹 |  |
|  | Resubmit in response to query or information request from HREC |  | 🗹 |  |
|  | Monitor HREC review progress using History tab |[ ] [ ]   |
|  | Assign each VIC and QLD site PI a role to access HREA |[ ] [ ]   |
|  | HREA role assigned to each site PI: |  |  |  |
|  | *Recommended* 🡪 | Read, create sub-forms |[ ]   |  |  |
|  |  | Read only |[ ]   |  |  |
|  |  | Read, write |[ ]   |  |  |
|  |  | Read, write, submit |[ ]   |  |  |
| If NMA ethics review is outside VIC or QLD | Create MDF (once only for the project) |[ ] [ ]   |
|  | Complete MDF |[ ] [ ]   |
|  | Upload ethics documents to MDF |[ ] [ ]   |
|  | Submit MDF |[ ] [ ]   |
|  | Assign each VIC and QLD site PI a role to access MDF |[ ] [ ]   |
| Research governance/SSA | Create SSA (must be HREA/MDF owner or have suitable role) |[ ] [ ] [ ]
|  | Transfer SSA to new owner *if applicable* |[ ] [ ] [ ]
|  | Assign site research team members a role to access SSA |[ ]  CPI is PI for their own site. |[ ]
|  | Complete SSA |  |  | 🗹 |
|  | Upload supporting documents to SSA |  |  | 🗹 |
|  | Request SSA signature(s) |  |  | 🗹 |
|  | Sign SSA |  |  | 🗹 |
|  | Submit SSA |  |  | 🗹 |
|  | Resubmit in response to information request from RGO |  |  | 🗹 |
|  | Monitor RGO review progress using History tab |[ ]   |[ ]
| Post-approval reporting to VIC HREC | Create post-approval form(must be HREA owner or have suitable role) |[ ] [ ]  PI may action urgent safety reporting if sponsor/CRO and CPI unavailable. |
|  | Complete post-approval form |[ ] [ ]   |
|  | Upload supporting documents to post-approval form *if applicable* |[ ] [ ]   |
|  | Sign post-approval form |  [ ] \* |[ ]   |
|  | Submit post-approval form |  [ ] \* |[ ]   |
|  | Resubmit in response to information request from HREC |  [ ] \* |[ ]   |
|  | Monitor HREC review progress using History tab |[ ] [ ]   |
|  | Assign each VIC site PI a role to access the post-approval form |[ ] [ ]   |
| Post-authorisation reporting to VIC RGO | Create post-authorisation form(must be SSA owner or have suitable role) |[ ] [ ] [ ]
|  | Transfer post-authorisation form to site PI *if applicable* |[ ] [ ]   |
|  | Assign site research team members a role to access post-authorisation form |[ ]  CPI is PI for their own site. |[ ]
|  | Complete post-authorisation form |  |  | 🗹 |
|  | Upload supporting documents to post-authorisation form |  |  | 🗹 |
|  | Request post-authorisation form signature(s) *if applicable* |  |  | 🗹 |
|  | Sign post-authorisation form |  |  | 🗹 |
|  | Submit post-authorisation form |  |  | 🗹 |
|  | Resubmit in response to information request from RGO |  |  | 🗹 |
|  | Monitor RGO review progress using History tab |[ ]   |[ ]
| \* Sponsor/CRO may sign and submit a **safety** or **breach** report in line with NHMRC’s [*Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods*](https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods) and [*Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods*](https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods). All other post-approval forms should be signed and submitted by the CPI. **Parties must adhere to the reviewing HREC’s policy on signatories.** |

# Appendix 4: Ionising radiation

If a research project involves exposing participants to ionising radiation, specific regulatory requirements and supporting documents are required. Flow diagram developed by *Victorian Hospital Medical Physicists*.

|  |
| --- |
|  |

**Research governance/SSA process**

Radiation risk category **greater** than approved by reviewing HREC

**Initial Review**: ethics approval certificate lists Radiation Risk Category if additional to SOC

**Amendment**: amendment approval lists Radiation Risk Category if additional to SOC

Each site prepares Radiation Notification or Medical Physicist’s Report as per site requirements

Standard of care

Additional to standard of care

Report with highest radiation dose + HREA Section M6.2.1.3.1 ‘Risk justification’ submitted by CPI to reviewing HREC

Each site prepares Medical Physicist’s Report listing Risk Category according to ARPANSA Code of Practice

RGO reviews site’s Radiation Notification or Medical Physicist’s Report + ethics approval certificate

Radiation risk category **same** or **less** than approved by reviewing HREC

Site’s PI should seek additional approval from the reviewing HREC via the CPI through an amendment application

Accepted for site authorisation

Sponsor to survey participating sites with respect to ionising radiation: Is it standard of care (SOC) or additional?

Amended protocol with changes to mode or frequency of ionising radiation procedures and/or new participating sites added

Protocol with ionising radiation procedures submitted to CPI in preparation for initial HREC review

# Appendix 5: Contacts for multi-site project

It is recommended to use a spreadsheet to capture contact details for all sites participating in a multi-site project.

**Excel template:** 

The Excel template link may not operate if viewing this document as a PDF. A Microsoft Word version of this document, along with the Excel template, is at [www.clinicaltrialsandresearch.vic.gov.au/research-governance-applications](http://www.clinicaltrialsandresearch.vic.gov.au/research-governance-applications). Alternatively, create a new spreadsheet using the suggested layout below.

**Project details tab**



**Site details tab**



# Appendix 6: Research agreement checklist

Use this checklist for completion and review of a research agreement.
Adapted from Alfred Health ‘Non Investigator Initiated Checklist’.

**Part 1: Select the type of research agreement used for the project.**

| **Type of research** | **Research agreement** |  |  |  |
| --- | --- | --- | --- | --- |
| [Teletrial](http://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/) | CTRA subcontract for studies conducted under a tele-trials model\** ***Must also select another research agreement from this list.***
* ***The checklist in Part 2 below does not apply for a tele-trials subcontract.***
 |[ ]
| [Clinical trial of a drug](http://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/) | CTRA – Medicines Australia Standard Form |[ ]
|  | CTRA – CRO acting as the local sponsor |[ ]
|  | CTRA – Collaborative or Cooperative Research Group (CRG) studies |[ ]
|  | CTRA – Phase 4 clinical trial (medicines) |[ ]
|  | CTRA – Phase 4 clinical trial (medicines) CRO acting as the local sponsor |[ ]
| [Clinical trial of a device](http://www.mtaa.org.au/clinical-investigation-research-agreements) | MTAA Standard CIRA |[ ]
|  | MTAA Standard CIRA Post Market |[ ]
|  | MTAA CIRA: Contract Research Organisation acting as the Local Sponsor |[ ]
|  | MTAA CIRA: Post Market Clinical Trial (Medical Devices) – Contract Research Organisation acting as Local Sponsor. |[ ]
| [Investigator initiated](http://www.clinicaltrialsandresearch.vic.gov.au/research-governance-applications) | Investigator initiated CTRA |[ ]
| Any | Non-standard research agreement* ***Legal review is advised; consult institution’s website or contact RGO.***
* ***Do not complete the checklist in Part 2 below.***
 |[ ]

\* Agreement between the primary site and satellite site; required for each teletrial satellite site, in addition to the CTRA (head agreement) between the sponsor and primary site.

**Part 2: Complete the checklist**

| **Sectionof CTRA or CIRA** | **Checklist item** | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- | --- |
| Details of the parties | Are the institution name, ABN and address correct? |[ ]   |  |
|  | Is the sponsor/CRG the same as that named on the CTN? |[ ]   |[ ]
|  | Are the sponsor/CRG full legal name, ABN and address correct? |[ ]   |  |
|  | Are the study name and protocol number correct? |[ ]   |  |
|  | Is the *Date of Agreement* **blank**?* *The date is recorded when the last party signs.*
 |[ ]   |  |
| Key information | Are the *Study Name* and local *Study Site* details correct? |[ ]   |  |
|  | Is the *Target Number of Study Participants* the same as stated on the ethics and/or research governance/SSA application? |[ ]   |  |
|  | Are the *Recruitment Period* dates correct? |[ ]   |  |
|  | Is the *Reviewing HREC* name correct? |[ ]   |  |
|  | Is all *Equipment Provided by Sponsor* listed? |[ ]   |[ ]
|  | Is the listed *Equipment Provided by Sponsor* approved by the TGA? |[ ]  [ ]  |[ ]
|  | Is *Equipment Provided by Sponsor* sourced from the Australian Sponsor as defined on the ARTG? |[ ]  [ ]  |[ ]
|  | If equipment is **not** approved by the TGA and/or **not** sourced from the Australian sponsor, is it listed on the CTN? |[ ]   |[ ]
| Payments | Are the terms and conditions of payment satisfactory? |[ ]   |  |
|  | Are the amounts exclusive of GST?* *If amount includes GST, the actual amount received will be less than that.*
 |[ ]   |  |
|  | Are the amounts satisfactory?* *Amounts must cover costs outlined in department declarations*
 |[ ]   |  |
|  | Is the currency Australian dollars? |[ ] [ ]   |
|  | If the currency is not Australian dollars, are the converted amounts satisfactory? |[ ]   |[ ]
|  | Will a start-up fee be paid if a pre-nup has not been signed? |[ ]   |[ ]
|  | Is the research team able to comply with any requirements to complete case report forms (CRFs) within a specified period? |[ ]   |[ ]
|  | Is the research team able to meet participant enrolment timelines? |[ ]   |[ ]
|  | Is the research team satisfied with the definition of ‘screen failure’ and the capped number of screen failures? |[ ]   |[ ]
|  | Will the research team be reimbursed for work associated with preparation of any future amendment applications, safety reports, progress reports, meetings etc? |[ ] [ ]   |
|  | Have any bonus payments been offered which could be considered an inducement to enrol additional participants? |[ ] [ ]   |
|  | Have archiving costs been included in the payment amounts? |[ ] [ ]   |
|  | Is a third party making payments on behalf of the local sponsor?* *Research team* ***must not*** *follow-up on overdue payments from a third party. Local sponsor is responsible for payment being made.*
 |[ ] [ ]   |
|  | Are there any terms which the research team are unsure about?* *If yes, contact the institution’s RGO.*
 |[ ] [ ]   |
|  | Are the account details complete and correct? |[ ]   |  |
| Form of indemnity for clinical trials\* | Is an unsigned indemnity inserted? |[ ]   |[ ]
| Insurance arrangements\* | Is a current insurance certificate, complying with the minimum requirements, inserted?* *Check the certificate expiry date to verify it is current.*
 |[ ]   |[ ]
| Guidelines for compensation for injury resulting from participation in a company-sponsored trial**\*** | Have the *Guidelines for Compensation* been attached or a link to them on the Medicines Australia or Medicine Technology Association of Australia website provided? |[ ]   |[ ]
| Study protocol identification***OR***Clinical investigation plan identification | Are all details correct? |[ ]   |  |
| Special conditions | Is *only* SEBS-endorsed wording included?* *Wording must either be endorsed by SEBS or reviewed by the institution’s legal counsel. Legal review may incur a fee.*
* *If the third party beneficiary clause is included, it must be endorsed by SEBS for the particular sponsor.*
 |[ ]   |  |

\* Section is not present in some CTRA and CIRA templates. Record N/A if section is not applicable.

# Appendix 7: Indemnity checklist

Use this checklist for completion and review of indemnity documents.
Adapted from Alfred Health ‘Non Investigator Initiated Checklist’.

****Part 1: Standard Form of Indemnity****

| **Section of Standard Formof Indemnity** | **Checklist item** | **Yes** | **No** |
| --- | --- | --- | --- |
| *To* clause | Is the institution defined as “the Indemnified Party”? |[ ]   |
|  | Are the institution’s name and ABN correct? |[ ]   |
| *From* clause | Is the sponsor defined as “the Sponsor”? |[ ]   |
|  | Are the sponsor’s full legal name and ABN correct? |[ ]   |
| *Re* clause | Are the study title and protocol number (or clinical investigation plan details) correct? |[ ]   |
| Paragraph 1 | Is the correct cohort selected as “the Participants”?〉 *Options are: patients of the Indemnified Party; non-patient volunteers.* |[ ]   |
|  | Is the correct name of the Principal Investigator recorded for “the Investigator”? |[ ]   |
|  | Is the indemnity defined as “Schedule 3” or “Exhibit X”?〉 *The signed indemnity must be separate from the CTRA/CIRA.* |  |[ ]

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 <multisite.ethics@health.vic.gov.au>

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